

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

David Rodbard, M.D.
January 18, 2023

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1 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

2 BEFORE THE PATENT TRIAL AND APPEAL BOARD

3 ABBOTT DIABETES CARE INC.,

4 Petitioner,

5 vs.

Patent No. 10,702,215

6 DEXCOM, INC.,

7 Patent Owner.

8
9
10 The deposition of DAVID RODBARD, M.D., called for
11 examination, taken before Margaret M. Lanier, CSR (IL),
12 RMR, CRR, Notary Public for the District of Columbia, at
13 700 K Street, NW, Washington, DC, 20001, on
14 January 18, 2023, at the hour of 9:00 a.m.

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24 REPORTED BY: Margaret M. Lanier, CSR, RMR, CRR
25 LICENSE NO.: 084-003036
 JOB NO.: 124209

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INDEX

WITNESS

EXAMINATION

DAVID RODBARD, M.D.
EXAMINATION BY MR. SARASWAT

4

EXHIBITS

NUMBER

MARKED FOR ID

Exhibit 1001	U.S. Patent No. 10,702,215	5
Exhibit 1002	Declaration of	8
Exhibit 2006	Dr. David Rodbard	
	Journal of Diabetes Science	26
	and Technology, Volume 4,	
	Issue 1, January 2010	
Exhibit 1005	Harper Patent	61
Exhibit 2007	Hand drawn glucose level	91
	chart, drawn by counsel	
Exhibit 1004	DexCom STS User's Guide	138
Exhibit 1008	Say Patent	161

(Witness administered an oath.)

DAVID RODBARD, M.D.,

having been first administered an oath, was examined and
testified 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, and we represent the patent owner,
DexCom. I'd like to start by going over some basic
ground rules and some definitions.

I'll be asking you some questions today about
a declaration you provided in case No. IPR 2022-00909.
Do you understand that?

A. Yes.

Q. When I refer to "this case" or "this matter,"
will you understand that I'm referring to case IPR
23022-00909?

A. Yes.

Q. Have you ever been deposed before?

A. No.

Q. Okay. So I'd like to just go over just quick
deposition rules.

I'll be asking you some questions and you must

1 give verbal answers to my questions so that the court
2 reporter can record them. Do you understand that?

3 A. Yes.

4 Q. If I ask you a question, you're required to
5 answer unless your lawyer instructs you not to. Do you
6 understand?

7 A. Yes.

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

10 A. Okay.

11 Q. Is there any reason you can't give truthful
12 and correct answers to my questions today?

13 A. No.

14 (Whereupon, Deposition Exhibit 1001 was
15 marked for identification.)

16 BY MR. SARASWAT:

17 Q. I've just handed you a document that's marked
18 Exhibit 1001 in the bottom right corner. Do you see
19 that?

20 A. Yes.

21 Q. Do you recognize Exhibit 1001?

22 A. Yes.

23 Q. This is U.S. Patent No. 10,702,215; is that
24 correct?

25 A. Yes.

1 Q. So in my questioning, if I refer to the
2 '215 Patent, will you understand that I'm referring to
3 U.S. patent No. 10,702,215?

4 A. Yes.

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

7 A. Yes.

8 Q. So if during my questioning I refer to a POSA
9 or a POSITA, will you understand that I'm referring to a
10 person of ordinary skill in the art?

11 A. Yes.

12 Q. Are you familiar with the term "continuous
13 glucose monitoring"?

14 A. Yes.

15 Q. So if during my questions I refer to CGM, will
16 you understand that I'm referring to continuous glucose
17 monitoring?

18 A. Yes.

19 Q. Did you do anything to prepare for today's
20 deposition?

21 A. Yes.

22 Q. What did you do?

23 A. I reviewed some documents related to this
24 particular document.

25 Q. When you say "related to this particular

1 document," do you mean --

2 A. The '215 Patent.

3 Q. Okay. which documents did you review?

4 A. I reviewed most of the documents that I cite
5 in my declaration.

6 Q. Okay. Did you review anything else aside from
7 those documents?

8 A. No.

9 Q. Okay. Did you meet with anyone in preparation
10 for today's deposition?

11 A. Yes.

12 Q. who did you meet with?

13 A. I met with Mr. Williams.

14 Q. Okay. And how long did you meet with him?

15 A. Two hours.

16 Q. Okay. So including the meeting that you had
17 with Mr. Williams, how much time total would you say you
18 spent preparing for this deposition?

19 A. I may have spent 30 hours.

20 Q. Okay. And so of that 30 hours, two hours was
21 spent meeting with Mr. Williams?

22 A. Correct.

23 Q. And the rest was spent reviewing documents?

24 A. Reviewing documents, yes.

25 Q. Now, did you also review the declaration that

1 you submitted in this case --

2 A. Yes.

3 Q. -- as part of the preparation for the
4 deposition?

5 A. Yes.

6 Q. Also, for the court reporter's benefit, just
7 please wait until I finish asking the questions --

8 A. Good idea.

9 Q. -- even if you --

10 A. Okay.

11 Q. -- before you start answering?

12 MR. WILLIAMS: That's an example.

13 THE WITNESS: Yes.

14 (Whereupon, Deposition Exhibit 1002 was
15 marked for identification.)

16 BY MR. SARASWAT:

17 Q. I'm going to show you another document.

18 Dr. Rodbard, I've handed you a document that's
19 marked 1002. Do you see that?

20 A. Yes.

21 Q. Do you recognize this document?

22 A. Yes.

23 Q. Is Exhibit 1002 the declaration that you
24 prepared for this case?

25 A. Yes.

1 Q. Is there anything in your declaration that you
2 wish to correct?

3 A. No.

4 Q. Okay. How much time would you say you spent
5 preparing this declaration that's Exhibit 1002?

6 A. I don't have an answer. I'd have to -- I
7 don't have a number in mind that would characterize
8 that.

9 Q. would you say it was more than 100 hours?

10 A. Yes.

11 Q. More than 200?

12 A. Possibly, probably not.

13 Q. All right. So let's look at Exhibit 1002,
14 which is your declaration. And could you please turn to
15 paragraph 5. Are you there?

16 A. Yes.

17 Q. Do you see where it says in the first sentence
18 of paragraph 5, "A description of my professional
19 background and qualifications is provided below"?

20 A. Yes.

21 Q. Then it goes on to say, "An additional account
22 of my work experience and qualifications is included in
23 my curriculum vitae which is labeled appendix A"?

24 A. Yes.

25 Q. Could you please turn to appendix A in

1 Exhibit 1002. I believe it starts on page 112.

2 At the top of appendix A on page 112, do you
3 see a section that's called "Education"?

4 A. Yes.

5 Q. Do you have any formal post-high school
6 education that's not listed in the education section of
7 your CV?

8 A. No.

9 Q. Okay. So if I'm looking at the CV, do you see
10 there's a line that says "BA"?

11 A. Yes.

12 Q. And so according to your CV, in 1960 you
13 earned a BA from State University of New York at Buffalo
14 in the division of sciences; is that right?

15 A. Correct.

16 Q. What topics did you study in this program?

17 A. The division of sciences was an
18 interdisciplinary program that included chemistry,
19 biology, geology, mathematics, calculus, and physics.

20 Q. I don't think they make those programs
21 anymore.

22 And then in 1964, you got your MD from Case
23 Western Reserve; is that correct?

24 A. Yes.

25 Q. And what topics did you study while earning

1 your MD?

2 A. Medicine, and they have what we'll call the
3 complete medical school curriculum which includes basic
4 sciences and clinical sciences.

5 Q. Okay. And then it says that from 1964 to
6 1965, you did your internship at King County Harborview
7 Hospital in Seattle; is that correct?

8 A. Yes.

9 Q. What topics did you study during your
10 internship?

11 A. This was principally medicine, but also
12 included surgery, emergency room, obstetrics,
13 gynecology, orthopedics, and outpatient medicine.

14 Q. Okay. And then from 1965 to 1966, you did
15 your residency in internal medicine at Hahnemann
16 Hospital at Drexel University; is that correct?

17 A. Yes.

18 Q. What topics did you study during your
19 residency?

20 A. Internal medicine.

21 Q. Okay. And then at the very bottom of the
22 education section, I see a line with a dash next to it
23 and then it says, "1988 graduate summer program in
24 epidemiology, Johns Hopkins University School of Hygiene
25 and Public Health."

1 Do you see that?

2 A. Yes.

3 Q. What does that dash mean?

4 A. I did not receive a degree or certificate. It
5 was an educational program but with no particular degree
6 or certificate attached to it.

7 Q. Have you ever taken any courses in computer
8 science or computer programming?

9 A. While I was at NIH, I took a number of
10 training programs in computers and information sciences.

11 Q. Okay. Can you tell me a little bit what you
12 learned in those programs?

13 A. Well, I would say use of computers in general
14 and use of common software that's utilized on computers.
15 I also did and learned computer programming in a variety
16 of languages, and you might say that I had a very
17 intensive on-the-job training.

18 Q. Okay. Do you recall which languages you
19 learned programming in?

20 A. Basic, FORTRAN, M-Lab and some MATLAB and some
21 others.

22 Q. Okay. And so in the course of these training
23 programs, did you write any programs yourself?

24 A. Yes.

25 Q. So in these courses that you took about

1 computer programming, did you learn what a function is
2 in the context of computer programming?

3 A. Yes.

4 Q. What's your understanding of what a function
5 is in the computer programming?

6 MR. WILLIAMS: Objection, form; outside the
7 scope.

8 You can answer.

9 BY THE WITNESS:

10 A. Function is usually a statement that indicates
11 a certain calculation or manipulation of the data and
12 any other elements.

13 BY MR. SARASWAT:

14 Q. Okay. So is it correct that a single function
15 can at different times take different data as inputs?

16 A. Yes.

17 Q. Okay. So if I have a function that takes one
18 value of data at one time and then a different value of
19 data at a different time, it's still the same function,
20 correct, it's just taking different data as inputs?

21 MR. WILLIAMS: Objection, form; outside the
22 scope.

23 BY THE WITNESS:

24 A. Yes.

25 BY MR. SARASWAT:

1 Q. Could you please turn in your declaration
2 Exhibit 1002 back to paragraph 7. Actually, sorry, now
3 that I've made you go to paragraph 7, I realize I want
4 you to go somewhere else.

5 A. That's okay.

6 Q. So could you please turn to paragraph 29. In
7 paragraph 29, it says:

8 "The '215 Patent relates to 'processing
9 analyte sensor data' for glucose" --

10 And then in parentheses there's a citation to
11 Exhibit 1001, column 2, lines 16 and 17. And it goes to
12 say:

13 (Continuing) -- "including purported
14 'systems and methods that allow a user to
15 receive alerts or alarms indicative of
16 glycemic condition in a more accurate and
17 useful way.'"

18 And then it cites to column 2, lines 17 to 19.
19 Do you see that?

20 A. Yes.

21 Q. And then in the next paragraph, paragraph 30
22 it says in the first sentence:

23 "The Challenged Claims of the '215 Patent
24 are generally directed to methods and
25 systems for setting indicators, such as

1 alerts and alarms for glucose levels."

2 Do you see that?

3 A. Yes.

4 Q. So in that sentence that I just read from
5 paragraph 30, when you said "indicators such as alerts
6 and alarms," did you mean that alerts and alarms are
7 both examples of indicators?

8 A. Yes.

9 Q. So in the '215 Patent, is there a difference
10 between an alert and alarm? Sorry, I realize I missed a
11 word.

12 In the '215 Patent is there a difference
13 between "an alert" and "an alarm"?

14 A. Yes.

15 Q. What is the difference?

16 A. I might need to consult the '215 Patent to see
17 if they speak specifically to that. I think I don't
18 know whether I'd be able to do that immediately.

19 Let's see...

20 (Witness reviews document.)

21 BY MR. SARASWAT:

22 Q. I'll withdraw that question and maybe come
23 back to it later. Let me ask a different question.

24 So setting aside the '215 Patent and just
25 thinking about the plain meaning of the words, is there

1 a difference between an alert and an alarm?

2 MR. WILLIAMS: Objection, form.

3 BY THE WITNESS:

4 A. Not necessarily.

5 BY MR. SARASWAT:

6 Q. Okay. I'm sorry, I think I interrupted you.

7 A. No, that's fine.

8 Q. Okay. So under what circumstances would you
9 say there is a difference between an alert and an alarm?

10 A. It depends on the way someone defines them.

11 Q. So can you give me an example of how somebody
12 might define them that makes them different?

13 A. I was thinking of an alarm clock, let's say.
14 It can be loud, or it could be a cell phone with a
15 different sound or with 20 different sounds.

16 So certainly the manner in which it is
17 presented can be different. And the other thing that
18 would come to mind would be they may represent either
19 different events or different levels of severity of an
20 event.

21 Q. I'm just reading back the last part of your
22 response.

23 You said, "They may represent either different
24 events or different levels of severity of an event"?

25 A. Yes.

1 Q. So is there one level of severity that you
2 would consider an alert versus a different level that
3 you consider an alarm?

4 MR. WILLIAMS: Objection to form; outside the
5 scope.

6 BY THE WITNESS:

7 A. Could you repeat that question.

8 BY MR. SARASWAT:

9 Q. So you said in response to one of my earlier
10 questions that alerts and alarms may represent either
11 different events or different levels of severity of an
12 event. Do you recall that?

13 A. Yes.

14 Q. So if I understood your answer correctly, I
15 think you're saying that based on the level of severity,
16 there's one level of severity -- sorry. I'll rephrase.

17 I think what you're saying is that there's
18 some level of severity that causes there to be a
19 distinction between an alert and an alarm; is that
20 right?

21 A. That's correct.

22 Q. What is that level of severity that you think
23 would represent the dividing line between an alert and
24 an alarm?

25 MR. WILLIAMS: Objection to form; outside the

1 scope.

2 BY THE WITNESS:

3 A. I think that can only be defined in a specific
4 context.

5 BY MR. SARASWAT:

6 Q. Okay. You said earlier that it's not
7 necessarily true that there is a difference between an
8 alert and an alarm, correct?

9 A. That's correct.

10 Q. Okay. So could we please now turn back to the
11 '215 Patent which is Exhibit 1001. Could you please
12 turn to column 9. Could you please look at line 58 that
13 begins with the words "figure 6." Are you there?

14 A. Yes.

15 Q. Do you see there in column 9 at lines 58 to 60
16 it says:

17 "Figure 6 is a flow chart illustrating a
18 process for dynamically and intelligently
19 providing a prediction alert/alarm in
20 accordance with an embodiment of the
21 disclosure."

22 Do you see that?

23 A. Yes.

24 Q. Could you please turn to figure 6 of the '215
25 Patent. It's sheet No. 8.

1 And do you see at the very top of the figure
2 there's an oval labeled No. 500?

3 A. Yes.

4 Q. In that oval it says, "Dynamically and
5 intelligently provide predictive alert/alarm"?

6 A. Yes.

7 Q. Now, could you please turn back to column 9.
8 And could you please look at line 64, it begins with the
9 words "figure 8." Are you there?

10 A. Yes.

11 Q. Do you see that it says in column 9 at line 64
12 to 67:

13 "Figure 8 is a flow chart illustrating a
14 process for dynamically and intelligently
15 monitoring the status after an
16 alert/alarm has been triggered in
17 accordance with the embodiment of the
18 disclosure."

19 A. Yes.

20 Q. We've seen a few places in the patent where it
21 uses the words alert/alarm, correct?

22 A. Yes.

23 Q. What do you think that means?

24 A. Either an alert or alarm or something that
25 resembles an alert or alarm.

1 Q. Does the use of that kind of language
2 alert/alarm in the '215 Patent mean that in the '215
3 Patent alerts and alarms are the same thing?

4 A. Here, it does. In figure 6 and figure 8, it
5 appears that they're lumping them together for some
6 reason.

7 Q. And so if there are other places in the
8 specification that use that same formulation
9 alert/alarm, would you agree in those places the
10 patent's treating alerts and alarms as the same?

11 MR. WILLIAMS: Objection to form.

12 BY THE WITNESS:

13 A. I would assume it's either an alert or an
14 alarm or something which is appropriately characterized
15 by either one of those two words.

16 BY MR. SARASWAT:

17 Q. Is it also possible when the patent uses that
18 alert/alarm language, that's referring to something
19 that's both an alert and an alarm?

20 A. It could be.

21 Q. So in the course of preparing your declaration
22 you read -- sorry. Withdrawn.

23 In the course of preparing your declaration,
24 did you read the entire '215 Patent?

25 A. Yes, I did.

1 Q. And did you understand everything in the '215
2 Patent?

3 A. I believe so.

4 Q. So can you please turn to column 1 of the '215
5 Patent. Do you see there's a section starting above
6 line 30 that says, "Background"?

7 A. Yes.

8 Q. The first sentence in that section says:
9 "The present systems and methods relate
10 to processing analyte sensor data from a
11 continuous analyte sensor."

12 Do you see that?

13 A. Yes.

14 Q. What does the word "analyte" mean here?

15 A. An analyte is a term usually used by chemists
16 to indicate a particular molecular entity that they are
17 trying to measure.

18 Q. Okay. Is glucose an example of an analyte?

19 A. Yes.

20 Q. And what is a continuous analyte sensor?

21 A. A continuous analyte sensor would mean
22 something that measures the analyte and measures it on a
23 continuing basis.

24 Q. Are there such things as noncontinuous analyte
25 sensors?

1 A. Yes.

2 Q. So what would be an example of a noncontinuous
3 analyte sensor?

4 A. A blood glucose meter, which contains a sensor
5 inside of it. The glucose sensor -- when someone is
6 measuring blood glucose with a finger stick, that's one
7 drop, one moment in time. So that's not continuous.

8 Q. Okay. I see.

9 And then what is analyte sensor data?

10 A. The sensor produces some output. The data is
11 the output.

12 Q. Okay. So in that first sentence when it says,
13 "the present systems and methods," does the phrase "the
14 present systems and methods" refer to the invention
15 described in the patent?

16 A. I presume so. Although it says "background,"
17 so it could be conceivably including things that have
18 been previously developed and/or patented.

19 Q. But it says "the present systems and methods,"
20 right?

21 A. Correct. But it says "background," so I don't
22 know if this is talking about something in the past or
23 something which is about to appear in the subsequent
24 material on these pages.

25 Q. Okay. So if we look at the next sentence in

1 the background it says:

2 "More particularly, the present systems
3 and methods relate to providing accurate
4 predictive alarms to a user."

5 Do you see that?

6 A. Yes.

7 Q. What does "predictive alarms" mean?

8 A. Obviously, it requires both a prediction and
9 alarms. In the present context we're talking about an
10 alarm related to some analyte. And so we're talking --
11 predictive alarms means that giving an alert or alarm,
12 little ambiguous there, about an analyte value which is
13 predicted to occur some time in the future.

14 Q. Okay. Now, do you see that it doesn't just
15 say "predictive alarms," it says "accurate predictive
16 alarms," right?

17 A. Yes.

18 Q. Is that because prior art predictive alarms
19 were considered to be inaccurate?

20 MR. WILLIAMS: Objection to form.

21 BY THE WITNESS:

22 A. Not necessarily.

23 BY MR. SARASWAT:

24 Q. Is it your understanding that prior to 2012,
25 which is the priority date of the '215 Patent,

1 predictive alarms were considered to be inaccurate?

2 A. No.

3 Q. why not?

4 A. There were predictive alarms, and some of
5 them, perhaps many of them, were working well. And they
6 were well in the sense of being accurate as we
7 generally, in common parlance, speak about accurate.

8 Q. So when you talk about accurate in the common
9 parlance, what do you mean?

10 A. well, it's vague, of course. One needs
11 to -- I mean, do they work, does the alarm get sounded
12 when there was a condition where there was an
13 expectation or a strong expectation or an actuality of
14 an event happening.

15 Q. Can you give me some examples of systems with
16 predictive alarms that you knew that worked well?

17 A. In the context of?

18 Q. In the context of continuous glucose
19 monitoring.

20 A. Okay. My understanding is that there was
21 another company that was doing predictive alarms, more
22 than one company doing predictive alarms.

23 Q. which companies?

24 A. MiniMed, also known as Medtronic, and
25 FreeStyle or Abbott or Navigator.

1 And in addition, there were people doing
2 predictive alarms, and I cite many of them in the
3 declaration and cite manuscripts that appear.

4 I would say one of the leaders in this field
5 was Stanford University and their pediatrics department.
6 They were doing predictive alarms, and they were working
7 in what was generally regarded in a satisfactory or
8 accurate manner.

9 Q. You said it was your understanding that there
10 were various companies doing predictive alarms. What is
11 that understanding based on?

12 A. I would prefer you to a patent by Saidara from
13 MiniMed. And I would -- there are also some earlier
14 patents from, I believe, Abbott regarding predictive
15 alarms.

16 Q. How do you spell Saidara?

17 A. S-a-i-d-a-r-a.

18 Q. Do you know the patent number?

19 A. No.

20 Q. Did you cite this Saidara patent in your
21 declaration?

22 A. No, I did not.

23 Q. Why not?

24 A. I didn't need to.

25

1 MR. SARASWAT: For this next document, I am
2 going to ask the court reporter to mark it as 2006.

3 (Whereupon, Deposition Exhibit 2006 was
4 marked for identification.)

5 BY MR. SARASWAT:

6 Q. Dr. Rodbard, the court reporter has just
7 handed you a document marked 2006. Do you see that?

8 A. Yes.

9 Q. Do you recognize Exhibit 2006?

10 A. No.

11 Q. Do you see at the top left on the first page
12 of Exhibit 2006 it says Journal of Diabetes Science and
13 Technology?

14 A. Yes.

15 Q. Are you familiar with the Journal of Diabetes
16 Science and Technology?

17 A. Yes.

18 Q. What is it?

19 A. It's a publication that reports articles of
20 interest to people working in diabetes and technology.

21 Q. Now, underneath where it says Journal of
22 Diabetes Science and Technology, do you see it says
23 volume 4, Issue 1, January 2010?

24 A. Yes.

25 Q. What does that mean?

1 A. That's the date when this issue of
2 the -- issue No. 1 occurred in January 2010.

3 Q. So does that mean that this article that I
4 handed you that's marked 2006 was published in Volume 4,
5 Issue 1, in January of 2010?

6 MR. WILLIAMS: Object to form.

7 BY THE WITNESS:

8 A. I believe that would be correct.

9 BY MR. SARASWAT:

10 Q. Now, in the top middle of the page it says:
11 "Methods of Evaluating the Utility
12 Continuous Glucose Monitor Alerts."

13 Do you see that?

14 A. Yes.

15 Q. And there's some names listed underneath?

16 A. Yes.

17 Q. Are those people listed underneath the authors
18 of the article?

19 A. Yes.

20 Q. So does Exhibit 2006 appear to you to be a
21 true and accurate copy of an article entitled, "Methods
22 of Evaluating the Utility of Glucose Monitor Alerts" by
23 Apurv Kamath and others published in the Journal of
24 Diabetes Science and Technology, Volume 4, Issue 1,
25 January 2010?

1 MR. WILLIAMS: Objection, form; outside the
2 scope.

3 BY THE WITNESS:

4 A. Yes. This appears to be an article from that
5 journal.

6 BY MR. SARASWAT:

7 Q. Okay. Could you please look at the page in
8 the article that has the number 65 on it.

9 A. Yes.

10 Q. Can you please look at the first full
11 paragraph in the left-hand column, the one that starts
12 with the words "this investigation."

13 A. Okay.

14 Q. So the first two sentences say:

15 "This investigation focused on the
16 evaluation of CGM alerts as they occur in
17 realtime and the predictive capability of
18 alerts to help patients avoid undesirable
19 excursions."

20 Do you see that?

21 A. Yes.

22 Q. When it says "undesirable excursions," what
23 does that mean to you?

24 MR. WILLIAMS: Objection, form; outside the
25 scope.

1 BY THE WITNESS:

2 A. I can interpolate, so to speak, from my own
3 knowledge that it's saying if we're talking about CGM
4 and glucose being measured by CGM and if we're talking
5 about patients that presumably have diabetes or some
6 other related condition, it's generally true we want to
7 keep their blood sugars in certain ranges.

8 So I presume an excursion is something that's
9 outside the desired or desirable range.

10 BY MR. SARASWAT:

11 Q. Reading on after the words "excursions," it
12 says:

13 "The alerts evaluated in this
14 investigation are threshold alerts that
15 sound when glucose readings cross a
16 patient selected level. These alerts are
17 distinct from alerts designed explicitly
18 to predict glucose excursions called
19 'projected' alerts."

20 Do you see that?

21 A. Yes.

22 Q. So am I correct that this article is using the
23 term "projected alerts" to describe what the '215 Patent
24 refers to as predictive alerts or alarms?

25 MR. WILLIAMS: Objection, form; outside the

1 scope.

2 BY THE WITNESS:

3 A. A projected alert may be similar or even
4 identical to a predicted alert.

5 BY MR. SARASWAT:

6 Q. In what circumstances might those things be
7 different?

8 A. I don't know. Both terms are used and they're
9 often used to refer to the same thing.

10 Q. Okay. So then reading on it says:

11 "with projected alerts, the trend of
12 glucose readings is extrapolated up to
13 30 minutes into the future. If the
14 extrapolated glucose readings cross a
15 threshold, an alert will sound. Like
16 threshold alerts, the projected alerts
17 are timed series events."

18 Do you see that?

19 A. Yes.

20 Q. And then it says:

21 "The first available realtime projected
22 alert was a GlucoWatch GT Biographer
23 'down alert' which extrapolated the
24 glucose trend forward 20 minutes."

25 Do you see that?

1 A. Yes.

2 Q. Is that statement consistent with your
3 understanding of the history of predictive alerts of CGM
4 particles?

5 A. Yes.

6 Q. So then it says:

7 "In a study intended to evaluate the
8 effectiveness of the 'down alert' at
9 predicting overnight hypoglycemia,
10 although the sensitivity to detect
11 hypoglycemia was improved from 8 percent
12 with the threshold alert to 77 percent
13 with the down alert, 65 percent of down
14 alerts were false (BG greater than 70 MG
15 per DL within plus or 30 minutes from the
16 alert) compared to 16 percent threshold
17 alert."

18 Do you see that?

19 A. Yes.

20 Q. What does that sentence mean to you?

21 A. That someone had reported the sensitivity and
22 specificity of alerts for the GlucoWatch GT and that
23 they compared sensitivity and specificity for threshold
24 events versus predicted events for that particular
25 device, in some, particular unclear what the setting

1 was.

2 Q. Am I correct that in this study they found
3 that 65 percent of the predictive alerts were false
4 alarms?

5 A. Of the so-called down alert, yes.

6 Q. And that's worse than the 16 percent false
7 alarm rate for the threshold alert, correct?

8 A. Yes.

9 Q. And the threshold alert is an alert that
10 compares the realtime glucose reading to a threshold,
11 right?

12 A. Yes.

13 Q. Are you familiar with the term "alarm
14 fatigue"?

15 A. Yes.

16 Q. What is alarm fatigue?

17 A. In the context of people with diabetes -- I
18 guess it would apply to anybody anywhere.

19 If you have any system where there's an alert
20 or alarm and if it keeps going off all the time, even
21 though that alert is supposed to be telling me or others
22 to do something, I might just get tired of it and say
23 forget about it or I'm not going to respond to that. Or
24 you might not even hear it, you may just push it out of
25 your mind. So people do have alarm alerts and it's

1 probably a real world phenomenon, irrespective of the
2 setting.

3 Q. If you have predictive alerts that have a high
4 false positive rate, could that cause a problem for the
5 user?

6 A. Yes.

7 Q. What kinds of problems?

8 A. It's annoying and it may lead to some kind to
9 be determined of alert fatigue.

10 Q. When you say "alert fatigue," is that the
11 thing as alarm fatigue?

12 A. Yes.

13 Q. Is alarm fatigue a safety problem?

14 A. Theoretically, it could be in some
15 circumstances. It depends on the particular situation.

16 Q. How would alarm fatigue lead to a safety
17 problem?

18 A. If there was a serious or if there was some
19 condition that needed to be handled in some way and the
20 alarm goes off, the alarm or alert is sounded but the
21 person is no longer responding to that alert, then the
22 condition may persist longer than it would have
23 otherwise and that could have some deleterious
24 consequences.

25 Q. Okay. You can put Exhibit 2006 to the side.

1 So if we turn back to the '215 Patent,
2 Exhibit 1001, let's look at column 1, line 31.

3 Do you see there's that sentence that starts
4 with the words "more particularly" that we were
5 discussing a few minutes ago.

6 A. 1001, right?

7 Q. Yes.

8 A. Which column?

9 Q. Column 1, starting at line 31.

10 A. Okay.

11 Q. When it says "more particularly the present
12 systems and methods relate to providing accurate
13 predictive alarms to a user," that means that the
14 systems and methods in the patent relate to providing
15 accurate predictive alarms to a user, correct?

16 MR. WILLIAMS: Objection to form.

17 BY THE WITNESS:

18 A. Yes.

19 BY MR. SARASWAT:

20 Q. Now, the claims of the '215 Patent recite a
21 first function and a second function, right?

22 MR. WILLIAMS: Objection to form.

23 BY THE WITNESS:

24 A. Let me look at the claims.

25 BY MR. SARASWAT:

1 Q. If you look at claim 1, for example, do you
2 see it mentions a first function and a second function?

3 A. Yes, and a second function, okay. So we have
4 two functions here.

5 Q. It might be easier if you look at -- that's
6 fine. Let's just take a look at claim 19 in the patent
7 if you have it. I'm looking at column 50 around line 7
8 in claim 19, there's also a recitation of a first
9 function.

10 A. Yes.

11 Q. And then down at line 11 it also recites a
12 second function?

13 A. Okay.

14 Q. Does the specification of the '215 Patent ever
15 say anywhere that the first function provides predictive
16 alerts or alarms?

17 A. I don't know. I'd have to read through the
18 entire thing to know whether it says that.

19 I'd say my general impression is that they do
20 not discuss the first function in terms of predictive
21 alarm or alert.

22 Q. So a specification only discusses the second
23 function as providing the predictive alerts or alarms,
24 right?

25 MR. WILLIAMS: Objection to form.

1 BY THE WITNESS:

2 A. No. I do not agree with that statement.

3 BY MR. SARASWAT:

4 Q. why not?

5 A. I don't believe that the second function is
6 defined and it is not necessarily defined as a
7 predictive alarm or alert.

8 MR. SARASWAT: I think we've been going for
9 about an hour on the record. Should we take a break? I
10 have 10:05 on my clock, so how about 10:15.

11 THE WITNESS: Very good.

12 (Whereupon, a recess was taken from
13 10:05 a.m. until 10:15 a.m.)

14 BY MR. SARASWAT:

15 Q. So, Dr. Rodbard, could you please look at the
16 table of contents in your declaration. It's the page
17 that starts with Roman numeral small I?

18 A. Yes.

19 Q. And so towards the bottom of the page is a
20 section numbered -- I think it's Roman numeral X
21 entitled, "facts and opinions relevant to the
22 unpatentability grounds asserted in the declaration"?

23 A. Yes.

24 Q. Underneath that is a section A which refers to
25 petition Grounds 1 and 2, right?

1 A. Yes.

2 Q. And underneath that is an entry for claim 1.
3 Do you see that?

4 A. Yes.

5 Q. So am I correct that your opinions about the
6 unpatentability of claim 1 in Grounds 1 and 2 are in the
7 section of your declaration entitled claim 1 starting on
8 page 34?

9 A. Yes.

10 Q. So could we please go and look at that
11 section.

12 So on page 34 we see section A entitled
13 "Petition Grounds 1 and 2, Claims 1-3, 12, 19, and 23
14 Are Obvious Over the User's Guide Alone or in Further
15 View of Harper," correct?

16 A. Yes.

17 Q. Underneath there's a section entitled claim 1,
18 right?

19 A. Yes.

20 Q. And so this is where your analysis starts from
21 claim 1 under Grounds 1 and 2, correct?

22 A. Correct.

23 Q. And underneath that we see a section marked
24 with a letter A that starts with words "1[Pre]"?

25 A. Yes.

1 Q. And then on page 35 there's a section that
2 starts with the letter B that starts with the words
3 "1[a]," right?

4 A. Yes.

5 Q. And then at the bottom of the page is a
6 section with the letter C that starts with the words
7 "1[b]," correct?

8 A. Yes.

9 Q. So this section that starts at the bottom of
10 page 35 with paragraph No. 62, is that the section where
11 you provide your opinions on limitation 1[b] in claim 1
12 for Grounds 1 and 2?

13 A. Yes.

14 Q. Limitation 1[b] recites:

15 "Evaluating sensor data using a second
16 function to determine whether a parameter
17 indicative glucose value meets one or
18 more nonuser settable second criteria."

19 Right

20 A. Correct.

21 Q. And your section on limitation of 1[b] is made
22 of paragraphs 62 to 72, correct?

23 A. Yes.

24 Q. Okay. So let's look at paragraph 62.

25 In paragraph 62, do you cite the specification

1 of the '215 Patent at all?

2 A. Looks like I cite it in paragraph 63.

3 Q. Okay. But not in paragraph 62?

4 A. I don't believe so. Let's see.

5 (Witness reviews document.)

6 BY THE WITNESS:

7 A. That is correct, I don't see it in paragraph
8 62.

9 BY MR. SARASWAT:

10 Q. Okay. As you pointed out earlier, you do cite
11 the specification in paragraph 63 kind of right at the
12 end on page 37, right?

13 A. (No response.)

14 Q. Sorry. I meant on page 36.

15 A. There's a citation on page 36.

16 Q. Okay. Now, if we look at the first sentence
17 of paragraph 63 it says:

18 "In my opinion, the User's Guide 'glucose
19 level' discussed above discloses the
20 claimed 'a parameter indicative of
21 glucose value' in element 1[b]."

22 Right?

23 A. Yes.

24 Q. So paragraph 63 in your declaration is about
25 the parameter indicative of glucose value language in

1 limitation 1[b], correct?

2 A. Correct.

3 Q. And you don't discuss any other parts of that
4 limitation, like the second function or the nonuser
5 settable criteria in that paragraph, do you?

6 A. I do not cite that in that paragraph.

7 Q. Okay. Now, if we look at the end of paragraph
8 63 on page 37 there's a footnote 4. Do you see that?

9 A. Yes.

10 Q. Now, in this footnote you do discuss the
11 second function language from limitation 1[b], right?

12 A. Correct.

13 Q. But in footnote 4, do you cite the
14 specification at all?

15 A. Do I cite what specification?

16 Q. Sorry.

17 In footnote 4 do you cite the '215 Patent
18 specification at all?

19 A. Yes, on the third line.

20 Q. Which part of the third line are you referring
21 to?

22 A. It says, "Claims 1 and 19 of the '215 Patent
23 recite..."

24 Q. Other than that sentence where you quote the
25 language from the claims, you don't cite any other part

1 of the specification in that footnote, do you?

2 A. This entire paragraph and section is referring
3 back to claim 1[b] on page 35. So that's where I'm
4 referring to the "parameter indicative of a glucose
5 value." So I'm referring to the language of the '215,
6 specifically claim 1[b]. That is to be understood in
7 the context of footnote 4.

8 Q. Right.

9 But all I'm asking is aside from quoting the
10 language from claims 1 and 19 of the '215 Patent that
11 recite the second function and hypoglycemic indicators,
12 you don't quote any other language from the '215 Patent
13 in footnote 4, do you?

14 A. No, I don't cite further specification of the
15 patent.

16 Q. Okay. Now, if we look at paragraph 64, which
17 is on the next page, here you're discussing the patent
18 owner's proposed construction of second function in the
19 District Court, correct?

20 A. Yes.

21 Q. Now, do you cite the specification of the '215
22 Patent in paragraph 64 aside from quoting the claim
23 language?

24 A. I don't believe so.

25 Q. Okay. And now let's look at paragraph 65.

1 The first sentence says:

2 "A POSITA would have understood that each
3 of Harper's projected glucose value
4 (i.e., a predicted glucose values) and
5 rate of change of glucose level is 'a
6 parameter indicative of glucose value,'
7 at least because both 'rate of change of
8 glucose values' and 'predicted glucose
9 value' are examples of sensor data based
10 on the user's glucose values and used to
11 indicate characteristics of a user's
12 glycemic level in the '215 Patent."

13 Do you see that?

14 A. Yes.

15 Q. After that there's a citation to the '215
16 Patent, column 26, line 50 to 60?

17 A. Yes.

18 Q. In paragraph 65, you're discussing the
19 parameter indicative of glucose value language from
20 limitation 1[b], correct?

21 A. Yes.

22 Q. You're not discussing the second function
23 language there, are you, in paragraph 65?

24 A. I'd have to go take a look at what I did cite
25 from the '215 Patent.

1 (witness reviews document.)

2 BY THE WITNESS:

3 A. I've read that section. Come back to the
4 question again, please.

5 BY MR. SARASWAT:

6 Q. So in paragraph 65 -- which language from
7 limitation 1[b] is paragraph 65 about?

8 MR. WILLIAMS: Objection to form.

9 BY THE WITNESS:

10 A. Help me get -- which section or which portion
11 are you asking of claim 1[b]?

12 BY MR. SARASWAT:

13 Q. So element 1[b] or limitation 1[b], it's
14 got -- if you turn back to page 35 -- sorry. I'm
15 looking at the wrong page -- yeah, it's on page 35 at
16 the bottom, it's kind a long limitation.

17 A. Okay.

18 Q. It says:

19 "Evaluating sensor data using a second
20 function to determine whether a parameter
21 indicative of glucose value meets one or
22 more nonuser settable second criteria."

23 Do you see that?

24 A. Yes.

25 Q. So if I look at paragraph 65 of your

1 declaration it says:

2 "A POSITA would have understood that each
3 of Harper's projected glucose value
4 (i.e., a predicted glucose values) and
5 rate of change of glucose level is 'a
6 parameter indicative of glucose
7 value...'"

8 And it goes on from there. Do you see that?

9 A. Yes.

10 Q. Am I correct that paragraph 65 of the
11 declaration is about the parameter indicative of glucose
12 value portion of limitation of 1[b]?

13 A. Yes.

14 Q. Sorry. I sometimes confuse words like
15 "element" and "portion."

16 And then in paragraph 66 you recite the entire
17 language of limitation 1[b], right?

18 A. Correct.

19 Q. Okay. But other than quoting the claim
20 language, you don't cite the specification there in that
21 paragraph, correct?

22 A. Correct.

23 Q. Now, after paragraph 66 is a subsection
24 starting with Roman numeral I, and it says:

25 "A POSITA would have and could have

1 combined Harper's alarm profile in the
2 low glucose alarm of the User's Guide."

3 Do you see that?

4 A. Yes.

5 Q. And then that subsection goes on, it looks
6 like, from paragraph 67 until 72?

7 A. Correct.

8 Q. And you don't discuss the second function
9 language from limitation 1[b] in any of those
10 paragraphs, do you?

11 A. Let me take a look.

12 Q. Sure.

13 (Witness reviews document.)

14 BY THE WITNESS:

15 A. Okay. I do not see a reference to the '215
16 Patent in terms of its detailed specifications.

17 BY MR. SARASWAT:

18 Q. Okay. So you don't see a reference to the
19 '215 Patent specification in paragraphs 67 to 72,
20 correct?

21 A. Yes. Help me understand what you mean by
22 "specifications."

23 Q. When I say "specification," I basically mean
24 any language that's not in the claims for these
25 purposes.

1 A. Okay.

2 Q. I know that the claims are written there, but
3 just for shorthand when I say "specification," I mean
4 the parts of all the claims?

5 A. Okay.

6 Q. So you don't discuss the specification in
7 paragraphs 67 to 72?

8 A. No.

9 Q. I think we determined that in the section of
10 your declaration regarding element 1[b], you discuss the
11 second function portion of that element in paragraphs 64
12 and 66 in footnote 4; is that right?

13 MR. WILLIAMS: Could you read that question
14 back.

15 MR. SARASWAT: So --

16 MR. WILLIAMS: You're going to withdraw the
17 question?

18 MR. SARASWAT: Yes. I'll withdraw the
19 question.

20 BY MR. SARASWAT:

21 Q. So am I correct that in the section of your
22 declaration regarding claim element 1[b] for Grounds 1
23 and 2, you discuss the second function language from
24 element 1[b] in paragraph 64 and 66 and footnote 4?

25 MR. WILLIAMS: Objection to form.

1 BY THE WITNESS:

2 A. Well, in paragraph 65 there is a reference to
3 the '215 Patent.

4 BY MR. SARASWAT:

5 Q. Right, but my question is different.

6 I'm just asking where you discuss the second
7 function language from limitation 1[b], and that's in
8 paragraphs 64 and 66 and footnote 4, right?

9 MR. WILLIAMS: Objection to form.

10 (Witness reviews document.)

11 BY THE WITNESS:

12 A. I point out in paragraph 66 that the
13 combination of User Guide and Harper does teach
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 second
17 criteria.

18 BY MR. SARASWAT:

19 Q. And so paragraph 66 was on my list of places
20 where you discussed that function.

21 A. Okay.

22 Q. So we do agree you do cite it there.

23 A. Okay.

24 Q. So you don't cite the specification of the
25 '215 Patent in your analysis of the second function

1 language from element 1[b], correct?

2 MR. WILLIAMS: Objection to form.

3 BY MR. SARASWAT:

4 Q. In the portions of your declaration where you
5 discuss element 1[b] under Ground 1, you don't cite the
6 specification of the '215 Patent in your analysis of the
7 second function language for element 1[b], do you?

8 MR. WILLIAMS: Objection to form.

9 BY THE WITNESS:

10 A. I cite the Harper reference, the Harper patent
11 in terms of how it is going about making predictions of
12 glucose.

13 BY MR. SARASWAT:

14 Q. Okay. But you don't cite the specification of
15 the '215 Patent when you're talking about the second
16 function language?

17 A. Correct.

18 Q. Why not?

19 A. I didn't believe it was necessary to make the
20 point. Regarding these 1[a] and 1[b], there are some
21 points to be made, but I didn't think that it was
22 necessary to go into the details of the specifications
23 within the '215 Patent.

24 Q. Okay. So in response to one of my earlier
25 questions, you said that you cite the Harper patent in

1 terms of how it is going about making predictions of
2 glucose. Do you recall that?

3 A. Yes.

4 Q. And now if we look at paragraph 64 of your
5 declaration, it says:

6 "In the District Court, patent owner
7 argues that the term 'second function'
8 should be construed as 'function that
9 provides a predictive alert/alarm.'"

10 And you cite Exhibit 1020 at 2. Then you say:

11 "Under patent owner's interpretation, in
12 my opinion, Harper teaches this
13 limitation."

14 And in parentheses it says "petition Ground
15 2." Do you see that?

16 A. Yes.

17 Q. You're opining that Harper meets the second
18 function limitation under the patent owner's
19 construction, correct?

20 A. Basically, yes.

21 Q. You didn't opine that the Guide alone meets
22 the second function under the patent owner's
23 construction, did you?

24 A. No.

25 Q. Does the Guide have any function that provides

1 a predictive alert or alarm?

2 A. Not that I'm aware of.

3 Q. Okay. So the Guide alone wouldn't disclose
4 the claimed second function under the patent owner's
5 construction, correct?

6 A. Correct.

7 Q. All right. So could you please turn back
8 again to your table of contents in your declaration.
9 Actually, you know what, I just realized we didn't keep
10 at looking at where we were looking. So let's go back
11 to page 34.

12 So, again, your analysis of claim 1 under
13 Grounds 1 and 2 starts here on page 34 in a section
14 entitled "claim 1," right?

15 A. Yes.

16 Q. And then if we go to page 35, there's a
17 section starting with the words "1[b]," and that's where
18 you analyze limitation 1[b] under Grounds 1 and 2,
19 correct?

20 A. Correct.

21 Q. Could you please read paragraph 62.

22 A. Yes.

23 "In my opinion, the User's Guide alone
24 (petition Ground 1) or in combination
25 with Harper (petition Ground 2) discloses

1 element 1[b]. For example, the User's
2 Guide discloses an automatic low glucose
3 alarm set at 55, separate from the low
4 glucose alert discussed above for
5 limitation 1[a]."

6 Continuing?

7 Q. Yes, please.

8 A. Exhibit 1004 at 56.

9 "when the STS sensor detects a glucose
10 level below 55, the STS receiver will
11 vibrate to notify the user of a very low
12 glucose value. The User Guide specifies
13 that the user 'cannot change or turn off
14 the low glucose alarm'" -- same reference
15 -- "which corresponds to the claimed
16 'nonuser settable second criteria.'
17 The automatic low glucose alarm thus
18 involves comparing the glucose values to
19 the nonglucose settable threshold set at
20 55 milligrams per deciliter, which is
21 'evaluating sensor data using a second
22 function to determine whether a parameter
23 indicative of glucose value meets one or
24 more nonuser settable criteria' as
25 claimed."

1 Q. Okay. So limitation 1[b] requires comparing a
2 parameter indicative of glucose value against one or
3 more nonuser settable criteria, correct?

4 A. Yes.

5 Q. And in paragraph 62, you're saying that the
6 Guide's 55 milligrams per deciliter low glucose alarm is
7 nonuser settable, correct?

8 A. Yes.

9 Q. But paragraph 62 doesn't say anything about
10 whether any criterion in Harper is nonuser settable,
11 correct?

12 A. I believe that's correct.

13 Q. Now, let's look at paragraph 64, which we had
14 looked at a couple minutes ago. It says:

15 "In the District Court, patent owner
16 argues that the term 'second function'
17 should be construed as 'function that
18 provides predictive alert/alarm.'"

19 There's a cite to Exhibit 1020 at 2. Do you
20 see that?

21 A. Yes.

22 Q. It says:

23 "Under patent owner's interpretation, in
24 my opinion, Harper teaches the limitation
25 (petition Ground 2). Harper teaches

1 using thresholds for glucose value,
2 thresholds for projected glucose value,
3 and/or thresholds for rate of change or
4 acceleration of the rate of change to
5 predict impending hypoglycemia
6 condition."

7 And it cites to Harper, correct?

8 A. Yes.

9 Q. And then it says:

10 "In particular, Harper discloses that
11 projected glucose values can be used to
12 trigger alarms for hypoglycemia
13 warnings."

14 And there's a cite to Harper paragraph 211,
15 right?

16 A. Yes.

17 Q. And then it says:

18 "Harper also discloses an alert condition
19 may be detected based on a threshold for
20 rate of change of glucose level for
21 predicting hypoglycemia conditions (e.g.,
22 3-4 milligrams deciliter per minute."

23 Do you see that?

24 A. Yes.

25 Q. And then there's a cite to paragraph 281,

1 right?

2 A. Yes.

3 Q. And then it says:

4 "Harper discloses that a low glucose
5 target indicator may be locked and/or
6 password protected to prevent a user from
7 changing the threshold range values such
8 that it is nonuser settable."

9 Do you see that?

10 A. Yes.

11 Q. So what you're saying there at the end is that
12 in Harper, there's a low glucose target that can be
13 locked or password protected, and if it's locked or
14 password protected, then the user won't be able to
15 change the threshold value, correct?

16 A. Correct.

17 Q. But if the user doesn't lock or password
18 protect the glucose target indicator, then it is user
19 settable, correct?

20 A. It's making the assumption that the user has
21 the ability to lock or unlock or utilize or nonutilize a
22 password.

23 Q. Well, if the user doesn't have the ability to
24 lock or unlock it or use the password, then who would?

25 A. It could be the manufacturer. It could be

1 potentially others, possibly including a healthcare
2 provider. Or it may just be locked at the get-go, just
3 automatically, routinely.

4 Q. Does Harper say who has the ability to lock or
5 unlock it or use the password?

6 MR. WILLIAMS: Objection to form.

7 BY THE WITNESS:

8 A. I would need to look at Harper in order to be
9 able to answer that question.

10 BY MR. SARASWAT:

11 Q. So you didn't cite anything in Harper that
12 teaches who, other than the user, has the ability to
13 lock or unlock the threshold, did you?

14 A. If you could provide me with the Harper
15 patent, I could take a look at it.

16 Q. Well, I'm not asking whether there is anything
17 in Harper, I'm asking whether you cited anything in
18 Harper that teaches.

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

21 BY THE WITNESS:

22 A. I don't believe -- it doesn't look as though
23 I'm addressing it here. I may be addressing it
24 elsewhere.

25 BY MR. SARASWAT:

1 Q. Okay. So if we look at paragraph 65, you say:
2 "A POSITA would have understood that each
3 of Harper's projected glucose value,
4 (i.e. a predicted values) and rate of
5 change of glucose level is 'a parameter
6 indicative of glucose value'..."

7 And then you go on to give reasons, right.

8 A. Yes.

9 Q. Now, at the end of paragraph 64 as we were
10 just looking at, you said that Harper discloses that a
11 low glucose target indicator may be locked and/or
12 password protected, right?

13 A. Correct.

14 Q. So the low glucose target indicator is not a
15 threshold for a rate of change of glucose level, is it?

16 A. Say that again, please.

17 Q. So what I'm trying to understand is you cite
18 this low glucose target indicator in Harper?

19 A. Yes.

20 Q. Is that low glucose target indicator a
21 threshold for rate of change of glucose level?

22 A. No.

23 Q. Is that low glucose target indicator a
24 threshold for projected glucose level?

25 A. It could be.

1 Q. what do you mean by that?

2 A. The low glucose threshold -- well, a realtime
3 glucose can be compared with a low glucose threshold. A
4 projected glucose can be compared with a threshold which
5 might be called TP for a predicted threshold that is a
6 threshold for a predicted value. Those may or may not
7 be identical.

8 So a low glucose threshold could, in some
9 instances, be utilized as a threshold for the predicted
10 glucose, or those two could be different.

11 Q. Does Harper say whether those two things are
12 the same or different?

13 A. I'd have to look at Harper to refresh my
14 memory on that.

15 Q. Did you cite anything in paragraph 65 from
16 Harper that says whether those things are the same or
17 different?

18 A. No.

19 Q. So I'd like you to look through your section
20 on limitation 1[b] in Ground 1, which is from paragraph
21 62 to 72, and I'd like you to tell me if you see
22 anywhere in this section where you allege that Harper's
23 projected glucose value or rate-of-change thresholds in
24 the Harper and Guide combination are not user settable.

25 MR. WILLIAMS: Objection to form.

1 BY THE WITNESS:

2 A. Repeat the question, please.

3 BY MR. SARASWAT:

4 Q. So what I'm trying to understand is -- I'd
5 like you to look through your section on limitation 1[b]
6 in Ground 1, which is from paragraph 62 to 72, and I'd
7 like you to tell me if you see anywhere in this section
8 where you allege that Harper's projected glucose value
9 or rate-of-change thresholds in the Harper Guide
10 combination are not user settable.

11 (Witness reviews document.)

12 BY THE WITNESS:

13 A. I don't believe it explicitly states that.

14 BY MR. SARASWAT:

15 Q. Okay. Do you think it implicitly states that?

16 A. Let me tell you my thinking about the matter.

17 Q. Okay.

18 A. Making a prediction of glucose or anything
19 else involves many different factors. There's not just
20 the low glucose level which is alluded to here and which
21 is considered, but there are other things.

22 Since this is a nonuser settable function, the
23 user doesn't need to know or enter or adjust or modify
24 or do anything to these other little things because
25 these other little things may be in some big,

1 complicated equation or calculation.

2 So, these are things that are built into the
3 system, and the user doesn't touch them or even know
4 that they're there. So, they don't have to say the user
5 can't set them if the user doesn't know that they're
6 there. It's some kind of fancy or simple logic that's
7 built into the system.

8 In other words, these other things that you've
9 mentioned are not user settable; the user never thinks
10 about them, never knows about them. They're invisible.
11 They're built into, they're cooked into the calculations
12 or the logic of the system.

13 Q. So, can you point me to a paragraph in your
14 declaration where you said what you just told me?

15 A. I would have to think about it.

16 (Witness reviews document.)

17 BY THE WITNESS:

18 A. I can't say offhand.

19 BY MR. SARASWAT:

20 Q. Okay. Now, if we look ahead to page 53 of
21 your declaration, do you see there's a section with a
22 letter E on limitation 19[d]?

23 A. Yes.

24 Q. And limitation 19[d] says:

25 "Evaluate sensor data using a second

1 function to determine whether a parameter
2 indicative of a glucose value meets one
3 or more nonuser settable second
4 criteria."

5 Right?

6 A. Correct.

7 Q. So limitation 19[d], like limitation 1[b] that
8 we were just looking at, recites that nonuser settable
9 second criteria language, correct?

10 A. Yes.

11 Q. Now, that section of your declaration on
12 limitation 19[d] is just that one paragraph 91, right?

13 A. That is correct.

14 Q. And all you're doing there is citing back to
15 the section we just looked at on limitation 19[d],
16 correct?

17 A. Yes.

18 Q. So there's no place anywhere in your
19 declaration where you opine that Harper's projected
20 glucose value or rate-of-change thresholds are nonuser
21 settable criteria, correct?

22 MR. WILLIAMS: Objection to form.

23 BY THE WITNESS:

24 A. I did comment that the Harper threshold for
25 low glucose can be locked or password protected.

1 BY MR. SARASWAT:

2 Q. But that's not a rate-of-change thresholds,
3 right?

4 A. That's correct.

5 Q. And that's not a projected glucose value
6 threshold, is it?

7 A. It could be sometimes. Other times, it could
8 be different.

9 Q. But Harper never says that, does it?

10 A. Actually, I believe Harper does. I'll be
11 happy to look at Harper if and when it's appropriate.

12 MR. SARASWAT: All right. I'm going to hand
13 you a document that's Exhibit 1005, which is Harper.

14 (Whereupon, Deposition Exhibit 1005 was
15 marked for identification.)

16 BY MR. SARASWAT:

17 Q. Just to kind of make sure we all know where we
18 are, so you said that the projected glucose value
19 threshold -- sorry.

20 You said that the projected glucose value
21 threshold could be nonuser settable or user settable,
22 and then you said you'd have to look at Harper to see if
23 Harper says that.

24 Can you show me where in Harper it says that.
25 (Witness reviews document.)

1 BY MR. SARASWAT:

2 Q. Do you have a sense of how much longer you'll
3 think you'll need?

4 A. So far, I haven't been able to find it.

5 Q. We can go back to that later. I did want to
6 ask you about paragraph 88 of Harper.

7 A. Okay.

8 Q. So about halfway down the paragraph right
9 after the word 314, there's a sentence that starts, "As
10 will be explained."

11 Do you see that?

12 A. Yes.

13 Q. It says:

14 "As will be explained in greater detail
15 below, the values corresponding to the
16 lower glucose target indicator 312 and
17 the upper glucose target indicator 314
18 may be changed by a user."

19 Correct?

20 A. Yes.

21 Q. So in that sentence, it's saying those values
22 are user settable, correct?

23 A. They also may not be changed by a user.

24 Q. But it doesn't say that in the sentence we
25 just read, correct?

1 A. Correct.

2 Q. It goes on to say:

3 "In another embodiment, the values of
4 lower glucose target indicator and the
5 upper glucose target indicator may only
6 be changed by a healthcare professional.
7 In such cases, a menu screen allowing a
8 user to change the lower glucose target
9 indicator 312 and the upper glucose
10 target indicator 314 may be locked and/or
11 password protected to prevent a user from
12 changing the threshold arranged values
13 without permission or authorization from
14 a healthcare professional, parent or
15 guardian."

16 Do you see that?

17 A. Yes.

18 Q. Does that mean that if permission or
19 authorization from a healthcare professional, parent or
20 guardian is given, that the user can change the
21 threshold?

22 A. You can ask whether it's the patient or
23 whether it's the healthcare professional that's making
24 the change.

25 Q. well, it says at the end, prevent a user from

1 changing the threshold arranged values "without
2 permission or authorization from a healthcare
3 professional, parent or guardian," right?

4 A. Can be only changed by a healthcare
5 professional, and they may be locked or password
6 protected.

7 So when it says "without permission," I think
8 it's saying under some circumstances, that could be
9 changed by the user.

10 Q. So could you please turn back to your
11 declaration, and please look at page 35 and look at
12 paragraph 61.

13 The first sentence says:

14 "In my opinion, the User's Guide
15 discloses element 1[a], at least
16 according owner's proposed
17 interpretation."

18 A. Yes.

19 Q. Here in paragraph 61 is where you offer your
20 opinion about how element 1[a] is met by the Guide
21 alone, correct?

22 A. Yes.

23 Q. And that paragraph goes on to say:

24 "For example, the User's Guide describes
25 'a low glucose alert' that can 'tell you

1 when your glucose values are out of your
2 target range.'" "

3 Citation to the Guide at 54, right?

4 A. Yes.

5 Q. Then it says:

6 "These alerts are stated to be based on
7 'realtime continuous glucose
8 measurements'" -- citation to page 9 --
9 "and the user can set a 'target range' of
10 'low glucose alert values from
11 60 milligrams per deciliter to 90
12 milligrams per deciliter (Id. at 54,
13 78-79), which corresponds to the claimed
14 'one or more user's settable first
15 criteria.'" "

16 Right?

17 A. Yes.

18 Q. And then it says:

19 "Similar to the '215 Patent's example
20 (see Exhibit 1001 at 21, 50 to 59,
21 claim 2) the low glucose alert in the
22 User's Guide thus involves comparing the
23 glucose values to the lower threshold of
24 the user set target range which is
25 'evaluating sensor data using a first

1 function' as claimed."

2 Correct?

3 A. Yes.

4 Q. So is it your opinion that the Guide meets
5 limitation 1[a] by comparing realtime glucose values to
6 a threshold?

7 A. Yes.

8 Q. Now, please take a look at paragraph 62. And
9 here you say in the first sentence:

10 "In my opinion, the User's Guide alone
11 (petition Ground 1) or in combination
12 with Harper (petition Ground 2) discloses
13 element 1[b]."

14 Do you see that?

15 A. Yes.

16 Q. So the section of your declaration starting
17 with paragraph 62 is where you offer your opinion
18 regarding how limitation 1[b] is met under either the
19 Guide alone or the Guide in combination with Harper,
20 right?

21 A. Yes.

22 Q. And if we keep reading in that paragraph, it
23 says:

24 "For example, User's Guide discloses 'an
25 automatic low glucose alarm set at

1 55 milligrams per deciliter,' separate
2 from the 'low glucose alert' discussed
3 above for limitation 1[a]."

4 Do you see that?

5 A. Yes.

6 Q. There's a citation to 56 of the Guide, right?

7 A. Yes.

8 Q. And then it says:

9 "And when the STS sensor detects a
10 glucose level below 55 milligrams per
11 deciliter (3.1 millimole per liter), the
12 STS receiver will vibrate to notify the
13 user of a very low glucose value."

14 Correct?

15 A. Yes.

16 Q. And then it says:

17 "The User's Guide specifies that a user
18 'cannot change or turn off the low
19 glucose alarm' which corresponds to the
20 claimed 'nonuser second settable
21 criteria.'"

22 Correct?

23 A. Correct.

24 Q. Then it says:

25 "The automatic low glucose alarm thus

1 involves comparing the glucose values to
2 the nonuser settable threshold set at
3 55 milligrams per deciliter, which is
4 'evaluating sensor data using a second
5 function to determine whether a parameter
6 indicative of glucose value meets one or
7 more nonuser settable criteria' as
8 claimed."

9 Right?

10 A. Yes.

11 Q. So is it your opinion that the Guide meets
12 limitation 1[b] by comparing the realtime glucose value
13 to a threshold?

14 A. To a threshold?

15 Q. Yes.

16 A. To a nonuser settable threshold, that's
17 correct.

18 Q. Okay. So am I correct that in your mapping of
19 claim 1 against the Guide, you're reading both the first
20 function and the second function on a comparison of the
21 realtime glucose value to some threshold?

22 A. Yes.

23 Q. Okay. Can you please turn column 23 in the
24 '215 Patent and look at line 25.

25 A. Column?

1 Q. Column 23.

2 A. whereabouts?

3 Q. Looking at line 25 that it's the line that
4 starts with the words, "figure 6." Are you there?

5 A. Yes.

6 Q. Okay. So it says:

7 "Figure 6 is a flow chart 500
8 illustrating a process for dynamically
9 and intelligently providing a prediction
10 alert/alarm in accordance with an
11 embodiment of a disclosure."

12 Do you see that?

13 A. Yes.

14 Q. Could you please look at figure 6?

15 A. Okay.

16 Q. So do you see that figure 6 has boxes labeled
17 500, 510, 520, 530, 540 and 550?

18 A. Yes.

19 Q. What does it say in box 530?

20 A. It says:

21 "Evaluate sensor data using a second
22 function to determine if one or more
23 second criteria are met."

24 Q. Okay. So there it says second function in
25 block 530, right?

1 A. Correct.

2 Q. So now let's turn to column 25 again and look
3 at -- sorry. I said 25 again. I meant let's look at
4 column 25.

5 A. 25?

6 Q. Yes. So we're looking at column 25. Look at
7 line 3.

8 Do you see there's a paragraph that begins
9 with the words "at block 530"?

10 A. Yes.

11 Q. So this paragraph is referring to the same
12 block 530 you just looked at in figure 6, correct?

13 A. Yes.

14 Q. It says:

15 "At block 530, processor module 214 may
16 be configured to evaluate the sensor data
17 using a second set of instructions or
18 criteria."

19 Do you see that?

20 A. Yes.

21 Q. So this paragraph is referring to the same
22 block 530 we just looked at in figure 6, correct?

23 A. Yes.

24 Q. And the text in block 530 refers to a second
25 function, right?

1 A. Yes.

2 Q. Here, it refers to a second section of
3 instructions. Sorry, when I say "here," I mean
4 at column 25 in the paragraph we were looking at from
5 lines 3 to 7, it refers to a second set of instructions,
6 correct?

7 A. Yes.

8 Q. So in the '215 Patent, is the second function
9 and second set of instructions -- sorry.

10 In the '215 Patent, are the second function
11 and the second set of instructions referred to in the
12 specification the same thing?

13 A. Is the second function -- I didn't get that.
14 Please repeat that.

15 Q. In the '215 Patent specification, does the
16 term "second function" mean the same thing as the term
17 "second set of instructions"?

18 MR. WILLIAMS: Objection to form.

19 (Witness reviews document.)

20 BY THE WITNESS:

21 A. It says, "in some embodiments," which means
22 sometimes the first set of instructions is different
23 than the second set of instructions. I understand that.
24 That means they may sometimes be the same or other times
25 they may be different.

1 BY MR. SARASWAT:

2 Q. So my question was different.

3 I think you just referred to the first and
4 second set of instructions.

5 A. Yes.

6 Q. My question is, so we saw in block 530 in
7 figure 6 there's the language "second function," right?

8 A. Block 530 in figure 6. It's second function,
9 that's correct.

10 Q. Okay. And then in column 25 in the paragraph
11 we were looking at from lines 3 to 7 which is about
12 block 530, it uses the term "second set of
13 instructions," correct?

14 A. Yes.

15 Q. So my question is about just the second of
16 both things. So is the second function the same thing
17 as the second set of instructions in the specification?

18 A. I don't know. I can't tell from that language
19 right here.

20 They're not saying the instructions which
21 constitute function No. 2, you know, which could be a
22 sign or a cosign or an algorithm. So they haven't
23 defined whether their use in this series of lines,
24 specifically line 5, is that the same -- is that a
25 definitive definition of the function? well, it might

1 be and it might not be.

2 You want to know whether the instructions in
3 520 are the same as the instructions in 530. And it
4 begins to be a little bit confusing or ambiguous because
5 there may be a whole series of instructions in box 520
6 and a whole series in 530, and they may be exactly the
7 same or they may be slightly different or there may be
8 additional instructions as part of 520, but not 530 or
9 vice versa.

10 So there's a little -- and they may use
11 different data or other parameters. So we cannot say
12 from this statement here that whether or not the
13 function in box 520 is the same as the function in box
14 530.

15 Q. Yes, but my question is not about whether
16 there's an equivalence between box 520 and box 530. I'm
17 only focused on box 530.

18 Box 530 says:

19 "Evaluate sensor data using a second
20 function to determine if one or more
21 second criteria are met."

22 Right?

23 A. That's correct, that's what 530 says.

24 Q. So, I'm ignoring 520 and just looking at 530.
25 So, 530 talks about a second function, right?

1 A. Yes.

2 Q. Now, if we look at column 25 in the paragraph
3 starting at line 3, it says at block 530:

4 "The processor module may be configured
5 to evaluate the sensor data using a
6 second set of instructions or criteria."

7 Right?

8 A. Yes.

9 Q. So, given that block 530 in the figure says
10 second function and given that the sentence I just read
11 that's referring to block 530 uses the term "second set
12 of instructions," is it your understanding that the
13 patent is basically using the term "second function" and
14 "second set of instructions" interchangeably?

15 A. Not interchangeably but similarly.

16 But if they wanted to, they could say the
17 function in box 530 consists of a set of instructions
18 and those instructions must be different than the ones
19 in block 520.

20 Q. So the processor module uses the second set of
21 instructions to perform a second function, correct?

22 A. Second set of instructions for the second
23 function at block 530, yes, it looks like that's the
24 second set of instructions or criteria.

25 Q. Okay. So the processor module is using the

1 second set of instructions to perform the second
2 function?

3 A. Correct.

4 Q. Okay. And then I'm going to go through a
5 similar exercise now with respect to block 520.

6 A. Okay.

7 Q. So if we look at block 520 in figure 6, we see
8 there's a reference to the first function, right?

9 A. Yes.

10 Q. So in block 520 in figure 6 it says:

11 "Evaluate sensor data using a first
12 function to determine if one or more
13 first criteria are met."

14 A. Yes.

15 Q. Okay. And if we look at column 23 at line 39,
16 there's a sentence that says:

17 "At block 520, the processor module 214
18 may be configured to evaluate the sensor
19 data using a first set of instructions or
20 criteria."

21 Do you see that?

22 A. Yes.

23 Q. So the a processor module is using the first
24 set of instructions to perform the first function; is
25 that right?

1 A. Yes.

2 Q. Okay. Isn't that what a function is in
3 computer science essentially, it's like a discreet
4 package of instructions or commands that can be reused?

5 MR. WILLIAMS: Objection to form; outside the
6 scope.

7 BY THE WITNESS:

8 A. Actually, a function can be defined outside of
9 the instructions that actually do the computation. A
10 function could be the sign of beta. There may be 2,000
11 or an number of enormous ways that could be done with
12 different algorithms and so on, just to remember that
13 function can be separate from the actual instructions.

14 Q. Could you please turn to page 157 of your
15 declaration which is where your claim listing starts.

16 A. Okay.

17 Q. It's probably easier for us to read than the
18 actual claims in the patent document.

19 If we look at claim 5 which is on page 158, it
20 says:

21 "The method of claim 1, wherein the
22 evaluating sensor data using a second
23 function to determine whether the
24 parameter indicative of glucose value
25 meets one or more second criteria

1 comprises evaluating a dynamic risk of
2 the predicted glucose value."

3 Do you see that?

4 A. Yes.

5 Q. So, claim 5 refers to evaluating sensor data
6 using a second function by evaluating a dynamic risk of
7 the predicted glucose value, right?

8 A. Yes.

9 Q. Are there other ways to perform the second
10 function that don't involve evaluating a dynamic risk of
11 the predicted glucose value?

12 A. One way to evaluate the second function by
13 which we need a nonuser settable evaluation of the
14 parameter indicative of a glucose value or something
15 like that.

16 Another way to do that comparison would be
17 simply to not include the dynamic risk, as I understand
18 it, based on the formulation by Guerra and Sparacino but
19 rather just use a predicted glucose value. Dynamic risk
20 is not the same as the glucose value per se, it includes
21 consideration of risk, whereas glucose is simply
22 glucose.

23 Q. Is there such a thing as a static risk of
24 predicted glucose value?

25 A. Yes.

1 Q. what would be the static risk of predicted
2 glucose value be?

3 A. There are many ways it could be done. Let me
4 give you first the intuitive common sense, everyday
5 logic kind of way. That is if your glucose were at 150,
6 it's very far away from a low threshold of 70. It's far
7 away from a high threshold of, say, 200. So that person
8 at that moment in time is at relatively low risk. Even
9 if they were to move up rapidly or down rapidly, they
10 still have no risk of going outside of that boundary.

11 On the other hand, if your glucose is 75 and
12 the lower your doctor or some doctor has told some
13 patient they shouldn't go below 70, the minute that
14 you're at 75, you have a higher static risk.

15 We don't know anything about it. We don't
16 know which direction it's going or how fast it's going,
17 but we know that 75, you know, you're sort of in the
18 neighborhood of a threshold.

19 If your glucose were 195, and if your doctor
20 or someone had told a patient somewhere that they really
21 shouldn't go above 200, then they would be at a high
22 risk for potentially going above 200.

23 So that's the static risk idea. It's simply
24 a -- it's a defined risk for any given glucose value.

25 Q. Okay.

1 A. That's defined by Guerra and the other is
2 defined by Sparacino, and it's defined by Kovatchev and
3 it's defined by Clark, among others, and it's discussed
4 by me in five of the referenced citations for this
5 declaration.

6 Q. So you just described the static risk. What's
7 the difference between a static risk and a dynamic risk?

8 A. The static risk just tells you you're in the
9 neighborhood of a barrier or of a threshold.

10 The dynamic risk means that we want to now
11 consider that static risk simultaneously with the rate
12 of change of glucose or the rate of -- if we know the
13 -- any time we know glucose, we can calculate the risk
14 according to a preset formula.

15 Many different formulas that could be used.
16 The Kovatchev formula for the low blood glucose index
17 was one of the first and it's the most well-known and
18 perhaps the most used and most validated.

19 So, the minute we know glucose, we can
20 calculate risk. If we also know the rate of change of
21 glucose with time, we can calculate the rate of change
22 of risk with time.

23 Q. Okay.

24 A. And so dynamic risk means that we're taking
25 into account the fact that glucose could be changing or

1 may be changing and then we're calculating a risk factor
2 that takes into account both the static risk -- it
3 starts from the static risk, the DR, the dynamic risk
4 equals SR times something which includes the rate of
5 change of glucose.

6 Q. Okay.

7 A. So, in effect, the dynamic risk is a
8 combination of consideration of the glucose value,
9 together with consideration of the rate of change of
10 glucose.

11 Q. Okay. So, I mean, I know that claim 5 recites
12 evaluating a dynamic risk, but they could have also
13 written a claim that evaluates a static risk, right?

14 A. Yes.

15 Q. And that would be a different way of
16 evaluating the sensor data using a second function than
17 evaluating the dynamic risk?

18 A. Correct.

19 Q. Now, claim 5 is a dependent claim from claim
20 1, correct?

21 A. I believe that's the way it's generally
22 interpreted.

23 Q. Yeah, because it's the method of claim 1.
24 So if the second function in claim 1 were
25 limited to providing predictive alerts, then claim 5

1 would specify one way of providing predictive alerts
2 which involves evaluating a dynamic risk, correct?

3 MR. WILLIAMS: Objection to form.

4 BY THE WITNESS:

5 A. Okay. It's evaluating a dynamic risk of the
6 predicted glucose value, so that -- I may need to hear
7 the question again as to what's being differentiated
8 from what.

9 Q. So I'm not sure it's necessary about
10 differentiation.

11 The question was, if the second function in
12 claim 1 were limited to providing predictive alerts,
13 then claim 5 would specify one way of providing
14 predictive alerts which involves evaluating the dynamic
15 risk of the predicted glucose value, correct?

16 A. Yes.

17 Q. And in that scenario, there could also be
18 others ways of providing predictive alerts such as
19 evaluating the static risk of the predictive glucose
20 value, correct?

21 A. The static value of the predictive glucose.

22 Q. The static risk of the predictive glucose
23 value?

24 A. Yes, you could have the status risk of a
25 predictive glucose value.

1 Q. So even if the second function is limited to
2 providing predictive alerts, claim 5 is still narrower
3 than claim 1, right?

4 A. I may be mistaken, but I don't see in claim
5 1[b] anything about a predictive alert.

6 Q. Yeah. Yeah. I get that.

7 But my question is, we discussed earlier that
8 if claim 1 were limited to providing predictive alerts,
9 there are, in theory, at least two different ways you
10 can provide the predictive alerts, one of which involves
11 evaluating the dynamic risk and one of which involves
12 evaluating the static risk, correct?

13 A. Let me take that sort of tentatively because
14 there could be other ways of doing it and I'm not quite
15 so clear on your use of whether it's more limited.

16 You can make a predictive alert or you could
17 calculate a predictive glucose value, you could
18 calculate the static risk of a predictive alert, a
19 predictive glucose, and you could calculate the dynamic
20 risk.

21 Q. Okay. And claim 5 is narrowing claim 1 down
22 to one of those options?

23 A. I think that's true.

24 Q. Okay. Again, in that hypothetical I was
25 talking about where in claim 1 the second function is

1 limited to providing predictive alerts, claim 5 would
2 still narrow claim 1 down to just that dynamic risk
3 option that we just discussed, correct?

4 A. Probably so, yeah.

5 MR. WILLIAMS: Do you want to break now for
6 lunch?

7 MR. SARASWAT: Sure.

8 (whereupon, a recess was taken from
9 12:00 p.m. until 12:40 p.m.)

10 BY MR. SARASWAT:

11 Q. So, Dr. Rodbard, during the lunch break, did
12 you discuss the substance of your testimony with anyone?

13 A. No.

14 Q. Could you please turn back again to the claim
15 listing in your declaration, which is on page 157. Look
16 at claim 1.

17 A. Okay.

18 Q. Claim in limitation 1[a] requires "evaluation
19 sensor data using a first function to determine whether
20 a realtime glucose value meets one or more user settable
21 first criteria," correct?

22 A. Yes.

23 Q. If we look at page 158 at claim 19, and we
24 look at 19[c], we see that 19[c] similarly recites
25 "evaluate sensor data using a first function to

1 determine whether a realtime glucose value meets one or
2 more user settable first criteria," correct?

3 A. Correct.

4 Q. So both claims 1 and claim 19 talk about
5 evaluating sensor data using a first function to
6 determine whether realtime glucose value meets nonuser
7 settable criteria, correct?

8 A. Yes.

9 Q. Does the specification of the '215 Patent ever
10 say that the second function compares a realtime glucose
11 value to a threshold?

12 A. No.

13 Q. Now, let's look at paragraph 63 of your
14 declaration. Here in paragraph 63 you say:

15 "In my opinion, the User's Guide 'glucose
16 level' discussed above discloses the
17 claimed 'a parameter indicative of
18 glucose value' in element 1[b]."

19 Do you see that?

20 A. Yes.

21 Q. Further down in that paragraph you cite column
22 26, lines 50 to 60 from the '215 Patent. Do you see
23 that?

24 A. No, I don't see the referenced citation.

25 Q. It's at the very bottom of page 36 to the top

1 of 37.

2 A. Okay. Yes, there's a reference to that 26, 50
3 to 60.

4 Q. Let's look at the '215 Patent and look at
5 column 26 and start looking at line 50.

6 A. Column 26.

7 Q. So we're looking at column 26, the paragraph
8 starting at line 50. It starts with the words "in some
9 embodiments"?

10 A. Yes.

11 Q. At the end of that paragraph, on line 56,
12 there's a sentence that starts with the word,
13 Consequently." Do you see that?

14 A. Yes.

15 Q. It says:

16 "Consequently, in some embodiments the
17 processor module 214 may be configured to
18 evaluate the sensor data using a second
19 function to determine whether a
20 predictive glucose value meets one or
21 more predictive alarm criteria."

22 Do you see that?

23 A. Yes.

24 Q. In that sentence, is there any mention of
25 realtime glucose value?

1 A. No.

2 Q. Okay. So if we look back at the claims again.
3 Turn back to page 158 of your declaration. And you see
4 limitation 1[b] says:

5 "Evaluating sensor data using the second
6 function to determine whether a parameter
7 indicative of glucose value meets one or
8 more nonuser settable second criteria."

9 Do you see that?

10 A. I'm not on the same page.

11 Q. Okay.

12 A. You're talking about 1[b]?

13 Q. Yes.

14 A. That's on page 157.

15 Q. And do you see the same "parameter indicative
16 of" language in limitation 19[d]?

17 A. Yes.

18 Q. So in your declaration, what meaning did you
19 give to the term "parameter indicative of" in the
20 claims?

21 A. Okay, very good.

22 My understanding is that a parameter
23 indicative of a glucose value is, in my view, not
24 properly defined, not definite.

25 So, what the common sense, plain language

1 interpretation is is anything that relates to a glucose
2 value, including possibly or probably or definitely the
3 realtime glucose value itself. Plus, it could be a
4 predictive value or it could be a rate of change or an
5 acceleration. So when we say "indicative," it becomes
6 very fuzzy just what it means.

7 As I think I have acknowledged in one of my
8 footnotes, my understanding is that the patent owner
9 would prefer to interpret that as a predictive glucose
10 value.

11 Q. All right. Can you show me where in your
12 declaration you specified the meaning that you're giving
13 to the term "parameter indicative of"?

14 (Witness reviews document.)

15 BY THE WITNESS:

16 A. What I was referring to just now, and I think
17 it's responsive to your question on page 37, I
18 understand I could read it:

19 "I've been informed that the District
20 Court litigation patent owner has
21 proposed the term "second function"
22 should be construed as a function that
23 provides a predictive alert or alarm."

24 well, that doesn't define "a parameter
25 indicative of," unless the parameter indicative of a

1 glucose value is indeed a predictive glucose value.
2 So I understand that that is the preferred or the
3 proposed definition for the patent owner; I regard the
4 term as being more general.

5 Q. Right.

6 So where did you provide your definition of
7 that term?

8 A. I did de facto when I made the statement or
9 when I indicate that in Ground 1 and Ground 2 when
10 referring to the User Guide for the STS sensor, I am
11 fairly explicitly -- fairly clearly make it clear that I
12 believe that the User Guide and the STS sensor can
13 fulfill, and actually does fulfill, this second function
14 when it compares the realtime glucose value to the
15 threshold, the nonuser settable threshold at 55, in
16 particular, 55 milligrams per deciliter.

17 So, that's where I'm utilizing the term --
18 that's where I'm showing or expressing the fact that a
19 parameter indicative of a glucose value can be, among
20 other things, a realtime glucose value, which is then
21 being used in a second function to compare it to the
22 nonuser settable threshold of 55, as specified in the
23 STS device.

24 Q. So if a realtime glucose value is a parameter
25 indicative of glucose value, then what meaning did you

1 give to parameter indicative of glucose value?

2 MR. WILLIAMS: Objection to form.

3 BY THE WITNESS:

4 A. The term "a parameter indicative of glucose
5 value" in my mind includes a realtime glucose value. It
6 is not identical to it. This is just one of many, maybe
7 a very, very large set of terms that could be considered
8 under the term "a parameter indicative of" a glucose
9 value. It's the most obvious one.

10 BY MR. SARASWAT:

11 Q. And where in your declaration did you say that
12 the parameter indicative of glucose value could be this
13 kind of large set that may include a realtime glucose
14 value?

15 A. I was using what I would call the common sense
16 and plain language definition of "parameter indicative
17 of."

18 If the authors of the patent wish to say a
19 predictive glucose value, they could have said
20 "predictive glucose value" everywhere instead of having
21 this -- I don't want to call it mumbo jumbo, but I'll
22 call it otherwise slightly mysterious, vague and
23 confusing and awkward term "parameter indicative of a
24 glucose value." That's making it much more difficult
25 than it needs to be.

1 But certainly parameter indicative of glucose
2 value, as far as I'm concerned, includes a glucose value
3 or includes specifically a realtime glucose value or a
4 substantively realtime glucose value.

5 Q. So is "parameter indicative of" a term of art?

6 A. I know what a parameter is. I use parameters
7 all the time in all sorts of -- I use that language all
8 the time to discuss all kinds of things, including
9 parameters of continuous glucose monitoring or
10 parameters of all kinds of data analysis, many of which
11 apply to glucose and related things related to diabetes.
12 So a "parameter" just means literally "para" and "meter"
13 means for to measure, or for measuring. It's something
14 that measures.

15 So it's something related to glucose. They
16 might have picked a better word. They might have
17 picked, for instance, predictive.

18 I read the '215 Patent many, many, many times
19 before I even understood or began to understand that,
20 oh, maybe these guys are hinting it might be something
21 relating to predictive.

22 Q. Given that you didn't think "parameter
23 indicative of" was a well-understood term, why didn't
24 you just apply the usage in the specification of
25 "parameter indicative of" as a predicted glucose value?

1 MR. WILLIAMS: Objection to form.

2 BY THE WITNESS:

3 A. That wasn't my job. That was the job for the
4 guys writing the '215 application. Why didn't they say
5 "predictive" in their language for the claims and for
6 the specifications?

7 BY MR. SARASWAT:

8 Q. If you give me a few minutes, I'm going to be
9 drawing something for you Dr. Rodbard.

10 A. Good.

11 MR. SARASWAT: I'm going to ask the court
12 reporter to mark this as Exhibit 2007.

13 (Whereupon, Deposition Exhibit 2007 was
14 marked for identification.)

15 THE WITNESS: May I share this with my
16 counsel?

17 MR. SARASWAT: Yes.

18 BY MR. SARASWAT:

19 Q. So I apologize for my handwriting, but what I
20 hope you can see from the graph is that -- what I have
21 given you is a graph that has a glucose level on the Y
22 axis and time on the X axis, and the glucose level over
23 the course of time from T1 to T3 has gone down.

24 Do you see that?

25 A. Yes.

1 Q. So in the graph I showed you, the glucose
2 value started at some positive number and ended at some
3 smaller positive number, correct?

4 A. Yes.

5 Q. So would you agree that the graph I showed
6 you, the glucose level is constantly trending down?

7 MR. WILLIAMS: Objection to form.

8 BY THE WITNESS:

9 A. It's trending down, and I don't know what the
10 word "constant" would mean.

11 BY MR. SARASWAT:

12 Q. So you would agree that the glucose level in
13 the graph I showed you between T equals 0 and T equals
14 T3 is trending down?

15 A. Correct.

16 Q. So the direction of change of the glucose
17 level in this graph is always negative, correct?

18 A. It's down and it can be designated as
19 negative, correct.

20 Q. And would you also agree with me that in the
21 graph that I gave you, the rate of change of glucose
22 value between time period T2 and T3 is larger than the
23 rate of change at the glucose value between time T1 and
24 T2?

25 A. Yes, with one qualifier. The qualifier is

1 that you need to know the error or uncertainty in each
2 of those measurements. I'm assuming if this is a real
3 biological or clinical glucose level, it's always
4 something we have uncertainty about.

5 So, depending on the degree of uncertainty,
6 the apparent change in slope may or may not be real or
7 meaningful. As drawn, yes it has a steeper slope.

8 Q. Okay. So would you agree with me that between
9 time period T2 to T3, the direction of rate of change is
10 positive because the rate of change is getting bigger?

11 MR. WILLIAMS: Objection to form; outside the
12 scope.

13 BY THE WITNESS:

14 A. Can I ask you to repeat the question. It
15 didn't make sense to me, so please repeat it. What's
16 positive?

17 BY MR. SARASWAT:

18 Q. Well, the rate of change between T2 and T3 is
19 larger than the rate of change between T1 and T2,
20 correct?

21 A. Yes.

22 Q. So because the rate is larger, would you agree
23 that the direction of the rate of change is positive
24 even though in the graph the rate of change is negative?

25 A. No, sir.

1 MR. WILLIAMS: Objection to form.

2 BY MR. SARASWAT:

3 Q. If the rate of change between T2 and T3 is
4 greater than the rate of change between T1 and T2, then
5 why isn't the direction of the rate of change positive?

6 MR. WILLIAMS: Objection to form.

7 BY MR. SARASWAT:

8 Q. Is the rate of change bigger?

9 MR. WILLIAMS: Objection to form; outside the
10 scope.

11 BY THE WITNESS:

12 A. We agree that the rate of change changed. The
13 rate of change between T2 and T3 is more negative than
14 the rate of change between T1 and T2. We agree it got
15 steeper. However, that should be designated as
16 something being positive. That's a different question
17 and I don't understand here what is being positive.

18 BY MR. SARASWAT:

19 Q. Well, the magnitude of the rate of change has
20 gone up, correct?

21 MR. WILLIAMS: Objection to form.

22 BY THE WITNESS:

23 A. That's right. The absolute magnitude is
24 greater, but the magnitude of the rate of change has
25 gotten more negative. So the magnitude, the absolute

1 value during the minus sign is now larger, we know that.
2 And then the slope, the actual slope, the actual trend,
3 the actual derivative is now more negative than it was
4 before. It might have been minus one here and now it's
5 minus three for the period between T2 and T3.

6 BY MR. SARASWAT:

7 Q. So would you agree that when you're
8 characterizing the rate of change of something, there's
9 both a magnitude and a direction?

10 MR. WILLIAMS: Objection to form; outside the
11 scope.

12 BY THE WITNESS:

13 A. There's an arithmetic value and there's a
14 sign. The sign would indicate the direction plus
15 usually meaning up and minus usually meaning down.

16 Evidently, when you're talking about the value
17 of the slope, you're talking about the absolute value of
18 the slope, which can be called the magnitude.

19 BY MR. SARASWAT:

20 Q. Okay. So we agree that in this graph that I
21 showed you, which is Exhibit 2007, the magnitude of the
22 slope between T2 and T3 is bigger than the magnitude of
23 the slope between T1 and T2, correct?

24 A. Correct.

25 Q. So if we're just focused on the magnitude, the

1 value of the magnitude has gone up, correct?

2 MR. WILLIAMS: Objection to form; outside the
3 scope.

4 BY THE WITNESS:

5 A. The absolute value of the magnitude during the
6 sign, just to reiterate, is now larger between T2 and T3
7 than between T1 and T2.

8 BY MR. SARASWAT:

9 Q. Okay. Because the value of the magnitude has
10 gone up between the T1-T2 time period and the T2-T3 time
11 period, the direction of change of magnitude is up,
12 correct?

13 MR. WILLIAMS: Objection to form; outside the
14 scope.

15 BY THE WITNESS:

16 A. The direction of the absolute magnitude has
17 gone up.

18 BY MR. SARASWAT:

19 Q. Okay. You can set that drawing aside. I
20 think actually you should --

21 A. I'll give it to you.

22 Q. If you could give her the previous thing I
23 marked, Exhibit 2006.

24 (Document tendered.)

25

1 BY MR. SARASWAT:

2 Q. All right. Let's turn back to your claim
3 listing in your declaration on page 157.

4 So if we look at the last limitation of
5 claim 1, limitation of 1[d], it says:

6 "Providing an output including a second
7 hypoglycemic indicator if the one or more
8 nonuser settable second criteria are
9 met."

10 Correct?

11 A. Yes.

12 Q. Actually, both the last two, 1[c] and 1[c],
13 talk about providing an output, correct?

14 A. Yes.

15 Q. Including hypoglycemic indicators, right?

16 A. Yes.

17 Q. And if we look at claim 19 on page 158,
18 limitation 19[g] talks about providing "an output based
19 on the activated hypoglycemic indicator." Do you see
20 that?

21 A. Yes.

22 Q. If we look at the two limitations above, 19[b]
23 and 19[f] the activated hypoglycemic indicator could be
24 either the first indicator on the second indicator,
25 correct?

1 MR. WILLIAMS: Objection to form.

2 BY THE WITNESS:

3 A. Both 19[e] and 19[f] refer to activating the
4 hypoglycemic indicator.

5 Q. Right.

6 So in 19[g] when it talks about providing an
7 output based on the activated hypoglycemic indicator,
8 the activated hypoglycemic indicator is going to be
9 either a first hypoglycemic indicator as recited in
10 19[e] or a second hypoglycemic indicator as written in
11 19[f], correct?

12 A. That is my interpretation.

13 Q. Okay.

14 A. But we have to recognize that "the" is
15 actually plural because there's two different ones
16 defined in E and F, or they could be the same. It could
17 be E and F or it could be similar for E and F.

18 Q. Okay. So let's turn to column 4 in the '215
19 Patent and look at lines 54 to 61.

20 There's a sentence that starts, "In an
21 embodiment..."

22 A. Yep.

23 Q. So it says:

24 "In an embodiment of a second aspect
25 providing output comprises transmitting a

1 message to an insulin delivery device,
2 including instructions associated with at
3 least one of, A, suspending insulin
4 delivery, B, initiating a hypoglycemia
5 and/or hyperglycemia minimizing
6 algorithm, C, controlling insulin
7 delivery or, D, information associated
8 with the hyperglycemia indicator."

9 Do you see that?

10 A. Yes.

11 Q. So, this sentence is talking about an output
12 including instructions and then it lists the four things
13 I just talked about, right?

14 MR. WILLIAMS: Objection to form.

15 BY THE WITNESS:

16 A. It lists the four options you've just
17 mentioned and the proviso that that's in an embodiment.
18 So this is one of unknown or infinite number of possible
19 embodiments.

20 BY MR. SARASWAT:

21 Q. Okay. And the four things on the list are
22 instructions that are telling the insulin delivery
23 device to do something, correct?

24 A. In this instance, yes.

25 Q. Okay. Now, let's look at column 19 and look

1 at line 24, the sentence that says:

2 "Thus, in certain of the present
3 embodiments, at a predetermined level or
4 event (low glucose level, no button
5 pressing after alert, etc.) that might
6 signify a loss of consciousness, the
7 processor module 214 may go into an
8 emergency response instruction mode."

9 Do you see that?

10 A. Yes.

11 Q. It says:

12 "This mode may include an alarm to alert
13 others in close proximity to the user
14 that something is wrong."

15 A. Yes.

16 Q. It says:

17 "For example, step-by-step instructions
18 on how to assist the unconscious user may
19 be shown on the smart phone's user
20 interface 222, such as administering
21 glucose tabs or another form of
22 carbohydrates, calling an ambulance,
23 etc."

24 Do you see that?

25 A. Yes.

1 Q. So, if something that's shown on the smart
2 phone's user interface, is that an example of an output?

3 A. I believe so.

4 Q. Okay. So here, in this instance, the patent
5 is saying that the output includes instructions to a
6 person to do something, correct?

7 A. Repeat the question.

8 Q. So in this instance that we've just been
9 talking about in column 19 at lines 24 to 34, the patent
10 is saying that the output includes instructions to a
11 person to do something, correct?

12 A. Or it could be ringing a bell. It may be the
13 emergency processor -- the mode may include an alarm to
14 alert others.

15 Is an alarm to alert others an instruction?
16 It's not an instruction to a user, it's an instruction
17 to an alarm bell or device or something like that.

18 It doesn't always go to a person. It may just
19 go into the air. But the other examples do talk about
20 giving instructions that hopefully will be perceived by
21 a person.

22 Q. Okay. And then let's look at column 29 at
23 line 13.

24 A. Okay.

25 Q. So there's a sentence that says:

1 "Some embodiments provide the necessary
2 sensor data useful for a hypoglycemic
3 hypo-avoidance system to be sent to the
4 insulin delivery device, for example, a
5 hypoglycemic indicator may include
6 information useful for determining when
7 and for long to suspend or reduce basal
8 insulin delivery (e.g., predicted glucose
9 value and prediction horizon, rate of
10 change of glucose, statis risk, dynamic
11 risk) or may send the actual instructions
12 (e.g., suspend basal delivery for 20
13 minutes)."

14 Do you see that?

15 A. Yes.

16 Q. So here the patent is talking about sending
17 instructions to an external device to have that device
18 do something, correct?

19 A. Except for the last one-and-a-half lines which
20 is apparently sending it to a person again because the
21 words "suspend basal delivery for 20 minutes" wouldn't
22 usually go to a device.

23 Q. Oh, okay. I see.

24 So it's talking about instructions either to a
25 device to do something or to a person to do something?

1 A. Yes.

2 Q. Okay.

3 A. I might comment that this idea of turning off
4 or changing the dosage of the insulin delivery or the
5 rate of insulin delivery was not new or novel with the
6 '215 that had been the subject of research by many
7 people in many labs worldwide for many years.

8 Q. Okay. So you would agree that in the three
9 portions of the specification that we just talked about,
10 it's talking about the output -- sorry. Withdrawn.

11 So in the three portions of the specification
12 we just looked at, where the specification talks about
13 an output containing instructions, those are
14 instructions to a person or to an external device,
15 correct?

16 A. Correct.

17 Q. All right. So I know we've been talking about
18 the Guide a lot which is Ground 1.

19 In Ground 2 you're combining the Guide with
20 Harper, correct?

21 A. Yes.

22 Q. So what is your understanding of what you have
23 to demonstrate to show that it would be obvious to
24 combine two references?

25 MR. WILLIAMS: Objection to form.

1 BY THE WITNESS:

2 A. In this case, we want to show one -- one
3 anywhere would need to show that there's a nexus, that
4 is, that they both apply, for instance, to continuous
5 glucose monitoring, that they referred to an alert or an
6 alarm, not just for the lows but also for the highs or
7 any other type of alarm that might be being considered
8 at that moment. And that it provides some help to the
9 presumptive end user to do something appropriate.

10 BY MR. SARASWAT:

11 Q. And is it also required to show that a POSITA
12 would have a reasonable expectation of success in
13 combining references?

14 A. Yes.

15 Both the User Guide and Harper are measuring
16 glucose and comparing it to a threshold, one or more
17 thresholds, or one or more criteria, and then signalling
18 or activating an alarm or activating an indicator,
19 which, in turn, can be manifested as an alarm or an
20 alert or other graphical, auditory, vibratory or other
21 kind of output that can actually touch and influence and
22 affect or educate or advise a user such as a patient.

23 Q. Let's look at paragraph 68 of the declaration.

24 So here in this paragraph you're arguing that
25 a POSITA would have been motivated to combine Harper

1 with a Guide; is that correct?

2 A. Yes.

3 Q. At the end of the paragraph, you say:

4 "As explained below, such a combination
5 is nothing more than combining prior art
6 elements according to known methods to
7 yield predictable results."

8 Correct?

9 A. Yes.

10 Q. So just so I understand, you're not proposing
11 to modify anything that's in Harper and the Guide,
12 you're just talking something from Harper and adding it
13 to the Guide, correct?

14 MR. WILLIAMS: Objection to form.

15 BY THE WITNESS:

16 A. We're taking the spirit and the purpose of
17 Harper, which I construe to mean the ability and the
18 mechanisms or portions of mechanisms to evaluate a
19 predicted glucose and we are adding that to the STS
20 sensor User Guide.

21 BY MR. SARASWAT:

22 Q. Okay. But my question was I just want to
23 confirm that you're not -- in this combination you're
24 not changing anything that's in the Guide or Harper when
25 you combine Harper and the Guide?

1 MR. WILLIAMS: Objection, form; asked and
2 answered.

3 BY THE WITNESS:

4 A. Not in these three lines starting as explained
5 below.

6 First of all, it was plain to everybody in the
7 field that a realtime alert may be too late. We talked
8 about the GlucoWatch data that you illustrated with your
9 Exhibit 2006. And there was a need to be able to obtain
10 a predictive alarm or alert.

11 So that's the fundamental feature here that
12 everybody -- everybody -- not everybody, but many
13 people, most people perhaps, would have thought that
14 this would be a desirable thing to do.

15 BY MR. SARASWAT:

16 Q. So in this combination, you're not changing
17 anything that's in the Guide, you're adding something
18 from Harper to the Guide that you think people would
19 have thought was desirable?

20 A. We're adding functionality.

21 Q. You're not modifying any existing
22 functionality in the Guide, you're adding existing
23 functionality from Harper?

24 A. That's correct.

25 Q. So if we look at paragraph 71, at the very end

1 you say:

2 "For the above described reasons, in my
3 opinion, a POSITA would have motivated
4 the incorporate the alarm profile of
5 Harper into the low glucose alarm in the
6 User's Guide."

7 A. I got to find that.

8 You said it's at the end of paragraph 71?

9 Q. Yes.

10 A. Starting with the sentence starting with,
11 "Indeed"?

12 Q. No, the last sentence. It says, "For the
13 above described reasons..."

14 A. I've read that sentence.

15 Q. What do you mean when you say "incorporate the
16 alarm profile of Harper into the low glucose alarm in
17 the User's Guide"?

18 A. We're saying that we want to take some,
19 possibly all, but certainly some of the functionality of
20 Harper for the detection of the fact that somebody is
21 going low.

22 Based all the information collected to that
23 very moment in time, we think there's a good probability
24 or a possibility that it will go below some threshold or
25 criterion that would potentially be undesirable for that

1 patient, for that person.

2 And so when we have detected the fact
3 that -- not that we're low right now this very instant,
4 this very second, but we think you're going to be low
5 sometime in the second 30 minutes or you're going to be
6 low sometime in the next 10 or 15 minutes. We may be
7 able to say we think you're going to be low in 10
8 minutes or in some specific time.

9 when that happens, we want to sound or we want
10 to authorize, activate and implement an alarm that we
11 believe the end user is likely to respond to or would be
12 able to respond to.

13 Q. Okay. So you're saying Harper has some
14 functionality that activates an alert if the glucose
15 level is predicted to cross some threshold, and you want
16 to take that functionality from Harper and add it to the
17 Guide, correct?

18 A. Add it to a device such as or similar to the
19 STS sensor.

20 Q. Okay. So what you would end with up in your
21 proposed combination for Ground 2 is the device as
22 described in the Guide, plus this additional function
23 from Harper of an alert that is activated if the glucose
24 value is predicted to cross a threshold?

25 MR. WILLIAMS: Objection to form.

1 BY THE WITNESS:

2 A. I believe that's correct.

3 BY MR. SARASWAT:

4 Q. Okay.

5 A. So at that point you have a predictable alarm
6 or alert.

7 Q. If we look back a little bit at paragraph 67.

8 A. Yes.

9 Q. You say:

10 "It would have been obvious to a POSITA
11 to combine Harper's disclosure of using
12 projected glucose value thresholds and/or
13 rate of change or acceleration of the
14 rate-of-change thresholds to predict
15 impending hypoglycemia condition with the
16 User's Guide."

17 Correct?

18 A. Yes.

19 Q. So you're saying that in your proposed
20 Guide/Harper combination, the -- withdrawn.

21 You're saying in your proposed Guide/Harper
22 combination, you are using the projected glucose value
23 thresholds and/or the rate of change or the acceleration
24 rate-of-change thresholds, correct?

25 A. Yes.

1 Q. So let's take a look at Harper. Let's look at
2 paragraph 202.

3 A. Hold on.

4 what are you reading?

5 Q. I was looking at paragraph 202.

6 A. Okay.

7 (Witness reviews document.)

8 BY THE WITNESS:

9 A. Yes.

10 BY MR. SARASWAT:

11 Q. At the start of that paragraph it says:

12 "In certain embodiments when the day
13 alarm time has been set, the menu
14 literally progresses to a 'glucose alarm'
15 threshold screen in which a user may
16 select varying glucose threshold levels
17 at which various alarms will sound for
18 low glucose levels, high glucose levels,
19 projected low glucose levels and
20 projected high glucose levels."

21 Correct?

22 A. Help me understand which line I'm in.

23 Q. There's no line numbers. It's the very, very
24 first sentence.

25 A. Okay. That's correct.

1 Q. So it says:

2 "The menu linearly progresses to a
3 'glucose alarm' threshold screen in which
4 a user may select varying glucose
5 threshold levels at which various alarms
6 will sound for low glucose levels, high
7 glucose levels, projected low glucose
8 levels, and projected high glucose
9 levels."

10 Do you see that?

11 A. Yes.

12 Q. So here it's saying that this -- sorry.
13 withdrawn.

14 Here, it's saying that the user can select the
15 projected low and high glucose levels using this glucose
16 alarm threshold screen, correct?

17 A. Correct.

18 Q. So this means that the projected low and high
19 glucose thresholds are user settable; is that correct?

20 MR. WILLIAMS: Objection to form.

21 BY THE WITNESS:

22 A. When we combine the User Guide for the STS
23 device with Harper, the User Guide is the place I look
24 to first to see that the criteria will be nonuser
25 settable.

1 BY MR. SARASWAT:

2 Q. Right.

3 If we're just looking at what Harper says,
4 Harper is saying that those projected low and high
5 glucose thresholds are user settable, right?

6 A. Harper says that here. I'd like to check to
7 see if it says anything anywhere else.

8 Q. If we look at paragraph 281 and we look at the
9 last sentence of that paragraph, it says:

10 "Although specific rates of change have
11 been mentioned, it is contemplated that
12 the rate-of-change thresholds and the
13 time period associated with the rate of
14 change may be selected and adjusted by
15 the user or a healthcare provider."

16 Correct?

17 A. That's what it reads.

18 Q. So here, just focusing on what Harper says,
19 Harper is saying that the rate-of-change thresholds is
20 user settable, correct?

21 MR. WILLIAMS: Objection to form.

22 BY THE WITNESS:

23 A. When we combine the User Guide with Harper,
24 then we have the ability to set one or more parameters,
25 one or more criteria, thresholds and so on to make a

1 nonuser setup.

2 BY MR. SARASWAT:

3 Q. Right.

4 But just focusing on what Harper is saying,
5 Harper is saying that the rate-of-change threshold is
6 user settable?

7 A. In Harper by itself, yes.

8 Q. Okay.

9 A. But it's pretty obvious that to me -- it's
10 pretty obvious, I think, to most people, maybe to
11 everybody, that a criterion such as a predicted alert
12 could also be made on the basis of nonuser settable
13 criteria.

14 Q. All right.

15 MR. SARASWAT: So everything the witness said
16 after yes is not responsive to my question, so I'm going
17 to move to strike it.

18 MR. WILLIAMS: Good luck.

19 BY MR. SARASWAT:

20 Q. Just to be clear, focusing on what Harper is
21 saying, Harper is saying that the rate-of-change
22 threshold is user settable, correct?

23 MR. WILLIAMS: Objection to form.

24 BY THE WITNESS:

25 A. He says it can be selected and adjusted by the

1 user or a healthcare provider.

2 BY MR. SARASWAT:

3 Q. Right.

4 So, the user is one of the people on the list
5 of people that can change the threshold, correct?

6 A. Yes.

7 Q. Now, earlier you said -- and I'm just reading
8 what you said. You said:

9 "It's pretty obvious, I think, to most
10 people, maybe to everybody, that a
11 criterion such as a predicted alert could
12 also be made on the basis of nonuser
13 settable criteria."

14 Did you say that?

15 A. Yes.

16 Q. Could you show me where in your criteria you
17 said this?

18 A. At a minimum, it's implied in Ground 1 and it
19 may be implied throughout. The...

20 (Witness reviews document.)

21 BY THE WITNESS:

22 A. I think that the -- I think that I cover that
23 in Grounds 4, 5 and 6.

24 BY MR. SARASWAT:

25 Q. But you don't cover it in Ground 2?

1 MR. WILLIAMS: Objection to form.

2 BY THE WITNESS:

3 A. Let's see.

4 (Witness reviews document.)

5 BY THE WITNESS:

6 A. Could you repeat the last sentence that you
7 stated or the last phrase.

8 BY MR. SARASWAT:

9 Q. So I had asked you where in your declaration
10 you said that it's obvious to most people that a
11 criteria such as predicted could also be made on the
12 basis of nonuser settable criteria and you said, "I
13 think I covered that in Grounds 4, 5 and 6."

14 A. That's correct, yes.

15 Q. So my question is, do you cover that in Ground
16 2?

17 A. No, I haven't found it so it probably isn't
18 there.

19 Q. Okay. Let's look at paragraph 68. In the
20 first sentence you're saying that a POSITA would have
21 been motivated to combine Harper's alarm profile with a
22 low glucose alarm from the User's Guide, correct?

23 A. Yes.

24 Q. I want to focus on a few sentences later on in
25 the paragraph. You say:

1 "Combining Harper's alarm profile with
2 the User's Guide would also allow a user
3 to better understand their glycemic
4 condition so as to maintained desired
5 glucose levels in interstitial fluid
6 and/or blood levels."

7 Do you see that?

8 A. No. Are we on paragraph 68?

9 Q. We're on the next page. I apologize. I think
10 I messed up my pagination. It's my fault.

11 Let's turn to paragraph 70. So you say in
12 paragraph 70:

13 "A POSITA would have understood from the
14 teachings of both the User's Guide and
15 Harper that additional alarm profiles
16 would increase the accuracy of
17 hypoglycemia warnings and provide
18 additional warning time for users."

19 Correct?

20 A. Yes.

21 Q. So that's one benefit that you're identifying
22 that you say would have come from combining Harper with
23 the Guide, correct?

24 A. Yes.

25 Q. And then you say:

1 "Combining the alarm profile of Harper
2 including thresholds for projected low
3 glucose levels and rate of change (first
4 derivative of glucose with respect to
5 time) or acceleration (second derivative
6 glucose with respect to time) with the
7 low glucose alarm of the User's Guide
8 would further the User's Guides stated
9 goal to provide a monitoring system that
10 'aids in the detection of episodes of
11 hypoglycemia' which may minimize these
12 excursions' by providing additional
13 warning time to the user."

14 Do you see that?

15 A. Yes.

16 Q. So that's another reason you identify for why
17 it would have been beneficial to combine Harper with the
18 Guide, correct?

19 A. Yes.

20 Q. Now, would these benefits still be there if in
21 the Harper Guide combination the projected glucose
22 thresholds or the rate-of-change thresholds were left
23 user settable the way they are in Harper?

24 MR. WILLIAMS: Objection to form.

25 BY THE WITNESS:

1 A. well, that is speculative. Of course, as a
2 question, I think I can make the statement that these
3 benefits and possibly additional benefits or many
4 additional benefits would -- as a result of combining
5 Harper with the User Guide could be and almost certainly
6 would be retained, would be present, whether one has
7 user settable or nonuser settable constants or
8 parameters.

9 You could do it with a user settable system,
10 you could do it with a nonuser settable system. But it
11 can be done with a nonuser settable set, either an
12 individual parameter or more than one parameter, more
13 than one criteria.

14 Q. Right. But my question isn't about whether
15 it's feasible to be done.

16 My question is, would the benefits you've
17 identified in paragraph 70 still be there if you had
18 user settable criteria as described in Harper?

19 A. Yes.

20 Q. So could you please turn again to your claim
21 listing on page 157 of your declaration. Let's look at
22 element 1[d]. It says:

23 "Providing an output including a second
24 hypoglycemic indicator if the one or more
25 nonuser settable second criteria are

1 met."

2 Do you see that?

3 A. Yes.

4 Q. And element 1[b] says:

5 "Evaluating sensor data using a second
6 function to determine whether a parameter
7 indicative of glucose value meets one or
8 more nonuser settable second criteria."

9 Correct?

10 A. Correct.

11 Q. So is it correct that elements 1[b] and 1[d]
12 are related in that you provide the output as specified
13 in 1[d] if the parameter indicative of glucose value
14 meets the nonuser settable criteria as recited in 1[b]?

15 MR. WILLIAMS: Objection to form.

16 BY THE WITNESS:

17 A. 1[b] does the evaluation and [d] does the
18 output.

19 BY MR. SARASWAT:

20 Q. Right.

21 So if the evaluation in 1[b] is met, then 1[d]
22 the output?

23 A. That's correct.

24 Q. And there's a similar relationship between
25 elements 19[f] and 19[d], right?

1 MR. WILLIAMS: Object to form.

2 BY THE WITNESS:

3 A. 19[f] -- and I assume you're referring to
4 19[d], is it?

5 BY MR. SARASWAT:

6 Q. Yes.

7 A. It sounded like B, but it may have been D that
8 you stated.

9 1[d] does the evaluation. 1[f] activates an
10 indicator but doesn't use the word output.

11 In fact, it's not exactly parallel to the 1[b]
12 and the 1[d], or for that matter the 1[a] and the 1[c]
13 because output is the 1[c], 1[d] and it is also, for the
14 record, in 19[g].

15 Q. Right.

16 But the point is in 19[d] there's evaluating
17 stuff that happens and in 19[f] you activate the second
18 hypoglycemic indicator --

19 A. Yes.

20 Q. -- if evaluating 19[d] passes?

21 A. I agree.

22 Q. So in Ground 2, which is the Guide/Harper
23 combination?

24 A. Yes.

25 Q. The parameter indicative -- sorry.

1 In Ground 2 which is your Guide/Harper
2 combination, the thing that you're saying is the
3 parameter indicative of glucose value is either the
4 projected glucose value or the rate of change of glucose
5 value from Harper; is that right?

6 A. Acceleration is also mentioned or it could be
7 some combination of the value and the rate of change or
8 the value and the rate of change and the acceleration,
9 or it could be something just as calculated from the raw
10 numbers.

11 Q. So you would agree that in order to show that
12 the Guide/Harper combination meets claim 1, you would
13 have to show that in the Guide/Harper combination you
14 provided output, including a second hypoglycemic
15 indicator, if the one or more user settable second
16 criteria are met by whatever it is from Harper you
17 pointed to as being the parameter indicative of the
18 glucose value?

19 MR. WILLIAMS: Objection to form.

20 BY THE WITNESS:

21 A. I'm sorry. I'd like to ask you to repeat the
22 question.

23 BY MR. SARASWAT:

24 Q. Let me try to rephrase that.

25 So you're saying that in the Guide/Harper

1 combination, the thing that you're pointing to as a
2 parameter indicative of glucose value is something from
3 Harper, right, it's under the projected glucose value or
4 the rate of change of glucose value or something else,
5 but it's coming from Harper, correct?

6 A. Simply based on them, yes.

7 Q. So in the Guide/Harper combination --
8 withdrawn.

9 And then limitation 1[d] says:

10 "Providing an output including a second
11 hypoglycemic indicator if the one or more
12 nonuser settable second criteria are
13 met."

14 Do you see that?

15 A. Yes.

16 Q. When it says "are met," it's referring back to
17 the language in limitation 1[b] when it talks about
18 "parameter indicative of glucose value meets one or more
19 nonuser settable second criteria," right?

20 A. Yes.

21 Q. So for the Guide/Harper combination to meet
22 claim 1, it would have to be the case that the
23 combination discloses providing an output including a
24 second hypoglycemic indicator if the parameter
25 indicative of glucose value that you identified in

1 Harper meets one or more user settable second criteria?

2 A. User settable or user nonsettable as the case
3 may be.

4 Q. I'm talking about what limitation 1[b] says.

5 You're saying that the parameter indicative of
6 glucose value is something from Harper, right?

7 MR. WILLIAMS: Objection to form.

8 BY THE WITNESS:

9 A. I believe it would be coming from Harper.

10 BY MR. SARASWAT:

11 Q. All right. Sorry, I realize I think I missed
12 a word in my previous question, in one of the earlier
13 questions. So let's try this again.

14 Do you agree that for the Guide/Harper
15 combination to meet claim 1, it would have to be the
16 case that the combination of Guide and Harper discloses
17 providing an output including a second hypoglycemic
18 indicator if the thing that you identified from Harper
19 as being the parameter indicative of glucose value meets
20 one or more nonuser settable criteria?

21 A. Yes, I believe that's correct.

22 Q. Okay. So if we look at paragraphs 74 and 75
23 of your declaration, are those the paragraphs where you
24 discuss limitation 1[d]?

25 A. They are relevant to 1[d]. They're discussing

1 an output.

2 Q. Well, it says up at the top. Above paragraph
3 74, you see that the text of limitation 1[d] is recited?

4 A. Yes, it is. Those paragraphs then are
5 intended to discuss limitation 1[d].

6 Q. So are paragraphs 74 and 75 the place where
7 you provide your analysis of limitation 1[d] in Grounds
8 1 and 2?

9 A. I discuss part of that.

10 Q. What do you mean you discuss part of that? Do
11 you discuss limitation 1[d] somewhere else for Ground 2?

12 A. No, probably later in one of the other
13 grounds. But this is at least a partial discussion
14 about the limitation on item claim 1[d].

15 Q. Is there any place in your declaration other
16 than paragraphs 74 and 75 where you discuss limitation
17 1[d] with respect to Ground 1 or Ground 2?

18 A. No.

19 Q. Okay. So paragraph 74 and 75 are where your
20 analysis for limitation 1[d] for Grounds 1 and 2 is
21 contained?

22 A. Correct.

23 Q. And in those paragraphs do you discuss Harper
24 at all?

25 A. Let's see.

1 (witness reviews document.)

2 BY THE WITNESS:

3 A. No, I don't believe so.

4 MR. SARASWAT: Okay. I think we've been going
5 for over an hour since lunch. Should we take a break?

6 MR. WILLIAMS: Sure.

7 (Whereupon, a recess was taken from
8 2:12 p.m. until 2:26 p.m.)

9 BY MR. SARASWAT:

10 Q. All right. Dr. Rodbard, could you please turn
11 to paragraph 117 in your declaration.

12 A. Okay.

13 Q. Okay. So here you're discussing the Shariati
14 reference, correct?

15 A. Yes.

16 Q. And you say in the -- looks like the third
17 sentence, you say:

18 "Shariati discloses that threshold can be
19 programmed into the computer system or
20 user selectable."

21 You cite to paragraph 571, correct?

22 A. Yes.

23 Q. And you say:

24 "Because Shariati teaches that the
25 threshold can be programmed into the

1 computer system as an alternative to
2 being user selectable, in my opinion a
3 POSITA would have understood that a
4 threshold that is programmed into the
5 computer system is not user settable,
6 i.e. a nonuser settable criteria."

7 Do you see that?

8 A. Yes.

9 Q. How do you know that the user isn't the one
10 that programmed the threshold into the computer system?

11 A. As a general rule -- in fact, almost always --
12 the user, if the user is the patient, they're not
13 computer programmers. And even if they were computer
14 programmers, they would have no reason to be familiar
15 with the programming or other special techniques or
16 languages that are built into any particular device.

17 So I think we have a pretty clear distinction
18 between the user such as a patient, even a patient who
19 himself works for a computer company and does computer
20 programming, even in a situation like that, we do not
21 think or expect that that kind of a person would be
22 programming the computer to adjust the thresholds or
23 algorithms being used to evaluate either a realtime or a
24 predicted glucose. So I regard that as -- you know,
25 really farfetched.

1 Q. So you're saying when Shariati says
2 "programmed into the computer system," that that has to
3 mean programmed in using a programming language?

4 A. Not necessarily. It could be -- for all we
5 know it's just a data statement somewhere. It's
6 something that goes into the computer, but it has to be
7 done by somebody who knows what they're doing with that
8 particular computer system and with that particular
9 program and application for a particular individual.

10 Q. So let's take a look at Shariati.

11 A. Yes.

12 Q. So let's look at paragraph 333 of Shariati.
13 Okay. Shariati spans two columns. So if we look at the
14 right-hand column, towards the middle you'll see a
15 sentence that starts with the words "in preferred
16 embodiments." Let me know when you're there.

17 (Witness reviews document.)

18 BY THE WITNESS:

19 A. Okay.

20 BY MR. SARASWAT:

21 Q. Here it says:

22 "In preferred embodiments, the processor
23 module is configured with a programmable
24 acquisition time, namely the
25 predetermined time interval for

1 requesting the digital value from the A/D
2 converter, is programmable by a user
3 within the digital circuitry of the
4 processing module."

5 Do you see that?

6 A. Yes.

7 Q. Here, Shariati is describing something that is
8 programmable by a user, correct?

9 A. No. This is not a user like a patient. This
10 is not an end user. This is probably an engineer or
11 computer scientist. Patients do not deal with analogue
12 to digital converters.

13 This is somewhere in the guts of the
14 electronics. This has no relationship -- they're using
15 the word u-s-e-r. But in the context of this sentence
16 and this paragraph and the entire Harper component, this
17 is not your end user, not even by a mile, by any
18 stretch. People don't worry about how you're doing the
19 A to D conversions.

20 Q. So you mentioned Harper in your answer right
21 now. You meant Shariati, correct?

22 A. I meant Shariati.

23 I've read over Shariati previously and I read
24 it now. And, in fact, I have been aware of this
25 particular word and I thought about it and decided no,

1 this has no relationship whatsoever to our end user, to
2 the patient or the mother of the patient, or the doctor
3 of the patient.

4 This is some kind of internal guts of some
5 fancy electronics. The end user is not worried about
6 the digital circuitry of the processor module or
7 acquisition times from 2 seconds to 512 seconds.

8 This is something about the internal gears of
9 the system. The patient, the user, the end user doesn't
10 go anywhere near that.

11 Q. Now, you didn't say anything that you just
12 told me in your declaration, did you?

13 MR. WILLIAMS: Objection to form.

14 BY THE WITNESS:

15 A. I don't know. I'd have to go and take a look.
16 Let me say I thought it through very carefully. It's
17 quite possible I didn't say anything because I thought
18 it was totally irrelevant and immaterial.

19 BY MR. SARASWAT:

20 Q. Okay. Just to be clear, the sentence is not
21 saying that the user kind of adjusts the A to D
22 converter in any way, it's just saying that the user
23 programs a time interval, correct?

24 A. Let's see. Program acquisition time. I don't
25 know what acquisition time means. Time to request

1 digital value from the A to D converter.

2 So apparently they're saying -- in this case
3 Shariati is saying that, oh, you're going to be
4 adjusting something between 2 seconds to 512 seconds is
5 preferred. It could be some other number.

6 Other acquisition time. Let me just tell you
7 that no patient that I've ever heard of using or not
8 using a CGM would be in there in the bowels of the
9 system to adjust the acquisition time.

10 Q. But that's not an opinion that you offered in
11 your declaration, is it?

12 A. No, I thought it was obvious. This is a
13 totally different meaning of the term "user" and it
14 doesn't impact what we're talking about otherwise
15 whatsoever. I can't go through here and make a catalog
16 of every possible word that there could even appear
17 somewhere else.

18 Q. I don't want you to do that.

19 A. So that's irrelevant.

20 Q. But you were aware of this language in
21 paragraph 333 that includes the words "programmable by a
22 user," but you didn't offer an opinion about it in your
23 declaration?

24 A. Yes. Once again, it was so farfetched, so out
25 of reason, just no context, no nexus.

1 Q. Now, let's turn to paragraph 118 of your
2 declaration.

3 A. In the initial part of 333 they talk about the
4 situation in which that particular type of manipulation
5 would be done, and it's quite clear that patients or end
6 users don't go into a system and adjust the infinite
7 impulse response, the IIR or the FIR filter. Now, this
8 is just very what we call fancy, elaborate, erudite
9 electronic engineering. In the context of 333, this
10 reenforces my thinking that has nothing to do with the
11 end user.

12 Q. So let's look at the end of 333.

13 In the sentence we were looking at before it
14 has the words programmable by a user. It's talking
15 about a programmable acquisition time, right?

16 A. Yes.

17 Q. And at the end it says:

18 "A programmable acquisition time is
19 advantageous in optimizing noise
20 filtration, time lag, and processing
21 battery power."

22 Do you see that?

23 A. Yes.

24 Q. And isn't optimizing battery power something
25 that even end users of devices want to do and frequently

1 have control over?

2 A. They don't have control over it. They don't
3 want to do it. They don't even know about it.

4 when they're talking about the user, they're
5 talking about the engineer who's building the system,
6 designing the system and/or optimizing the system. It's
7 one of their guys in the back rooms fiddling around with
8 the electronics. This is not the end user.

9 Q. If it's the engineer that's doing this, then
10 why is it programmable? why wouldn't the engineer put a
11 fixed value in there?

12 A. Because he doesn't know what the right value
13 is. He might be fiddling around trying to figure out
14 what works best. He's the guy who needs to figure out
15 how to get it to minimize noise, to filter out the
16 noise, to get smoother curves, smoother rates of change
17 estimates, better rates of change estimates, minimize
18 the time lag between the blood glucose level and the
19 interstitial fluid glucose level as measured by the
20 sensor. Trying to go from the interstitial fluid being
21 measured by the sensor and trying to back-calculate what
22 the devil the blood level might be at that time because
23 the lag had been a problem at one point and people
24 didn't figure out how to deal with it. At the same
25 time, they want to make sure that it's going to be

1 minimizing battery power.

2 So all of that's being done in a stage of the
3 development of the system which is long, long before it
4 ever hits the street, before it ever goes into clinical
5 trials. They have to get their bloody system working.
6 And that's what sort of, in this case I'm afraid, why
7 Dr. Shariati used, or somebody used, what I would regard
8 as an inappropriate word.

9 Q. But once all those settings you talked about
10 are optimized in the development stage, they would be
11 fixed into the system, right?

12 A. Yes.

13 Q. So why would it be described as a programmable
14 acquisition time if it's fixed into the system?

15 MR. WILLIAMS: Objection, form.

16 BY THE WITNESS:

17 A. Same story. Nobody -- nobody, no patient
18 worries about how the filters are doing at smoothing out
19 the moderately or sometimes significantly noisy signals
20 that are coming out of the sensor. This is a pre pre
21 pre pre pre process. It's just out of context.

22 BY MR. SARASWAT:

23 Q. Dr. Rodbard, are you familiar with smartphones
24 like the iPhone?

25 A. Yes.

1 Q. So are you aware that on different smartphones
2 there are settings that allow you to do things like
3 disable background downloading of data to save power?

4 MR. WILLIAMS: Objection, outside the scope.

5 BY THE WITNESS:

6 A. I'm aware they have some function of something
7 like that.

8 BY MR. SARASWAT:

9 Q. So there are examples in the real world of
10 end-user devices that give the end user some kind of
11 control over settings that affect power of consumption,
12 correct?

13 MR. WILLIAMS: Same objection.

14 BY THE WITNESS:

15 A. Yeah, I don't see a connection between that
16 and what we were just talking about in Shariati. But,
17 yes, I'm aware that there are things that can reduce the
18 burden on the battery of a cell phone that will save
19 power.

20 BY MR. SARASWAT:

21 Q. Let's look at paragraph 118 of your
22 declaration.

23 So here, if I understand this correctly, is
24 where you're providing an alternate argument that it
25 would have been obvious that the threshold programming

1 computer system would not be user settable, right?

2 A. Yes.

3 Q. Okay. And you say, it's kind a long sentence
4 so I'm just going to start from part way through. But
5 you say, looking towards the bottom of page 75:

6 "...it would have been obvious to a
7 POSITA that a threshold 'programmed into
8 the computer system' would be nonuser
9 settable at least because the
10 manufacturer, not a typical user,
11 programs the computer system of CGM
12 systems, such as that disclosed in
13 Shariati, and in CGM systems as developed
14 and commercialized to date there is no
15 user interface through which a user could
16 modify the program on which the computer
17 system operates."

18 Do you see that?

19 A. Yes.

20 Q. Now, Shariati itself discloses a user
21 interface that lets the user modify the operation of the
22 device, doesn't it?

23 A. I don't know where you're referring to.

24 Q. Let's look at paragraph 338. Are you there?

25 A. Yes.

1 Q. So it says:

2 "Figures 3A to 3D are schematic views of
3 a receiver 300 including representations
4 of estimated glucose values on its user
5 interface in first, second, third and
6 fourth embodiments respectively."

7 Do you see that?

8 A. Yes.

9 Q. And at the bottom of the paragraph it says:

10 "In some embodiments the user interface
11 can also include a keyboard, a speaker
12 and a vibrator, as described below with
13 reference to figure 4A."

14 Do you see that?

15 A. Yes.

16 Q. So a keyboard is an example of a user
17 interface, right?

18 A. I've never seen a CGM with a keyboard.

19 Q. But that's what Shariati is disclosing, right?

20 MR. WILLIAMS: Objection to form.

21 BY THE WITNESS:

22 A. Shariati is envisioning some embodiments which
23 may or may not have ever been implemented anywhere with
24 a user interface and with a keyboard and speaker and
25 vibrator. That's, let's say, a little an unusual.

1 I think it's a little bit hard to carry around
2 a keyboard on your arm or your abdomen or even in a
3 backpack. People, when they go about their everyday
4 life, they're not dealing with user interfaces of that
5 type and they're not wanting to, needing to, or trying
6 to get into the CGM to tweak it a little bit.

7 BY MR. SARASWAT:

8 Q. So in paragraph 118 when you refer to program
9 or programming, do you consider setting a threshold to
10 be an example of programming?

11 A. Let me just go back to the paragraph.

12 (Witness reviews document.)

13 BY THE WITNESS:

14 A. No, I do not regard setting a threshold as
15 being a program.

16 BY MR. SARASWAT:

17 Q. I think earlier you were saying that, in your
18 view, when Shariati talks about something being
19 programmed into the system, that means it's programmed
20 into the system by the manufacturer before it's shipped
21 to the end user; is that right?

22 A. Yes.

23 Q. But isn't it possible for a device to have a
24 setting that's programmed into the device by the
25 manufacturer and then later changeable by the end user?

1 MR. WILLIAMS: Objection, form.

2 BY THE WITNESS:

3 A. I have to think about that.

4 (Whereupon, Deposition Exhibit 1004 was
5 marked for identification.)

6 BY MR. SARASWAT:

7 Q. Maybe I can make it a little bit easier. I'm
8 going to hand you Exhibit -- I think it's Exhibit 1004
9 which is the Guide.

10 Could you please turn to -- it's page 51. It
11 also says on the bottom in the stamp page 26 of 57.

12 A. Okay.

13 Q. Do you see on page 51 of the Guide there's
14 this paragraph that starts with the words "after
15 successful calibration"?

16 A. I see that.

17 Q. It says at the end:

18 "The default high and low glucose alerts
19 are set at 80 milligrams per deciliter
20 (4.4 millimols per liter) and 200
21 milligrams per deciliter (11.1 millimols
22 per liter) but can be changed to fit your
23 personal diabetes goals."

24 Correct?

25 A. Correct.

1 Q. Am I correct that what the Guide is saying
2 here is that there's a default value for these high and
3 low glucose alerts that was programmed by the
4 manufacturer and then the user can change those values?

5 A. It's evidently the case, yes.

6 Q. So how do you know that that's not also the
7 case with the things Shariati described as being
8 programmed?

9 A. Here on this page, page 26 of 57 of the User
10 Guide, we're talking about a default set of values. By
11 the way, the upper and lower limits of 80 and 200,
12 that's kind of a -- there is no, I think, special
13 God-given value. This is an arbitrary value. Different
14 people, different patient, different doctors use
15 different values.

16 So it's well-known in advance that there is no
17 such universal answer. It is something that needs to be
18 customized to the individual. So they're calling it a
19 default value, it's a placeholder value of one kind or
20 another, but they're allowing that to be changed.

21 So I would agree that that is a user-settable
22 number for those two particular numbers, but I don't
23 call that programming. This is not programming into, in
24 this case, the STS User Guide. I would call it an
25 initial setting, kind of a trial balloon setting. And

1 the user is not programming; the user is selecting.

2 There may even be a scroll bar that lets them
3 click up and down to decide whether they want 60, 70,
4 80, 90. Or it may be that they actually enter the
5 keyboard or use an arrow to adjust numbers, whatever the
6 case may be.

7 But this is a different animal than what we're
8 talking about with user settable -- what we're talking
9 about with the low glucose alarm in the setting of a
10 nonuser-settable function, as in the case of the low
11 glucose alarm.

12 The low glucose alarm, the 55, that is
13 programmed in. That cannot be changed by the end user.
14 That is my idea of what "programming in" means, and that
15 is my idea of what I believe Shariati was talking about
16 when he talks about something being programmed in.
17 Programmed in, it's in.

18 The upper and lower, the 80 and the 200, those
19 are much softer. They are much less important. The
20 performance of the system wouldn't depend a hell of a
21 lot, whether it's 60, 70 or 80 or whether it's 180, 200
22 or 250.

23 Q. I understand you have a view of what
24 programming means, but I'm trying to understand what the
25 references mean by program.

1 So if we look at the sentence just before the
2 one we just read on page 51 it says:

3 "In addition to discreet glucose value,
4 your STS system will alert you when your
5 glucose levels are outside of your
6 programmed alert levels."

7 Do you see that?

8 A. Yes.

9 Q. So here, isn't the Guide using the term
10 "programmed" to describe something that a user can set?

11 A. A better word would have been selected.
12 They're selecting it, they're not programming it in the
13 same sense that, you know, when we talk about program,
14 it means it's going into the code; it's going into the
15 computer code. It's not a wheel that you turn and
16 select any number you want.

17 Q. Right. But I know you disagree with the
18 terminology, but the Guide using this word program to
19 describe something the user can set in this case?

20 A. The Guide is using the word "programmed." I
21 think that's a little bit sloppy and misleading, but the
22 user didn't really program it. They entered it; they
23 selected it. They didn't program it.

24 Q. Did you -- sorry, I want to make sure I don't
25 misquote you here.

1 So you said earlier in your response to one of
2 my questions, part of your answer was:

3 "They're not programming it in the same
4 sense that, you know, when we talk about
5 program, it means it's going into the
6 code; it's going into the computer code.

7 Do you recall saying that?

8 A. Yes.

9 Q. Did you cite in your declaration any reference
10 that supports your interpretation of the word
11 "programming"?

12 A. Probably not, because I'm not even
13 sure -- this is a matter of English language usage or
14 English language usage among a population of
15 individuals, let's say, computer programmers, or others
16 that work with high tech or work with information
17 technology. So if something's programmed in, it's
18 programmed in. That's like solid, you know...

19 Q. All right. So let's now turn back to
20 paragraph 118 of your declaration. So paragraph 118 is
21 where you argued that it would have been obvious that
22 the threshold programming into the computer system would
23 not be user settable; is that correct?

24 A. Nonuser settable, correct.

25 Q. This is the only paragraph where you discuss

1 your analysis for why it would have been obvious to make
2 the thresholds programmed into the computer system
3 nonuser settable; is that correct?

4 MR. WILLIAMS: Object to form.

5 BY THE WITNESS:

6 A. I regard a threshold programmed into the
7 computer system as being nonuser setup.

8 BY MR. SARASWAT:

9 Q. Right. But I mean in paragraph 118, you're
10 making an alternative obviousness argument, correct?

11 A. I'm saying that Shariati, in this context, is
12 discussing what would be a nonuser settable criteria.

13 Q. Right. But then you also say:

14 "To the extent the patent owner argues
15 that Shariati does not expressly disclose
16 that the predicted hypoglycemia alarm
17 threshold is nonuser settable, in my
18 opinion it would have been obvious."

19 And then you go on from there, right?

20 A. (No response.)

21 Q. I'm just trying to confirm that what you're
22 saying here in paragraph 118 is you're giving an
23 alternative argument for why it would have been obvious
24 to make that threshold nonuser settable; is that right?

25 A. Let me read the continuation of that sentence.

1 Q. Sure.

2 A. "At least because a manufacturer, not a
3 typical user, programs the computer system of the CGM
4 systems, CGM systems such as that disclosed in Shariati
5 or envisioned by Shariati, and CGM systems as developed
6 and commercialized to date there's no interface through
7 which a user could modify the program on which the
8 computer system operates."

9 I think that's true, that it's kind of a
10 sealed system because you don't want people messing
11 around with it and possibly resulting in dangerous or
12 disastrous results. It's got to be a secure system.

13 Q. So all you're saying here in paragraph 118 is
14 that a POSITA would understand that Shariati says that
15 those settings are not user settable?

16 MR. WILLIAMS: Objection, form.

17 BY THE WITNESS:

18 A. It would be obvious to a POSITA that the
19 threshold would not be user settable and that a POSITA
20 would understand that this would achieve the same
21 functionality as being nonuser settable.

22 BY MR. SARASWAT:

23 Q. Okay. So you are giving an obviousness
24 analysis in paragraph 118, right? You just said
25 obvious.

1 A. It would be able to do what a nonuser settable
2 system would be able to do. It would achieve the goal.

3 Q. Right.

4 And you explained all of this in paragraph 118
5 in support of your argument that it would have been
6 obvious to make the thresholds nonuser settable,
7 correct?

8 A. It would have been obvious to make what
9 nonuser settable?

10 Q. The predicted hypoglycemia alarm threshold.

11 A. Yeah, this could achieve making the
12 nonuser -- could achieve making the predicted glucose
13 decisionmaking nonuser settable.

14 Q. And you didn't offer any analysis in paragraph
15 118 regarding a reasonable expectation of success, did
16 you?

17 MR. WILLIAMS: Objection to form.

18 BY THE WITNESS:

19 A. Let's see what we've got here.

20 In my view if you program it into the
21 computer, it becomes nonuser settable and therefore the
22 nonuser settable criterion is met. And therefore
23 it -- "it" meaning the combination of the STS sensor and
24 the logic and concepts and proposed mechanisms of Harper
25 become successful, they're done. You make it nonuser

1 settable.

2 MR. WILLIAMS: The witness said Harper and I'm
3 thinking he meant Shariati.

4 THE WITNESS: I meant to say Shariati. So the
5 sentence stands as it was, if it's a halfway decent
6 sentence, but with the name "Shariati" in there instead
7 of "Harper," or I could try to recompose it.

8 MR. SARASWAT: That's okay.

9 BY MR. SARASWAT:

10 Q. Let's look at the last citation sentence you
11 have in paragraph 118. You say:

12 "See id." --

13 "id." meaning Shariati?

14 A. Yes.

15 Q. (Continuing):

16 -- "at 363-64 (contemplating thresholds
17 set only by the manufacturer:

18 '[c]linical risk zones 444 can be set by
19 a manufacturer, customized by a doctor
20 and/or set by a user via button 302."

21 Do you see that?

22 A. Yes.

23 Q. And the emphasis on "and/or" is something that
24 you added; is that right?

25 A. I believe so.

1 Q. So if Shariati is saying here that the
2 clinical risk zones can be set by a user via a button,
3 then how is that a threshold set only by the
4 manufacturer?

5 MR. WILLIAMS: Objection to form.

6 BY THE WITNESS:

7 A. Anything we do with a CGM obviously can
8 be -- a CGM can be set up using adjustable parameters or
9 using fixed parameters a priori. And if it's set by the
10 manufacturer, then it's not a priori, it's as it goes
11 onto the street.

12 Now, we all know that people differ widely --
13 and that applies to people with diabetes or people using
14 insulin or people using a glucose meter. So there
15 could, at least hypothetically, be situations where
16 something might -- where it might be desirable to have a
17 doctor adjusting the value. It may have greater or
18 lesser consequence.

19 For instance, maybe the limit shouldn't be 55,
20 maybe it should be 54, maybe it should be 56. Maybe for
21 somebody else, it might be 75. So there are situations
22 in the real world where it's not unreasonable to have a
23 doctor adjusting a value.

24 The situation with a user and end user is much
25 more problematic, because depending on the degree of

1 education on this particular system or the nature of
2 their particular clinical condition or their coaching or
3 advice from their doctor or other healthcare
4 professional. Obviously, users can make a poor choice,
5 or even a dangerous choice. For that matter, even a
6 doctor can make a dangerous choice. Even a manufacturer
7 can make a dangerous choice.

8 So what I'm getting at is that there are a lot
9 of nuances in what is meant by "user settable." But I
10 don't know, for instance, whether Shariati's thinking
11 about a system that's being developed and is therefore
12 still somewhat experimental, as opposed to, shall we
13 say, a more mature system.

14 So what he's saying here is that clinical risk
15 zones can be set by a manufacturer. In other words,
16 clinical risk zones are very much like what we have with
17 the STS low glucose alert as opposed to the alarm.

18 When they're talking about clinical risk
19 zones, that's something which is -- a clinical risk zone
20 by itself is relatively soft as opposed to the kind of
21 threshold we have at the number of glucose equal 55 in
22 the context of the low glucose alarm.

23 So I see that as being somewhat analogous to
24 what is going on with the low glucose alert as opposed
25 to the low glucose alarm.

1 Q. I'm just trying to under the logic behind your
2 characterization of Shariati.

3 You say in that parenthetical, "contemplating
4 thresholds set only by the manufacturer." Do you see
5 that? I'm looking at paragraph 118 of your declaration.

6 A. I'm looking at my declaration.

7 Q. Paragraph 118 of your declaration.

8 A. Okay. Here we go, 118.

9 Q. There's a citation sentence:

10 "See id. at 363-64 (contemplating
11 thresholds set only by the
12 manufacturer" --

13 And then you have a colon and there's a
14 quotation from Shariati.

15 A. Yes.

16 Q. And the quotation from Shariati is:

17 "Clinical risk zones 444 can be set by a
18 manufacturer, customized by a doctor,
19 and/or a user via button 302."

20 A. Okay.

21 Q. So how does the language that you quoted
22 support your proposition that Shariati contemplates
23 thresholds set only by the manufacturer?

24 A. Please take a look at page 109, paragraph 169.
25 Or there's alternative places in the same declaration

1 that accomplish the same thing.

2 You'll notice 4B. We also have figure 4B
3 directly in Shariati. Take a look at what Shariati
4 calls "clinical risk zones 444." I'll be happy to call
5 that to your attention. There's 444.

6 These are the clinical risk scores at the
7 bottom of figure 4B. For instance, a blood sugar of
8 70 might be mild risk and 60 might be moderate risk and
9 50 might be terrible risk. We don't know which names
10 he's called them.

11 So, he's referring with 444 to that band of
12 horizontal lines in this diagram 4B. There's a
13 corresponding set of horizontal lines also called 444 at
14 the top for the hyperglycemia. And he's saying that
15 those can be adjusted. I've got no problem with that.

16 Those are clinical risk levels, those are not
17 thresholds. They're not the thresholds that are being
18 used to trigger the alarm. Those are in exactly the
19 same spirit as the low glucose alerts. Whereas, you
20 know, the low glucose alerts can be and are set by the
21 end user.

22 And so no particular harm would be done if
23 somebody were to set one of these lines -- in fact, you
24 don't just get one line, there's a whole bunch of lines.
25 You don't necessarily have to show all of the lines, but

1 the user could set those and that's different than the
2 threshold that we're talking about in the case of a
3 55 milligram per deciliter low glucose alarm where it's
4 a threshold as opposed to a clinical risk level.

5 Q. So you're saying that the clinical risk zones
6 444 in Shariati are user settable?

7 A. They can be user settable. I don't know if
8 he -- I believe he's saying that they can be user
9 settable. But that doesn't affect the fact that if I
10 want to give the person an alarm because I think they're
11 going to have their glucose crashing or dropping off in
12 15 minutes, that kind of an alarm I would expect to see
13 as programmed into the computer.

14 Q. Okay.

15 MR. WILLIAMS: When you reach a logical
16 breaking point, I'd ask for a break.

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

18 (Whereupon, a recess was taken from
19 3:21 p.m. until 3:30 p.m.)

20 BY MR. SARASWAT:

21 Q. Dr. Rodbard, would you take a look at
22 paragraph 123 of your declaration where you provide your
23 opinion for why Shariati discloses claim 3. Is that
24 right?

25 A. Let me just read it a little bit.

1 (Witness reviews document.)

2 BY THE WITNESS:

3 A. Okay.

4 BY MR. SARASWAT:

5 Q. Okay. So this paragraph 123 is where you
6 provide your opinion on why Shariati discloses claim 3;
7 is that right?

8 A. Yes.

9 Q. And so you talk about a directional arrow
10 that's disclosed in Shariati. Do you see that, around
11 the middle of the paragraph?

12 A. Directional arrow, yes.

13 Q. And then you say in the last sentence:

14 "In my opinion, displaying this
15 directional arrow on the receiver would
16 involve 'determining whether a direction
17 of rate of change meet a rate of change
18 criterion' as claimed."

19 Do you see that?

20 A. Yes.

21 Q. Why is it the case that displaying the
22 directional arrow would involve determining whether a
23 direction of rate of change meets a rate of change
24 criteria?

25 A. If you don't mind, I'd like to review what

1 I've got in the citations I've already addressed.

2 (witness reviews document.)

3 BY THE WITNESS:

4 A. I've read those three citations that I have.
5 when I cite figure 4C in paragraph 123, it
6 should also be citing figure 4D. So 4D is a part of
7 that C and B.

8 Okay. I'd be happy to take your questions on
9 that.

10 BY MR. SARASWAT:

11 Q. So my question is this: You say in the last
12 sentence of that paragraph:

13 "In my opinion, displaying this
14 directional arrow on the receiver would
15 involve 'determining whether a direction
16 of rate of change meets a rate of change
17 criterion' as claimed."

18 what I would like to understand is what is the
19 basis for that opinion?

20 A. Figures 4C and 4D show the rate of change.
21 They show what the direction of the rate of change.
22 Certainly, in 4D we have arrows which could be up, which
23 means increasing; down, which means decreasing; moving
24 to the right, which would be flat or nearly flat.

25 we have two other intermediary possibilities,

1 but I regard this as generic. We're not limited to
2 45-degree angles between those four arrows. It could be
3 any angle, just a matter of taking the rate of change
4 for a specified period of time and calculating the
5 corresponding angle as accurately as one might want to
6 do that, as one might want to do as is used by others in
7 other documented activities prior to the date of the
8 '215 Patent.

9 Likewise, 4C is showing the glucose level and
10 showing the direction of change of the glucose in a
11 different representation that may be more clear-cut to
12 some people.

13 Each person may have a preference for either
14 4D or 4C, or, for that matter, showing the actual
15 glucose in 4B, because 4B really should have been
16 included here in this discussion. In fact, it's cited
17 by at least one of those paragraphs, either 363 or 369
18 and 370, 4B was mentioned.

19 Looking at a graph such as this allows one to
20 evaluate not only the glucose level but also the rate of
21 change of glucose just by the slope of the curve. And
22 the...

23 Q. why do you need to consider a rate of change
24 criterion in order to display a directional arrow?

25 A. well, the directional arrow is the rate of

1 change. It's a graphical representation of the rate of
2 change of the glucose.

3 Q. Well, the directional arrow is showing the
4 direction of change. Why do you need to know the rate
5 of change to show a directional arrow?

6 MR. WILLIAMS: Objection to form.

7 BY THE WITNESS:

8 A. When evaluating the glucose data as they're
9 coming in, one first has to calculate the momentary --
10 the instantaneous realtime glucose value. One can also
11 calculate the rate of change and the acceleration. Or
12 the rate of range of rate of change, which is another
13 word for acceleration. We can do that every time a new
14 data point becomes available.

15 And then you can analyze those data, those
16 three parameters -- glucose, rate of change,
17 acceleration. You can analyze them. You can display
18 them graphically which is what we're doing here.

19 In a graph such as 4D, one could decide what
20 the maximum rate of change you regard as safe or usual,
21 like what is the maximum reduction in glucose rate that
22 you would regard as normal, safe, usual, and one could
23 have criteria that will decide whether or not to give an
24 alarm, let's say, on the basis of rate of change
25 considered mainly by itself.

1 Those would be nonuser settable criteria that
2 would be built into the program; they would be
3 programmed in.

4 Q. Well, direction of change and rate of change
5 are two different things, right?

6 A. Correct.

7 Q. So if you knew the direction of change, you
8 could display a directional arrow, correct?

9 A. Yes.

10 Q. So you don't need to know the rate of change
11 to display a directional arrow; is that correct?

12 A. That's true.

13 Q. Okay.

14 A. Let me just point out that the figure 4C is
15 addressing the glucose level combined with a rate of
16 change combined with a direction of the rate of change.
17 Likewise, 4B allows the user to observe both the glucose
18 level and the rate of change.

19 Q. What you just told me about figures 4C isn't
20 in your declaration, is it?

21 MR. WILLIAMS: Objection to the form.

22 BY THE WITNESS:

23 A. It is in my declaration elsewhere at this
24 particular section.
25

1 BY MR. SARASWAT:

2 Q. where?

3 A. That would be under Ground 3 before we get to
4 Shariati and I'm going to refer back to what I call
5 table 1.

6 Q. So you're saying you explained it in Ground 3
7 before we get to Shariati?

8 A. Yes.

9 Q. But the arrows in Shariati are just showing
10 direction of change, correct?

11 MR. WILLIAMS: Objection to form.

12 BY THE WITNESS:

13 A. I'd have to go back to see how he refers to
14 them, but they clearly show a direction. I believe they
15 could also show magnitude.

16 BY MR. SARASWAT:

17 Q. well, in the language you quote from Shariati
18 in paragraph 123, there's no reference to magnitude, is
19 there?

20 MR. WILLIAMS: Objection to form.

21 BY THE WITNESS:

22 A. Did you say 123?

23 BY MR. SARASWAT:

24 Q. Yes, paragraph 123 of your declaration.
25 So in the language from Shariati that you

1 quote in paragraph 123 of your declaration, is there any
2 reference to magnitude?

3 MR. WILLIAMS: Objection to form.

4 (Witness reviews document.)

5 BY THE WITNESS:

6 A. Excuse me. I think we have what I'll call a
7 little misunderstanding.

8 In claim 3 where they're suggesting that --
9 where 215 is talking about a user-settable first
10 criteria regarding amplitude or direction, in fact, we
11 do have that here.

12 This arrow is indicating the amplitude and
13 this doesn't just mean you're going north. It means
14 it's going north and it's going very sharply north.
15 This means that you have a strongly rapidly rising
16 glucose. If you're -- I'll take the third case
17 where --

18 Q. Sorry. Can you just clarify for the record
19 what figure you're pointing to?

20 A. We're looking at figure 4D from Shariati.

21 Q. Okay.

22 A. And these directional arrows -- actually,
23 they're using the direction to show the magnitude of the
24 rate of change. The line that is labeled as 462 in
25 figure 4D which is going vertically upwards, that means

1 you have a very rapidly rising upstroke. It doesn't
2 mean you're going north, it means you're going -- in
3 fact, the direction that we're showing here which is
4 straight up is just showing you have the greatest
5 amplitude, that you have the strongest amplitude.

6 If you were on the third line over 90 degrees
7 to the one labeled 462, that's a horizontal line and
8 that means that your glucose is not changing. The
9 glucose rate of change is, on average, very nearly zero.

10 If you take the antithesis of the line labeled
11 462, if you take a look at the one that's pointing
12 downward, which if you were on the compass, it would be
13 pointing to the south, that means glucose is going down
14 rapidly. This is your amplitude. So we have the
15 amplitude and we have the direction.

16 Anything above the horizontal line in this
17 complex of 462 means that it's going up. Anything below
18 the horizontal line means that the glucose is going down
19 with varying degrees of amplitude.

20 So we have the amplitude of the rate of change
21 and we have the direction. It's either up, up strongly,
22 up mildly, up weakly, or flat.

23 Q. But this explanation that you just gave me
24 about figure 4D is nowhere in your declaration, is it?

25 A. No.

1 Q. Okay.

2 A. Because everybody knows this. Anybody with a
3 CGM knows this. This is not something new. This has
4 been and for a long time. It's built into nearly every
5 one of the devices currently on the market and on the
6 market well preceding the so-called 215. I mean, arrows
7 were in there.

8 Q. All right. You didn't cite figure 4D in
9 paragraph 123 in your declaration, did you?

10 A. I believe that's correct and I would believe
11 in the category of a typographical error.

12 Q. Let's turn to paragraph 143 of your
13 declaration.

14 So towards the bottom of page 93 in
15 paragraph 143, you have a sentence:

16 "Say's threshold 'may be programmable by
17 the patient and/or medical
18 professional.'"

19 And you cite Say at column 45, lines 28 to 31.
20 You go on to say:

21 "...which in my opinion suggests to a
22 POSITA the threshold value may or may not
23 be settable by user."

24 Do you see that?

25 A. Yes. Do we want to look at Say?

1 Q. One second. Okay.

2 Then you go on to the say in the next sentence
3 which is on page 94:

4 "For example, Say describes 'actual
5 threshold values that are designed into
6 the alarm system 104' that may include
7 criteria for voltage or current or other
8 electrical signals emanating from the
9 sensor."

10 Do you see that?

11 A. Yes.

12 Q. So let's look at Say and let's look
13 at -- first of all, first I'll give you the document.

14 (Whereupon, Deposition Exhibit 1008 was
15 marked for identification.)

16 BY MR. SARASWAT:

17 Q. So for that sentence in your declaration that
18 quotes the phrase "designed into," you cite Say at
19 column 45, lines 22 to 26; is that right?

20 A. Yes.

21 Q. So let's look at column 45, lines 22 to 26.

22 Those lines are part of a larger paragraph
23 that begins at line 8, right?

24 A. Yes.

25 Q. Okay. So if we look in that paragraph at line

1 15, it says:

2 "The alarm system 104 is triggered when
3 the data from the processing circuit 109
4 reaches or exceeds a threshold value."

5 A. That's correct.

6 Q. (Continuing:)

7 "Examples of threshold values for blood
8 glucose levels are about 60, 70, or 80
9 milligrams per deciliter for
10 hyperglycemia."

11 And then it goes on to give more thresholds
12 for different conditions. Do you see that?

13 A. Yes.

14 Q. Then it says:

15 "The actual threshold values that are
16 designed into the alarm system 104 may
17 correspond to interstitial fluid glucose
18 concentrations or electrode measurements
19 (e.g., current values or voltage values
20 obtained by conversion of current
21 measurements) that correlate to the
22 above-mentioned blood glucose levels."

23 A. Correct.

24 Q. Do you see that?

25 when Say refers to threshold values that are

1 designed into the alarm system, it's referring to
2 threshold values for things like current or voltage that
3 correlate to certain blood glucose levels; is that
4 right?

5 A. Correct.

6 Q. Just so I understand what's going on there,
7 the idea is that if your blood glucose level is, let's
8 say, 80 milligrams per deciliter, there's some kind of
9 sensor inside the device that needs to know when you get
10 to that level, and it may be measuring a different
11 quantity that corresponds to 80 milligrams per
12 deciliter; is that right?

13 A. Yes. It's got either voltage or current.

14 Q. Okay. So what's being designed into the
15 system is not the number 80 milligrams per deciliter,
16 it's whatever the voltage or current measurement number
17 is that corresponds to that 80 milligrams per deciliter;
18 is that right?

19 MR. WILLIAMS: Objection to form.

20 BY THE WITNESS:

21 A. I disagree with your statement. I don't think
22 that's accurate. I believe that what is being
23 programmed in, in fact, is either a blood glucose of
24 80 or the voltage that is being used -- if the voltage
25 is 7 microvolts coming out of the sensor and if that's

1 the one that corresponds to an 80 milligram per
2 deciliter, you either put in the 80 milligrams per
3 deciliter or the .7 microvolts or whatever it is or so
4 many amperes.

5 what is being programmed in is a level that
6 identifies the blood level. The blood level for that
7 target or for that threshold is being represented in the
8 computer program.

9 It may be represented either as a digital
10 number like 80.000, or it can be represented as 0.7
11 microvolts or 0.1 milliamps, but the thing that is being
12 programmed in is the level that we're interested in, the
13 level that is being translated back to the glucose
14 level, the clinical glucose level that we're trying to
15 use as the threshold for making a decision, for
16 instance, whether or not to trigger an alarm.

17 Q. When Say talks about -- this is around line 25
18 in column 4 -- "interstitial fluid glucose
19 concentrations or electrode measurements (e.g., current
20 values of voltage values obtained by conversion of
21 current measurements) that correlate to the
22 above-mentioned blood glucose levels," what does it mean
23 for a value to correlate to the above-mentioned blood
24 glucose levels?

25 MR. WILLIAMS: Objection to form and outside

1 the scope.

2 BY THE WITNESS:

3 A. Any CGM needs to be calibrated. The CGM
4 itself includes the sensor which there's some chemical
5 reactions occur, electrochemical reactions, that result
6 in a signal, volt or current that is correlated with the
7 glucose level in the tissue immediately surrounding the
8 sensor. So that needs to be correlated and there are
9 many different ways to do that. There are well-known
10 standardized ways to do that.

11 That allows anyone to convert the voltage
12 coming out of the sensor into an estimate of the blood
13 glucose level that you can measure by drawing blood at
14 exactly the same time.

15 we don't have a way of measuring the
16 interstitial fluid glucose, so we can't calibrate the
17 voltage coming out of the sensor for the interstitial
18 fluid glucose because you'd have to have something stuck
19 into the tissue, into the person's body and somehow or
20 other try to measure the glucose that's right there
21 right immediately next to the sensor.

22 So we don't know the exact interstitial fluid
23 glucose, but one can calculate it using modeling of
24 various types. So that's where the correlation comes
25 from. Basically, we're trying to measure either blood

1 glucose or interstitial fluid glucose. We can measure
2 blood glucose and calibrate the signal from the sensor
3 against the blood. We can't do that at the interstitial
4 fluid.

5 Q. Okay. So you're basically trying to measure
6 blood glucose by measuring some other quantity, like a
7 voltage or a current, and doing a calculation that says
8 a certain voltage or a current corresponds to a certain
9 blood glucose level?

10 A. That's correct, yes.

11 Q. Now, if we look at the bottom of the paragraph
12 that we were looking at in column 45, it says:

13 "The analyte monitor device may be
14 configured so that threshold levels for
15 these or any other conditions may be
16 programmable by the patient and/or a
17 medical professional."

18 Do you see that?

19 A. Yes.

20 Q. When it refers to "these or any other
21 conditions" in the sentence I just read, is that
22 referring to the hypoglycemia, impending hypoglycemia,
23 impending hyperglycemia and hyperglycemia mentioned
24 earlier in that paragraph?

25 A. It's a little bit obscure. That is...

1 Q. So let me try to help you out. If you look up
2 further in that paragraph in column 45 at line 11, it
3 says:

4 "For example, if glucose is the analyte,
5 then the on-skin sensor control unit 44
6 may include an alarm system 104 that
7 warns the patient of conditions such as
8 hypoglycemia, hyperglycemia, impending
9 hypoglycemia, and/or impending
10 hyperglycemia."

11 Do you see that?

12 A. Yes.

13 Q. Having read that, do you agree that in that
14 last sentence of the paragraph when it refers to "these
15 or any other conditions," it's referring to those four
16 medical conditions I just mentioned?

17 A. For the hypoglycemia and hyperglycemia, one
18 could imagine a set of patient-selected levels where you
19 would say, okay, I'm below 70, I'm hypoglycemic, or I'm
20 above 180, I'm hyperglycemic, so the patient can select
21 what they're going to call is hypo or hyper.

22 Now, for impending hypo and impending hyper,
23 it is much more complicated because impending hyper and
24 impending hypo, we're dealing with, I believe, a
25 predicted glucose at some period in time from the

1 present time. And there, it's much more difficult or
2 maybe impossible for the patient or the healthcare
3 provider to set a threshold.

4 So, I don't see how the patient would set a
5 threshold for the predicted level. That has to be done
6 when the device is being created, designed, programmed,
7 so that thresholds for the predicted glucose and the
8 predicted hypoglycemia or predicted hyperglycemia, you
9 can't just pick a number like 80 because we're not
10 talking about a number of 80 for a realtime glucose
11 level. The glucose levels wouldn't have reached 80,
12 they're somewhere above 80 but they might be coming
13 down.

14 Now one needs to have a way to predict where
15 they're going and also estimate how accurate that
16 prediction is and then select a glucose level that will
17 give the best performance.

18 Q. All right. Now, nothing that you just told me
19 is in your analysis of say in the declaration, is it?

20 A. Let me take a look back at that.

21 (Witness reviews document.)

22 BY MR. SARASWAT:

23 Q. Let's just focus on paragraph 143.

24 It's not in paragraph 143, is it?

25 A. Let's take a look.

1 C therefore teaches that thresholds that are
2 not programmable by the user but rather designed into
3 the system and/or set by people who do not use the
4 system themselves that are professionals and/or
5 engineers or programmers acting on the recommendations
6 of professionals.

7 Q. Right, but in your previous answer, for
8 example, you said with that -- let me withdraw the
9 question.

10 In your previous answer, for example, you said
11 with reference to predicted glucose:

12 "It's much more difficult or maybe
13 impossible for the patient or the
14 healthcare provider to set a threshold."

15 That is not explained in paragraph 143, is it?

16 A. What is stated is that Say is teaching that
17 one needs to evaluate the sensor data using a second
18 function to determine whether parameter indicative of a
19 glucose value meets one or more nonuser settable second
20 criteria.

21 Q. Right.

22 So you're stating that Say meets the
23 limitation, but you're not providing the explanation
24 that you gave me earlier where you said that it's much
25 more difficult or may be impossible for the healthcare

1 provider to set a threshold for predicted glucose?

2 A. That's right. I stand by that statement. The
3 predicted alarm or activation of an alarm for a
4 predicted glucose requires a series of calculations that
5 are not known by the user and ordinarily would not be
6 known by the healthcare provider.

7 Q. Let's look earlier in paragraph 143. You have
8 a sentence on page 193 where you say:

9 "Say also teaches the alarm system may be
10 activated when the 'rate of change or
11 acceleration of the rate of change in
12 analyte level increase or decrease
13 reaches or exceeds a threshold rate or
14 acceleration.'"

15 Do you see that?

16 A. No, I haven't found that yet.

17 "Say also teaches," is that the line?

18 Q. Yes.

19 (Witness reviews document.)

20 BY MR. SARASWAT:

21 Q. You say after that:

22 "As discussed above for element 1[b] in
23 Grounds 1 and 2, a POSITA would have
24 understood that realtime measurements of
25 glucose values and rate of change of

1 glucose values are examples of the
2 claimed 'parameter indicative of a
3 glucose value' in the '215 Patent."

4 Do you see that?

5 A. Yes.

6 Q. So in your analysis of element 19[d] for say,
7 you're saying that the glucose values or rate of change
8 of glucose value are the parameter indicative of a
9 glucose value that's mentioned in the claim, right?

10 MR. WILLIAMS: Objection to form.

11 BY THE WITNESS:

12 A. 19[d], let's see, parameter indicative of
13 glucose value.

14 In the claim, of course, it does not say which
15 parameters they are. In my discussion in my declaration
16 I'm indicating that rate of change and acceleration, for
17 that matter the original glucose, realtime glucose
18 itself, saying those are representative of things that
19 would be considered or may need to be considered when
20 trying to determine whether there's an indication for an
21 alarm or alert or some other activity such as that.

22 So we're evaluating the sensor data using a
23 sensor function, but it isn't necessarily rate of change
24 by itself or acceleration by itself or glucose level by
25 itself. It may be something combining those in some

1 possibly simple but possibly complicated manner that can
2 be used to evaluate -- and the purpose of the evaluation
3 is to enable step or element 19[f] to decide whether or
4 not to activate the second hypoglycemic indicator.

5 So it isn't that we have just acceleration and
6 rate of change. We have acceleration and rate of
7 change, the original and various combination of those
8 things that can be evaluated to decide whether an alarm
9 is needed.

10 One of the ways to evaluate it would be to use
11 one or another means to calculate a predicted glucose
12 and then establish criteria for that predicted glucose.

13 Q. Let's look at the last sentence in paragraph
14 143. It says:

15 "Thus in my opinion, Say's comparison of
16 the rate of change of glucose or
17 acceleration of the rate of change of
18 glucose to a threshold rate or
19 acceleration (e.g., to warn of impending
20 hypoglycemia) teaches 'evaluate sensor
21 data using a second function to determine
22 whether a parameter indicative of a
23 glucose value meets one or more nonuser
24 settable second criteria,' as claimed."

25 Do you see that?

1 A. Yes.

2 Q. So your opinion is that the rates of change of
3 glucose or the acceleration of the rate of change of
4 glucose are the parameter indicative of glucose value;
5 is that right?

6 A. They are two of the possible -- two of the
7 important parameters indicative of a glucose value.

8 Q. And they're the only two that you mentioned in
9 this sentence where you say, "Thus, in my opinion"?

10 A. Yes, but I'm also at least implying that
11 various combinations of the glucose level and the rate
12 of change and the acceleration would be coming into
13 play. I didn't say it was a linear relationship to
14 either rate of change or acceleration, because we're not
15 interested in the rate of change by itself. We're
16 interested in do we think this person is going to
17 experience a hypo within the next -- and it's typically
18 30 minutes.

19 But having the raw data and the rate of change
20 and the acceleration and perhaps having additional data
21 for that individual already collected, either on the
22 current session or on previous sessions, or using data
23 from other subjects, other people, and knowing, if you
24 will, the properties of these data, then that's what
25 enables one to set up a system to evaluate sensor data

1 to determine whether to recommend to the activating
2 circuit in 19[f], whether to say that the logical test
3 has past and yes, you should announce an alarm or alert.

4 Q. But you would agree that if someone were
5 reading what you wrote in paragraph 143 and they read
6 the last sentence where it says, "Thus, in my
7 opinion" --

8 A. Yes.

9 Q. -- they would see the only things you
10 mentioned are the rate of change of glucose or the
11 acceleration of the rate of change of glucose?

12 A. I would say yes, that allows one to evaluate
13 sensor data using a second function to determine whether
14 the parameter meets one or more nonuser settable second
15 criteria.

16 Q. We've seen in a couple places blood glucose
17 thresholds expressing the units of MG per DL?

18 A. Correct.

19 Q. That's milligrams per deciliter?

20 A. Correct.

21 Q. Would a threshold for rate of change or
22 acceleration of rate of change also be expressed in the
23 same units of milligrams per deciliter?

24 A. No.

25 Q. For that kind of threshold, for any kind of

1 rate threshold, you need some kind of time value in the
2 unit, correct?

3 A. Correct.

4 Q. Let's go to paragraph 146. This is in the
5 section that starts "A POSITA would have and could have
6 combined the User's Guides low glucose alarms with Say's
7 alarm system," right?

8 A. Yes.

9 Q. You say at the bottom of page 95 to the top of
10 page 96:

11 "Combining the User's Guide disclosure of
12 a nonuser settable threshold with Say
13 merely combines prior art elements
14 according to known methods to yield
15 predictable results, and 'alarm system'
16 based on both 'user settable' and
17 'nonuser settable' criteria."

18 Correct?

19 A. Yes.

20 Q. So you're not saying that in your -- strike
21 that.

22 So in your proposed combination of the Guide
23 and Say, you're not proposing that you modify Say's
24 thresholds in any way, are you?

25 MR. WILLIAMS: Objection to form.

1 BY THE WITNESS:

2 A. I can't evaluate that. I'd have to go back
3 and double-check Say's teachings.

4 BY MR. SARASWAT:

5 Q. I'm not asking about Say's teachings. I'm
6 asking about what you said the combination would be.

7 A. Do I have Say sitting here?

8 (witness reviews document.)

9 BY MR. SARASWAT:

10 Q. Let's just look at paragraph 145 of your
11 declaration. These are the paragraphs where you
12 say -- these are the paragraphs in your section
13 entitled, "A POSITA would have and could have combined
14 the User's Guide's low glucose alarm with Say's alarm
15 system," correct?

16 A. Yes.

17 Q. Are you saying anywhere in those paragraphs
18 that in your combination of Say and the Guide you would
19 modify Say's thresholds at all?

20 (witness reviews document.)

21 BY THE WITNESS:

22 A. It would not be necessary. I would agree that
23 I'm indicating that it may be possible to utilize -- to
24 combine the User Guide, the STS sensor and Say's alarms
25 without modification.

1 BY MR. SARASWAT:

2 Q. Okay. Are you arguing anywhere in this
3 section at paragraphs 145 to 149 that in the Say and
4 Guide combination, you would be comparing a rate of
5 change to the Guide's low-glucose threshold?

6 A. No, I don't believe that we would be -- well,
7 okay. That's interesting. One could potentially use
8 the low-glucose threshold from the Guide as a criterion
9 or one of more criteria to utilize the system of Say.

10 Q. My question is different.

11 My question is, are you arguing that in the
12 combination you would take the rate-of-change value
13 that's disclosed in Say and compare that rate of change
14 to the 55-milligram-per-deciliter threshold in the
15 Guide?

16 A. No, I'm not saying that. I'm quite sure I
17 haven't said that, and that's not what I would intend to
18 do or want to do or expect to do.

19 we could ask whether a predicted value is as
20 low as the value from the low glucose alarm.

21 Q. Right. But you can't compare a rate of change
22 to a 55-milligram-per-deciliter-glucose threshold?

23 A. Correct. Those are different entities.

24 Q. And you can't compare acceleration to a
25 55-milligram-per-deciliter-glucose threshold?

1 A. Not by itself, except in so far as the
2 combination of the realtime glucose, the acceleration
3 and the rate of change allows you to predict a glucose
4 and then you could ask is that glucose likely to be at
5 or below 55, for example, within a specified period of
6 time.

7 Q. Right. But setting that aside, it would be
8 nonsensical to take an acceleration and compare that to
9 a blood glucose threshold?

10 A. That's an apples and oranges situation.

11 Q. Okay.

12 MR. SARASWAT: why don't we take a ten-minute
13 break.

14 THE WITNESS: We can do that.

15 (Whereupon, a recess was taken from
16 4:35 p.m. until 4:46 p.m.)

17 BY MR. SARASWAT:

18 Q. Okay. Dr. Rodbard, could we please look at
19 paragraph 146 of your declaration. I want to look at
20 the last sentence. It says:

21 "A POSITA would have understood from the
22 User's Guides and Say's teachings that
23 the combination would result in
24 hypoglycemic and/or impending
25 hypoglycemic indicators, each of which

1 could be activated based on user settable
2 and/or nonuser settable criteria."

3 Is that right?

4 A. That's what the sentence says. I haven't had
5 a chance to digest it yet in context here.

6 Q. So if you got hypoglycemic and/or impending
7 hypoglycemic indicators and you've got user settable
8 and/or nonuser settable criteria, then there's four
9 different combinations of those things; is that correct?

10 A. Correct.

11 Q. So you could have -- one of those possible
12 combinations is that they're both nonuser settable,
13 right? The hypoglycemic indicators could be activated
14 based on nonuser settable criteria and the impending
15 hypoglycemic indicators could be activated based on
16 nonuser settable criteria, right, that's one
17 possibility?

18 A. Yes.

19 Q. That possibility wouldn't meet the claims,
20 would it?

21 MR. WILLIAMS: Objection to form.

22 BY THE WITNESS:

23 A. If the glucose -- the acute or realtime
24 glucose value, that is in the claims it's nonsettable in
25 the claims for '215. And for the impending, that is a

1 nonuser settable, as specified by '215.

2 If the other two possibilities also existed,
3 systems could be built that would operate in those other
4 two options.

5 BY MR. SARASWAT:

6 Q. We're talking about claim 19. Let's take a
7 look at claim 19 which is on page 158 of your
8 declaration.

9 A. Okay.

10 Q. So limitation 19[c] is:

11 "Evaluate sensor data using a first
12 function to determine whether a realtime
13 glucose value meets one or more user
14 settable first criteria."

15 Do you see that?

16 A. Yes.

17 Q. So if both the hypoglycemic and impending
18 hypoglycemic indicators are checked against nonuser
19 settable criteria, then you would meet limitation 19[c],
20 right?

21 MR. WILLIAMS: Objection to form.

22 BY THE WITNESS:

23 A. You've got the realtime, you've got the first
24 function. My understanding is that the first function
25 involves a user settable criteria.

1 BY MR. SARASWAT:

2 Q. Right, right, that's what the claims say. But
3 I'm talking about what are the four possibilities that
4 we discussed to implement the combination?

5 A. That's right, there's other possibilities.

6 Q. But that first possibility I was talking about
7 where both the hypoglycemic and impending hypoglycemic
8 thresholds are nonuser settable could not meet
9 limitation 19[c], could it?

10 A. That would not be identical with 19[c].

11 Q. Because there's no nonuser -- sorry.
12 There's no user settable first criteria as
13 required?

14 A. Yes.

15 Q. So in that possibility, that's one of the four
16 possibilities we couldn't meet claim 19 because we
17 failed 19[c], right?

18 MR. WILLIAMS: Objection, form.

19 BY THE WITNESS:

20 A. I'm having a little trouble understanding
21 that. I may need some time to think about it, because
22 the -- let me just say I have no opinion about that
23 right now.

24 BY MR. SARASWAT:

25 Q. If there's no user settable first criteria,

1 then is it possible to meet limitation 19[c]?

2 A. I'll say tentatively no.

3 Q. We just discussed one of the four
4 possibilities which is both the hypoglycemic and the
5 impending hypoglycemic alarms have nonuser-settable
6 criteria.

7 Now, would you agree that another possibility
8 is that both the hypoglycemic and impending hypoglycemic
9 alarms have user-settable criteria?

10 A. That would still be compatible with 19[c].

11 Q. But would it be compatible with 19[d]?

12 A. Probably not.

13 Q. Okay. So the third possibility is the
14 hypoglycemic alarms have nonuser-settable criteria and
15 the impending hypoglycemic alarm has user settable
16 criteria, could that meet 19[c] or 19[d]?

17 A. Give me the situation again.

18 Q. So the situation is the hypoglycemic alarms
19 have nonuser-settable criteria.

20 A. Yes.

21 Q. And the impending hypoglycemic alarms have
22 nonuser settable criteria.

23 A. And you want to know whether this would be, if
24 you will, a suitable replacement for 19[d]? would that
25 invalidate 19[d], is that the question you're asking?

1 Q. Basically.

2 If you had a system like that, would it
3 satisfy limitation 19[d]?

4 MR. WILLIAMS: Objection to form.

5 BY THE WITNESS:

6 A. Probably not.

7 BY MR. SARASWAT:

8 Q. Because it's backwards?

9 A. Right. By the way, all four of those
10 different categories could conceivably work also.

11 Q. I'm not asking about whether they can work,
12 I'm just asking about whether they'd meet the claims.

13 A. Yes.

14 Q. We've now discussed three of the four
15 possibilities.

16 The fourth possibility is that the
17 hypoglycemic alarm has user-settable criteria and the
18 impending hypoglycemic alarm has nonuser-settable
19 criteria?

20 A. That would satisfy this claim.

21 Q. Yes. So, we agree that of the four
22 possibilities we discussed -- let me just back up.

23 So, again, looking back at paragraph 146, in
24 that last sentence -- I'll wait until you're there.

25 So, the last sentence of 146 says:

1 "A POSITA would have understood from the
2 User's Guides and Say's teachings that
3 the combination would result in a
4 hypoglycemic and/or impending
5 hypoglycemic indicators, each of which
6 could be activated based on user-settable
7 and/or nonuser-settable criteria."

8 A. Yes, that's as to all four cases.

9 Q. And we agreed that there were four
10 possibilities for those two combinations?

11 A. Yes.

12 Q. And of those four possibilities, only one of
13 them meets the claims, right?

14 A. Meets exactly 19[c] and [d].

15 Q. Okay. The other three possibilities fail to
16 meet either 19[c] or 19[d]?

17 MR. WILLIAMS: Objection to form.

18 THE WITNESS: They fail to meet 19[c] and
19 19[d] jointly.

20 BY MR. SARASWAT:

21 Q. Okay. But they fail to meet the claim
22 ultimately because they --

23 A. But these are individual elements of the
24 claim. So at least one of the other cases is going to
25 meet -- is going to be simpatico, so to speak, would

1 have been more or less synonymous with either 19[c] and
2 another would have been synonymous with the element of
3 19[d] taken by itself.

4 Q. Right, but to satisfy a claim you have to meet
5 the all the elements, right?

6 A. Probably so. That's my understanding.

7 Q. So in three of those four possibilities we
8 discussed, there's at least one element you wouldn't
9 meet so you wouldn't meet the claim, right?

10 A. I hadn't been thinking about it in that way,
11 so I'm not quite comfortable with that at this point.

12 Q. So you agree that in the combination you
13 discussed in that last sentence in paragraph 146,
14 there's four different possibilities for hypoglycemic
15 and/or impending hypoglycemic indicators, each of which
16 could be activated based on user settable and nonuser
17 settable criteria?

18 A. That's correct, yes.

19 Q. And you didn't analyze in your declaration
20 which of those four possibilities would meet the claim,
21 did you?

22 A. Well, we've just gone through it and it is, I
23 think, clear that of the four possibilities, only the
24 one is, shall we say, rigorously meeting 19[c] and [d].

25 Q. But you didn't go through that four

1 possibilities analysis that you and I just went through
2 in the declaration?

3 A. Not in the declaration. Obviously, I thought
4 about it, that's why I had written it in paragraph 146.

5 Q. Let's turn to paragraph 160. That's on page
6 103. Do you see that?

7 A. Yes.

8 Q. If you look on the previous page 102, you'll
9 see there's a section E entitled, "Petition Ground 6
10 Claims 19 and 23 are Rendered Obvious By Say in view of
11 Shariati." Do you see that?

12 A. Yes.

13 Q. So here in paragraph 160, we're talking about
14 Ground 6 which is based on a combination of Say and
15 Shariati, right?

16 A. Yes.

17 Q. Okay. So I'm going to look at paragraph 160
18 and you say:

19 "In my opinion, Say in combination with
20 Shariati teaches element 19[d]."

21 Then you say:

22 "As discussed for element 19[d] in Ground
23 5, Say discloses that its alarm system
24 may be activated when the rate of change
25 or acceleration of the rate of change in

1 glucose level reaches or exceeds a
2 threshold which are parameters indicative
3 of a glucose value as claimed."

4 Do you see that?

5 A. Yes.

6 Q. So, here, in paragraph 160 when you're talking
7 about the parameters indicative of glucose value
8 language in limitation 19[d], you're only referring to
9 Say; is that right?

10 A. In this paragraph 160 I'm only referring to
11 Say.

12 Q. In paragraph 161 you say:

13 "Regardless, as explained below, it would
14 have obvious to combine with Say with
15 Shariati which discloses the claimed
16 nonuser-settable criteria as previously
17 explained for elements 1[b] and 19[d] in
18 Ground 4."

19 Do you see that?

20 A. Okay.

21 Q. So the point is, in paragraph 161 you're
22 discussing the nonuser-settable criteria language from
23 19[d], right?

24 A. Yes.

25 Q. And you're mapping that on to Shariati in

1 paragraph 161?

2 A. Yes.

3 Q. So in paragraph 160 when you're discussing the
4 parameters indicative of a glucose value language from
5 the limitation, you only cite Say, and then in paragraph
6 161 when you discuss the nonuser-settable criteria
7 language from the limitation, you only map it on to
8 Shariati?

9 A. That seems to be the case.

10 Q. Okay.

11 MR. SARASWAT: All right. I have no further
12 questions at this time.

13 MR. WILLIAMS: Let's take a short break.

14 (Whereupon, a recess was taken from
15 5:04 p.m. until 5:12 p.m.)

16 MR. WILLIAMS: We have no questions for the
17 witness. The witness will read and sign.

18 MR. SARASWAT: We're done.

19 THE COURT REPORTER: Rough and two two-day
20 delivery?

21 MR. SARASWAT: Yes.

22 MR. WILLIAMS: We'll do the same. We'll take
23 the two-day delivery, that's fine and the rough.

24 (Proceedings concluded at 5:15 p.m.)

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CERTIFICATE OF COURT REPORTER

UNITED STATES OF AMERICA)
DISTRICT OF COLUMBIA)

I, MARGARET M. LANIER, Notary Public in the
District of Columbia, certify that the witness appeared
before me; that the witness was duly sworn; that I was
authorized to and did stenographically report the
proceedings in the above transcript; and that the
transcript is a true and complete record of my
stenographic notes.

I further certify that I am not a relative,
employee, attorney or counsel of any of the parties, nor
am I a relative or employee of any of the parties'
attorneys or counsel connected with the action to my
knowledge, nor am I financially interested in the
action.

Margaret Lanier

MARGARET M. LANIER, CSR, RMR, CRR
Notary Public in and for the District of Columbia
My commission expires: July 13, 2026

CERTIFICATE OF COURT REPORTER

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DISTRICT OF COLUMBIA)

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before me; that the witness was duly sworn; that I was
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transcript is a true and complete record of my
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employee, attorney or counsel of any of the parties, nor
am I a relative or employee of any of the parties'
attorneys or counsel connected with the action to my
knowledge, nor am I financially interested in the
action.

Margaret Lanier

MARGARET M. LANIER, CSR, RMR, CRR

Notary Public in and for the District of Columbia

My commission expires: July 13, 2026

District of Columbia: SS

Subscribed and sworn to before me, in my presence,
this 6th day of February, 2023

Joseph E. Bradley
Joseph E. Bradley, Notary Public, D.C.

My commission expires March 31, 2023.



Exhibits	10,702,215 5:23 6:3	12:00 83:9	1960 10:12
Exhibit 2006 3:13 26:3,9,12 27:20 33:25 96:23 106:9	100 9:9	12:40 83:9	1964 10:22 11:5
Exhibit 1001 3:11 5:14,18,21 14:11 18:11 34:2 65:20	1001 5:14,18,21 14:11 18:11 34:2,6 65:20	13 101:23	1965 11:6,14
Exhibit 1002 3:12 8:14,23 9:5,13 10:1 14:2	1002 8:14,19,23 9:5,13 10:1 14:2	143 160:12,15 168:23,24 169:15 170:7 172:14 174:5	1966 11:14
Exhibit 1004 3:16 51:8 138:4,8	1004 51:8 138:4,8	145 176:10 177:3	1988 11:23
Exhibit 1005 3:14 61:13,14	1005 61:13,14	146 175:4 178:19 183:23,25 185:13 186:4	19[b] 97:22
Exhibit 1008 3:16 161:14	1008 161:14	149 177:3	19[c] 83:24 180:10,19 181:9,10,17 182:1, 10,16 184:14,16,18 185:1,24
Exhibit 2006, id 3:13 26:3,9,12 27:20 33:25 96:23 106:9	102 186:8	15 108:6 151:12 162:1	19[d] 59:22,24 60:7,12,15 86:16 119:25 120:4, 16,20 171:6,12 182:11,16,24,25 183:3 184:16,19 185:3 186:22 187:8, 17,23
Exhibit 2007 3:15 91:12,13 95:21	1020 49:10 52:19	150 78:5	19[d] 186:20
0	103 186:6	157 76:14 83:15 86:14 97:3 118:21	19[e] 98:3,10
0.1 164:11	104 162:2,16 167:6	158 76:19 83:23 86:3 97:17 180:7	19[f] 97:23 98:3,11 119:25 120:3,17 172:3 174:2
0.7 164:10	104' 161:6	16 14:11 31:16 32:6	19[g] 97:18 98:6 120:14
1	109 149:24 162:3	160 186:5,13,17 187:6, 10 188:3	1[a] 38:3 48:20 64:15,20 66:5 83:18 120:12
1 21:4 26:23 27:2,5,24 34:2,9 35:1 36:25 37:2,6,7,13,17,21 38:11,12 40:22 41:10 46:22 48:5 50:12,13,14,18,24 57:20 58:6 66:11 68:19 76:21 80:20, 23,24 81:12 82:3,8, 21,25 83:2,16 84:4 88:9 97:5 103:18 114:18 121:12 122:22 123:15 124:8,17,20 157:5 170:23	11 35:11 167:2	161 187:12,21 188:1,6	1[a] 51:5 67:3
1-3 37:13	11.1 138:21	169 149:24	1[b] 38:7,11,14,21 40:1, 11 41:3,6 42:20 43:7,11,13 44:12,17 45:9 46:10,22,24 47:7 48:1,5,7,20 50:17,18 51:1 52:1 57:20 58:5 60:7 66:18 68:12 82:5 86:4,12 119:4,11,14, 17,21 120:11 122:17 123:4 170:22 187:17
10 108:6,7	112 10:1,2	17 14:11,18	
	117 125:11	180 140:21 167:20	
	118 131:1 134:21 137:8 142:20 143:9,22 144:13,24 145:4,15 146:11 149:5,7,8	19 14:18 35:6,8 37:13 40:22 41:10 83:23 84:4 97:17 99:25 101:9 180:6,7 181:16 186:10	
	12 37:13	193 170:8	
	123 151:22 152:5 153:5 157:18,22,24 158:1 160:9	195 78:19	

1[b] 39:21 66:13 84:18 1[c] 97:12 120:12,13 1[d] 97:5 118:22 119:11, 13,21 120:9,12,13 122:9 123:24,25 124:3,5,7,11,14,17, 20 1[f] 120:9 1[pre] 37:24 2 2 14:11,18 36:25 37:6, 13,21 38:12 46:23 49:10,15 50:13,18, 25 52:19,25 65:21 66:12 72:21 88:9 103:19 108:21 114:25 115:16 120:22 121:1 124:8, 11,17,20 129:7 130:4 170:23 2,000 76:10 20 16:15 30:24 102:12, 21 200 9:11 78:7,21,22 138:20 139:11 140:18,21 2006 26:2,3,7,9,12 27:4, 20 33:25 96:23 106:9 2007 91:12,13 95:21 2010 26:23 27:2,5,25 2012 23:24 202 110:2,5 2022-00909 4:14 21 65:20	211 53:14 214 70:15 75:17 85:17 100:7 215 6:2 7:2 14:8,23 15:9, 12,16,24 18:11,24 20:2,24 21:1,4 23:25 29:23 34:1,20 35:14 39:1 40:17,22 41:5, 10,12,21 42:12,15, 25 45:15,19 47:3,25 48:6,15,23 65:19 68:24 71:8,10,15 84:9,22 85:4 90:18 91:4 98:18 103:6 154:8 158:9 160:6 171:3 179:25 180:1 22 161:19,21 222 100:20 23 37:13 68:23 69:1 75:15 186:10 23022-00909 4:19 24 100:1 101:9 25 68:24 69:3 70:2,3,4, 5,6 71:4 72:10 74:2 164:17 250 140:22 26 42:16 84:22 85:2,5, 6,7 138:11 139:9 161:19,21 28 160:19 281 53:25 112:8 29 14:6,7 101:22 2:12 125:8 2:26 125:8	3 3 70:7 71:5 72:11 74:3 151:23 152:6 157:3, 6 158:8 3-4 53:22 3.1 67:11 30 7:19,20 14:21 15:5 21:6 30:13 31:15 108:5 173:18 300 136:3 302 146:20 149:19 31 34:2,9 160:19 312 62:16 63:9 314 62:9,17 63:10 333 127:12 130:21 131:3,9,12 338 135:24 34 37:8,12 50:11,13 101:9 35 38:1,10 41:3 43:14, 15 50:16 64:11 36 39:14,15 84:25 363 154:17 363-64 146:16 149:10 369 154:17 37 39:12 40:8 85:1 87:17 370 154:18 39 75:15 3:21 151:19	3:30 151:19 3A 136:2 3D 136:2 4 4 26:23 27:4,24 40:8, 13,17 41:7,13 46:12, 24 47:8 98:18 114:23 115:13 164:18 187:18 4.4 138:20 44 167:5 444 146:18 149:17 150:4,5,11,13 151:6 45 160:19 161:19,21 166:12 167:2 45-degree 154:2 462 158:24 159:7,11,17 4:35 178:16 4:46 178:16 4A 136:13 4B 150:2,7,12 154:15, 18 156:17 4C 153:5,20 154:9,14 156:14,19 4D 153:6,20,22 154:14 155:19 158:20,25 159:24 160:8 5 5 9:15,18 72:24 76:19 77:5 80:11,19,25 81:13 82:2,21 83:1 114:23 115:13
---	--	--	---

186:23	59	70	96
50	65:20	31:14 78:6,13	175:10
35:7 42:16 65:20	5:04	116:11,12 118:17	
84:22 85:2,5,8 150:9	188:15	140:3,21 150:8	A
500	5:12	162:8 167:19	a.m.
19:2 69:7,17	188:15	71	36:13
51	5:15	106:25 107:8	A/d
138:10,13 141:2	188:24	72	128:1
510		38:22 45:6,19 46:7	Abbott
69:17	6	57:21 58:6	24:25 25:14
512	6	74	abdomen
129:7 130:4	18:13,17,24 20:4	123:22 124:3,6,16,	137:2
520	69:4,7,14,16 70:12,	19	ability
69:17 73:3,5,8,13,	22 72:7,8 75:7,10	75	54:21,23 55:4,12
16,24 74:19 75:5,7,	114:23 115:13	78:11,14,17 123:22	105:17 112:24
10,17	186:9,14	124:6,16,19 135:5	above-mentioned
53	60	147:21	162:22 164:22,23
59:20	18:15 42:16 65:11	77	absolute
530	84:22 85:3 140:3,21	31:12	94:23,25 95:17 96:5,
69:17,19,25 70:9,12,	150:8 162:8	78-79	16
15,22,24 72:6,8,12	61	65:13	acceleration
73:3,6,8,14,16,17,	64:12,19 98:19	8	53:4 87:5 109:13,23
18,23,24,25 74:3,9,	62	8	117:5 121:6,8
11,17,23	38:10,22,24,25 39:3,	18:25 19:9,13 20:4	155:11,13,17 170:11
54	8 50:21 52:5,9 57:21	31:11 161:23	171:16,24 172:5,6,
65:3,12 98:19	58:6 66:8,17	80	17,19 173:3,12,14,
147:20	63	138:19 139:11	20 174:11,22 177:24
540	39:2,11,17,24 40:8	140:4,18,21 162:8	178:2,8 186:25
69:17	84:13,14	163:8,11,15,17,24	acceleration.'
55	64	164:1,2 168:9,10,11,	170:14
51:3,10,20 52:6	19:8,11 41:16,22	12	accomplish
67:1,10 68:3 88:15,	46:11,24 47:8 49:4	80.000	150:1
16,22 140:12 147:19	52:13 56:9	164:10	accordance
148:21 151:3 178:5	65	88	18:20 19:17 69:10
55-milligram-per-	28:8 31:13 32:3	62:6	account
deciliter	41:25 42:18,23 43:6,	9	9:21 79:25 80:2
177:14	7,25 44:10 47:2 56:1	9	accuracy
55-milligram-per-	57:15	9	116:16
deciliter-glucose	66	18:12,15 19:7,11	accurate
177:22,25	44:16,23 46:12,24	65:8	14:16 23:3,15 24:6,
550	47:8,12,19	90	7,8 25:8 27:21
69:17	67	65:11 140:4 159:6	34:12,15 163:22
56	19:12 45:6,19 46:7	91	168:15
51:8 67:6 85:11	109:7	60:12	accurately
147:20	68	93	154:5
57	104:23 115:19 116:8	160:14	achieve
138:11 139:9	7	94	144:20 145:2,11,12
571	7	161:3	acknowledged
125:21	14:2,3 35:7 71:5	95	87:7
58	72:11 163:25 164:3	175:9	acquisition
18:12,15			127:24 129:7,24,25
			130:6,9 131:15,18

133:14 acting 169:5 activate 108:10 120:17 172:4 activated 97:19,23 98:7,8 108:23 170:10 179:1,13,15 184:6 185:16 186:24 activates 108:14 120:9 activating 98:3 104:18 174:1 activation 170:3 activities 154:7 activity 171:21 actual 76:13,18 95:2,3 102:11 154:14 161:4 162:15 actuality 24:13 acute 179:23 add 108:16,18 added 146:24 adding 105:12,19 106:17, 20,22 addition 25:1 141:3 additional 9:21 73:8 108:22 116:15,18 117:12 118:3,4 173:20 addressed 153:1 addressing 55:23 156:15 adjust 58:23 126:22 130:9 131:6 140:5 adjustable 147:8 adjusted 112:14 113:25	150:15 adjusting 130:4 147:17,23 adjusts 129:21 administered 4:1,3 administering 100:20 advance 139:16 advantageous 131:19 advice 148:3 advise 104:22 affect 104:22 134:11 151:9 afraid 133:6 agree 20:9 36:2 47:22 92:5,12,20 93:8,22 94:12,14 95:7,20 103:8 120:21 121:11 123:14 139:21 167:13 174:4 176:22 182:7 183:21 185:12 agreed 184:9 ahead 59:20 aids 117:10 air 101:19 alarm 15:10,13 16:1,9,13 17:3,19,24 18:8 19:24,25 20:14,19 23:10,11 24:11 32:7, 13,16,20,25 33:11, 13,16,20 35:21 36:7 45:1,2 50:1 51:3,17 52:6 66:25 67:25 85:21 87:23 100:12 101:13,15,17 104:6, 7,18,19 106:10 107:4,5,16 108:10 109:5 110:13,14 111:3,16 115:21,22	116:1,15 117:1,7 140:9,11,12 143:16 145:10 148:17,22,25 150:18 151:3,10,12 155:24 161:6 162:2, 16 163:1 164:16 167:6 170:3,9 171:21 172:8 174:3 175:7,15 176:14 177:20 182:15 183:17,18 186:23 alarm' 51:14 67:19 alarms 14:15 15:1,6 17:10 20:3,10 23:4,7,9,11, 15,16,18 24:1,4,16, 21,22 25:2,6,10,15 29:24 32:4 34:13,15 35:16,23 53:12 110:17 111:5 175:6 176:24 182:5,9,14, 18,21 alert 15:10,13 16:1,9 17:2,19,23 18:8 19:24,25 20:13,19 23:11 30:3,4,15,22, 23 31:8,12,13,16,17 32:5,7,9,19,21 33:9, 10,20,21 35:21 36:7 50:1 51:4 53:18 64:25 65:10,21 67:2 82:5,16,18 87:23 100:5,12 101:14,15 104:5,20 106:7,10 108:14,23 109:6 113:11 114:11 141:4,6 148:17,24 171:21 174:3 alert/alarm 18:19 19:5,16,21 20:2,9,18 69:10 alert/alarm.' 49:9 52:18 alerts 14:15 15:1,5,6 17:10 20:3,10 27:12,22 28:16,18 29:13,14, 16,17,19,23,24 30:11,16 31:3,14,22 32:3,25 33:3 35:16, 23 65:6 80:25 81:1,	12,14,18 82:2,8,10 83:1 138:18 139:3 150:19,20 algorithm 72:22 99:6 algorithms 76:12 126:23 allege 57:22 58:8 allowing 63:7 139:20 alluded 58:20 alternate 134:24 alternative 126:1 143:10,23 149:25 ambiguous 23:12 73:4 ambulance 100:22 amperes 164:4 amplitude 158:10,12 159:5,14, 15,19,20 analogous 148:23 analogue 128:11 analysis 37:20 47:25 48:6 50:12 90:10 124:7, 20 143:1 144:24 145:14 168:19 171:6 186:1 analyte 14:9 21:10,11,14,15, 18,20,21,22,24 22:3, 9 23:10,12 166:13 167:4 170:12 analyze 50:18 155:15,17 185:19 Anant 4:9 and/or 22:18 53:3 54:5 56:11 63:10 99:5 109:12,23 116:6 132:6 146:20,23
---	---	--	--

149:19 160:17 166:16 167:9 169:3, 4 178:24 179:2,6,8 184:4,7 185:15 angle 154:3,5 angles 154:2 animal 140:7 announce 174:3 annoying 33:8 answering 8:11 answers 5:1,12 antithesis 159:10 anymore 10:21 apologize 91:19 116:9 apparent 93:6 apparently 102:20 130:2 appears 20:5 28:4 appendix 9:23,25 10:2 apples 178:10 application 91:4 127:9 applies 147:13 apply 32:18 90:11,24 104:4 appropriately 20:14 Apurv 27:23 arbitrary 139:13 argued 142:21 argues 49:7 52:16 143:14	arguing 104:24 177:2,11 argument 134:24 143:10,23 145:5 arithmetic 95:13 arm 137:2 arranged 63:12 64:1 arrow 140:5 152:9,12,15, 22 153:14 154:24,25 155:3,5 156:8,11 158:12 arrows 153:22 154:2 157:9 158:22 160:6 art 6:6,10 23:18 90:5 105:5 175:13 article 27:3,18,21 28:4,8 29:22 articles 26:19 aspect 98:24 asserted 36:22 assist 100:18 assume 20:13 120:3 assuming 93:2 assumption 54:20 attached 12:6 attention 150:5 auditory 104:20 authorization 63:13,19 64:2 authorize 108:10 authors 27:17 89:18	automatic 51:2,17 66:25 67:25 automatically 55:3 average 159:9 avoid 28:18 aware 50:2 128:24 130:20 134:1,6,17 awkward 89:23 axis 91:22 B BA 10:10,13 back 14:2 15:23 16:21 18:10 19:7 34:1 41:3 43:3,14 46:14 50:7, 10 60:14 62:5 64:10 83:14 86:2,3 97:2 109:7 122:16 132:7 137:11 142:19 157:4,13 164:13 168:20 176:2 183:22,23 back-calculate 132:21 background 9:19 21:6 22:16,21 23:1 134:3 backpack 137:3 backwards 183:8 balloon 139:25 band 150:11 bar 140:2 barrier 79:9 basal 102:7,12,21 based 17:15 25:11 42:9 53:19 65:6 77:18	97:18 98:7 107:22 122:6 175:16 179:1, 14,15 184:6 185:16 186:14 basic 4:11 11:3 12:20 basically 45:23 49:20 74:13 165:25 166:5 183:1 basis 21:23 113:12 114:12 115:12 153:19 155:24 battery 131:21,24 133:1 134:18 began 90:19 begins 18:13 19:8 70:8 73:4 161:23 bell 101:12,17 beneficial 117:17 benefit 8:6 116:21 benefits 117:20 118:3,4,16 beta 76:10 BG 31:14 big 58:25 bigger 93:10 94:8 95:22 Biographer 30:22 biological 93:3 biology 10:19 bit 12:11 73:4 109:7 137:1,6 138:7 141:21 151:25 166:25 block 69:25 70:9,12,15,22, 24 72:6,8,12 74:3,9, 11,19,23 75:5,7,10,
--	---	---	---

17 blood 22:4,6 29:7 79:16 116:6 132:18,22 150:7 162:7,22 163:3,7,23 164:6,22, 23 165:12,13,25 166:2,3,6,9 174:16 178:9 bloody 133:5 body 165:19 bottom 5:18 11:21 36:19 38:5,9 43:16 84:25 135:5 136:9 138:11 150:7 160:14 166:11 175:9 boundary 78:10 bowels 130:8 box 69:19 73:5,13,16,17, 18 74:17 boxes 69:16 break 5:8 36:9 83:5,11 125:5 151:16,17 178:13 188:13 breaking 151:16 Buffalo 10:13 building 132:5 built 59:2,7,11 126:16 156:2 160:4 180:3 bunch 150:24 burden 134:18 button 100:4 146:20 147:2 149:19 C c]linical 146:18	calculate 79:13,20,21 82:17, 18,19 155:9,11 165:23 172:11 calculated 121:9 calculating 80:1 154:4 calculation 13:11 59:1 166:7 calculations 59:11 170:4 calculus 10:19 calibrate 165:16 166:2 calibrated 165:3 calibration 138:15 call 11:2 89:15,21,22 131:8 139:23,24 150:4 157:4 158:6 167:21 called 10:3 29:18 57:5 95:18 150:10,13 calling 100:22 139:18 calls 150:4 capability 28:17 carbohydrates 100:22 carefully 129:16 carry 137:1 case 4:14,17,18 8:1,24 10:22 104:2 122:22 123:2,16 130:2 133:6 139:5,7,24 140:6,10 141:19 151:2 152:21 158:16 188:9 cases 63:7 184:8,24 catalog 130:15	categories 183:10 category 160:11 cell 16:14 134:18 certificate 12:4,6 CGM 6:15 28:16 29:3,4 31:3 130:8 135:11, 13 136:18 137:6 144:3,4,5 147:7,8 160:3 165:3 Challenged 14:23 chance 179:5 change 42:5,7 44:5 51:13 53:3,4,20 54:15 56:5,15,21 63:8,20, 24 67:18 79:12,20, 21 80:5,9 87:4 92:16,21,23 93:6,9, 10,18,19,23,24 94:3, 4,5,8,12,13,14,19,24 95:8 96:11 102:10 109:13,23 112:10,14 114:5 117:3 121:4,7, 8 122:4 132:16,17 139:4 152:17,23 153:16,20,21 154:3, 10,21,23 155:1,2,4, 5,11,12,16,20,24 156:4,7,10,16,18 157:10 158:24 159:9,20 170:10,11, 25 171:7,16,23 172:6,7,16,17 173:2, 3,12,14,15,19 174:10,11,21,22 177:5,13,21 178:3 186:24,25 changeable 137:25 changed 62:18,23 63:6 64:4,9 94:12 138:22 139:20 140:13 changing 54:7 63:12 64:1 79:25 80:1 103:4	105:24 106:16 159:8 characteristics 42:11 characterization 149:2 characterize 9:7 characterized 20:14 characterizing 95:8 chart 18:17 19:13 69:7 check 112:6 checked 180:18 chemical 165:4 chemistry 10:18 chemists 21:15 choice 148:4,5,6,7 circuit 162:3 174:2 circuitry 128:3 129:6 circumstances 16:8 30:6 33:15 64:8 citation 14:10 39:15 42:15 65:3,8 67:6 84:24 146:10 149:9 citations 79:4 153:1,4 cite 7:4 25:2,3,20 38:25 39:2,10 40:6,13,15, 17,25 41:14,21 42:24 44:20 47:22, 24 48:5,10,14,25 49:10 52:19 53:14, 25 55:11 56:17 57:15 84:21 125:21 142:9 153:5 160:8, 19 161:18 188:5 cited 55:17 154:16 cites 14:18 53:7
---	---	---	--

citing 60:14 153:6 claim 35:1,6,8 37:2,6,7,17, 21 38:11 41:3,6,22 43:11 44:19 46:22 50:12,14 65:21 68:19 76:15,19,21 77:5 80:11,13,19,23, 24,25 81:12,13 82:2, 3,4,8,21,25 83:1,2, 14,16,18,23 84:4 97:2,5,17 118:20 121:12 122:22 123:15 124:14 151:23 152:6 158:8 171:9,14 180:6,7 181:16 183:20 184:21,24 185:4,9, 20 claimed 39:20 50:4 51:15,25 65:13 66:1 67:20 68:8 84:17 152:18 153:17 171:2 172:24 187:3,15 claims 14:23 34:20,24 37:13 40:22,25 41:10 45:24 46:2,4 76:18 84:4 86:2,20 91:5 179:19,24,25 181:2 183:12 184:13 186:10 clarify 158:18 Clark 79:3 clear 82:15 88:11 113:20 126:17 129:20 131:5 185:23 clear-cut 154:11 click 140:3 clinical 11:4 93:3 133:4 147:2 148:2,14,16, 18,19 149:17 150:4, 6,16 151:4,5 164:14 clock 16:13 36:10	close 100:13 coaching 148:2 code 141:14,15 142:6 collected 107:22 173:21 colon 149:13 column 14:11,18 18:12,15 19:7,11 21:4 28:11 34:2,8,9 35:7 42:16 68:23,25 69:1 70:2, 4,6 71:4 72:10 74:2 75:15 84:21 85:5,6,7 98:18 99:25 101:9, 22 127:14 160:19 161:19,21 164:18 166:12 167:2 columns 127:13 combination 47:13 50:24 57:24 58:10 66:11,19 80:8 105:4,23 106:16 108:21 109:20,22 117:21 120:23 121:2,7,12,13 122:1, 7,21,23 123:15,16 145:23 172:7 175:22 176:6,18 177:4,12 178:2,23 181:4 184:3 185:12 186:14,19 combinations 173:11 179:9,12 184:10 combine 103:24 104:25 105:25 109:11 111:22 112:23 115:21 117:17 176:24 187:14 combined 45:1 156:15,16 175:6 176:13 combines 175:13 combining 103:19 104:13 105:5 116:1,22 117:1	118:4 171:25 175:11 comfortable 185:11 commands 76:4 comment 60:24 103:3 commercialized 135:14 144:6 common 12:14 24:7,8 78:4 86:25 89:15 companies 24:23 25:10 company 24:21,22 126:19 compare 88:21 177:13,21,24 178:8 compared 31:16,23 57:3,4 compares 32:10 84:10 88:14 comparing 51:18 52:1 65:22 66:5 68:1,12 104:16 177:4 comparison 68:20 77:16 172:15 compass 159:12 compatible 182:10,11 complete 11:3 complex 159:17 complicated 59:1 167:23 172:1 component 128:16 comprises 77:1 98:25 computation 76:9 computer 12:7,8,15 13:1,2,5 76:3 125:19 126:1,5, 10,13,19,22 127:2,6, 8 128:11 135:1,8,11, 16 141:15 142:6,15, 22 143:2,7 144:3,8	145:21 151:13 164:8 computers 12:10,13,14 conceivably 22:17 183:10 concentrations 162:18 164:19 concepts 145:24 concerned 90:2 concluded 188:24 condition 14:16 24:12 29:6 33:19,22 53:6,18 109:15 116:4 148:2 conditions 53:21 162:12 166:15,21 167:7,15, 16 configured 70:16 74:4 75:18 85:17 127:23 166:14 confirm 105:23 143:21 confuse 44:14 confusing 73:4 89:23 connection 134:15 consciousness 100:6 consequence 147:18 consequences 33:24 consideration 77:21 80:8,9 considered 23:19 24:1 58:21 89:7 104:7 155:25 171:19 consistent 31:2 consists 74:17 constant 92:10 constantly 92:6
---	---	--	---

constants 118:7	converters 128:12	179:9,10 185:18	143:12 152:24
constitute 72:21	cooked 59:11	correctly 17:14 134:23	155:23 156:1 158:10
construction 41:18 49:19,23 50:5	copy 27:21	correlate 162:21 163:3 164:21,23	161:7 169:20 172:12 174:15 175:17 177:9 179:2,8,14,16 180:14,19,25 181:12,25 182:6,9, 14,16,19,22 183:17, 19 184:7 185:17 187:16,22 188:6
construe 105:17	corner 5:18	correlated 165:6,8	criteria' 51:24 68:7
construed 49:8 52:17 87:22	correct 5:12,24 7:22 9:2 10:15,23 11:7,16 13:14,20 17:21 18:8, 9 19:21 22:21 27:8 29:22 32:2,7 34:15 37:5,15,21,22 38:7, 20,22 39:7 40:1,2,12 41:19 42:20 44:10, 18,21,22 45:7,20 46:21 48:1,17 49:19 50:5,6,19,20 52:3,7, 11,12 53:7 54:15,16, 19 56:13 60:6,9,13, 16,21 61:4 62:19,22, 25 63:1 64:21 66:2 67:14,22,23 68:17, 18 70:1,12,22 71:6 72:9,13 73:23 74:21 75:3 80:18,20 81:2, 15,20 82:12 83:3,21 84:2,3,7 92:3,15,17, 19 93:20 94:20 95:23,24 96:1,12 97:10,13,25 98:11 99:23 101:6,11 102:18 103:15,16,20 105:1,8,13 106:24 108:17 109:2,17,24 110:21,25 111:16, 17,19 112:16,20 113:22 114:5 115:14,22 116:19,23 117:18 119:9,10,11, 23 122:5 123:21 124:22 125:14,21 128:8,21 129:23 134:12 138:24,25 139:1 142:23,24 143:3,10 145:7 156:6,8,11 157:10 160:10 162:5,23 163:5 166:10 174:18,20 175:2,3, 18 176:15 177:23	correlation 165:24	criteria,' 172:24
consult 15:16		correspond 162:17	criteria.' 65:15 67:21
consumption 134:11		corresponds 51:15 65:13 67:19 163:11,17 164:1 166:8	criterion 52:10 107:25 113:11 114:11 145:22 154:24 177:8
contained 124:21		cosign 72:22	criterion' 152:18 153:17
contemplated 112:11		counsel 91:16	cross 29:15 30:14 108:15, 24
contemplates 149:22		County 11:6	current 161:7 162:19,20 163:2,13,16 164:19, 21 165:6 166:7,8 173:22
contemplating 146:16 149:3,10		couple 52:14 174:16	curriculum 9:23 11:3
contents 36:16 50:8		courses 12:7,25	curve 154:21
context 13:2 18:4 23:9 24:17,18 32:17 41:7 128:15 130:25 131:9 133:21 143:11 148:22 179:5		court 5:1 8:6 26:2,6 41:19 49:6 52:15 87:20 91:11 188:19	curves 132:16
continuation 143:25		cover 114:22,25 115:15	customized 139:18 146:19 149:18
continuing 14:13 21:23 51:6 146:15 162:6		covered 115:13	CV 10:7,9,12
continuous 6:12,16 21:11,20,21 22:7 24:18 27:12 65:7 90:9 104:4		crashing 151:11	D
control 132:1,2 134:11 167:5		created 168:6	dangerous 144:11 148:5,6,7
controlling 99:6		criteria 38:18 40:5 43:22 47:17 51:16 52:3 60:4,9,21 69:23 70:18 73:21 74:6,24 75:13,20 76:25 83:21 84:2,7 85:21 86:8 97:8 104:17 111:24 112:25 113:13 114:13,16 115:11,12 118:13, 18,25 119:8,14 121:16 122:12,19 123:1,20 126:6	dash 11:22 12:3
conversion 162:20 164:20			data 13:11,15,18,19,20 21:10 22:9,10 38:15 42:9 43:19 47:14 51:21 59:25 65:25
conversions 128:19			
convert 165:11			
converter 128:2 129:22 130:1			

68:4 69:21 70:16 73:11,19 74:5 75:11, 19 76:22 77:5 80:16 83:19,25 84:5 85:18 86:5 90:10 102:2 106:8 119:5 127:5 134:3 155:8,14,15 162:3 169:17 171:22 172:21 173:19,20, 22,24,25 174:13 180:11 data' 14:9 date 23:25 27:1 135:14 144:6 154:7 DAVID 4:2 day 110:12 de 88:8 deal 128:11 132:24 dealing 137:4 167:24 decent 146:5 decide 140:3 155:19,23 172:3,8 decided 128:25 deciliter 51:20 52:6 53:22 65:11,12 67:11 68:3 88:16 138:19,21 151:3 162:9 163:8, 12,15,17 164:2,3 174:19,23 deciliter,' 67:1 decision 164:15 decisionmaking 145:13 declaration 4:14 7:5,25 8:23 9:1, 5,14 14:1 20:21,23 25:3,21 36:16,22 37:7 39:24 44:1,11 46:10,22 48:4 49:5	50:8 59:14,21 60:11, 19 64:11 66:16 76:15 79:5 83:15 84:14 86:3,18 87:12 89:11 97:3 104:23 115:9 118:21 123:23 124:15 125:11 129:12 130:11,23 131:2 134:22 142:9, 20 149:5,6,7,25 151:22 156:20,23 157:24 158:1 159:24 160:9,13 161:17 168:19 171:15 176:11 178:19 180:8 185:19 186:2,3 decrease 170:12 decreasing 153:23 default 138:18 139:2,10,19 define 16:12 87:24 defined 18:3 36:6 72:23 76:8 78:24 79:1,2,3 86:24 98:16 defines 16:10 definite 86:24 definition 72:25 88:3,6 89:16 definitions 4:12 definitive 72:25 degree 12:4,5 93:5 147:25 degrees 159:6,19 deleterious 33:23 delivery 99:1,4,7,22 102:4,8, 12,21 103:4,5 188:20,23 demonstrate 103:23 department 25:5	depend 140:20 dependent 80:19 depending 93:5 147:25 depends 16:10 33:15 deposed 4:21 deposition 4:24 5:14 6:20 7:10, 18 8:4,14 26:3 61:14 91:13 138:4 161:14 derivative 95:3 117:4,5 describe 29:23 141:10,19 describes 64:24 161:4 describing 128:7 description 9:18 designated 92:18 94:15 designed 29:17 161:5,18 162:16 163:1,14 168:6 169:2 designing 132:6 desirable 29:9 106:14,19 147:16 desired 29:9 116:4 detail 62:14 detailed 45:16 details 48:22 detect 31:10 detected 53:19 108:2 detection 107:20 117:10 detects 51:9 67:9	determine 38:16 43:20 47:15 51:22 60:1 68:5 69:22 73:20 75:12 76:23 83:19 84:1,6 85:19 86:6 119:6 169:18 171:20 172:21 174:1,13 180:12 determined 33:9 46:9 determining 102:6 152:16,22 153:15 developed 22:18 135:13 144:5 148:11 development 133:3,10 device 31:25 88:23 99:1,23 101:17 102:4,17,22, 25 103:14 108:18,21 111:23 126:16 135:22 137:23,24 163:9 166:13 168:6 devices 131:25 134:10 160:5 devil 132:22 Dexcom 4:11 diabetes 26:12,15,20,22 27:24 29:5 32:17 90:11 138:23 147:13 diagram 150:12 differ 147:12 difference 15:9,12,15 16:1,9 18:7 79:7 differentiated 81:7 differentiation 81:10 difficult 89:24 168:1 169:12, 25 digest 179:5
---	---	--	--

digital 128:1,3,12 129:6 130:1 164:9 directed 14:24 direction 78:16 92:16 93:9,23 94:5 95:9,14 96:11, 16 152:16,23 153:15,21 154:10 155:4 156:4,7,16 157:10,14 158:10,23 159:3,15,21 directional 152:9,12,15,22 153:14 154:24,25 155:3,5 156:8,11 158:22 directly 150:3 disable 134:3 disagree 141:17 163:21 disastrous 144:12 disclose 50:3 143:15 disclosed 135:12 144:4 152:10 177:13 discloses 39:19 50:25 51:2 53:10,18 54:4 56:10 64:15 66:12,24 84:16 122:23 123:16 125:18 135:20 151:23 152:6 186:23 187:15 disclosing 136:19 disclosure 18:21 19:18 69:11 109:11 175:11 discreet 76:3 141:3 discuss 35:20 40:3,10 45:8 46:6,10,23 47:6 48:5 83:12 90:8 123:24 124:5,9,10,11,16,23 142:25 188:6	discussed 39:19 47:20 51:4 67:2 79:3 82:7 83:3 84:16 170:22 181:4 182:3 183:14,22 185:8,13 186:22 discusses 35:22 discussing 34:5 41:17 42:18,22 123:25 125:13 143:12 187:22 188:3 discussion 124:13 154:16 171:15 display 154:24 155:17 156:8,11 displaying 152:14,21 153:13 distinct 29:17 distinction 17:19 126:17 District 41:19 49:6 52:15 87:19 dividing 17:23 division 10:14,17 DL 31:15 174:17 doctor 78:12,19 129:2 146:19 147:17,23 148:3,6 149:18 doctors 139:14 document 5:17 6:24 7:1 8:17, 18,21 15:20 26:1,7 39:5 43:1 45:13 47:10 58:11 59:16 61:13,25 71:19 76:18 87:14 96:24 110:7 114:20 115:4 125:1 127:17 137:12 152:1 153:2 158:4 161:13 168:21 170:19 176:8,20 documented	154:7 documents 6:23 7:3,4,7,23,24 dosage 103:4 double-check 176:3 downloading 134:3 downward 159:12 drawing 91:9 96:19 165:13 drawn 93:7 Drexel 11:16 drop 22:7 dropping 151:11 dynamic 77:1,6,10,17,19 79:7,10,24 80:3,7, 12,17 81:2,5,14 82:11,19 83:2 102:10 dynamically 18:18 19:4,14 69:8 E e.g 53:21 102:8,12 162:19 164:19 172:19 earlier 17:9 18:6 25:13 39:10 48:24 82:7 114:7 123:12 137:17 142:1 166:24 169:24 170:7 earned 10:13 earning 10:25 easier 35:5 76:17 138:7 educate 104:22 education 10:3,6 11:22 148:1	educational 12:5 effect 80:7 effectiveness 31:8 elaborate 131:8 electrical 161:8 electrochemical 165:5 electrode 162:18 164:19 electronic 131:9 electronics 128:14 129:5 132:8 element 39:21 43:13 44:15 46:10,11,22,24 48:1, 5,7 51:1 64:15,20 66:13 84:18 118:22 119:4 170:22 171:6 172:3 185:2,8 186:20,22 elements 13:12 105:6 119:11, 25 175:13 184:23 185:5 187:17 emanating 161:8 embodiment 18:20 19:17 63:3 69:11 98:21,24 99:17 embodiments 71:21 85:9,16 99:19 100:3 102:1 110:12 127:16,22 136:6,10, 22 emergency 11:12 100:8 101:13 emphasis 146:23 enable 172:3 enables 173:25 end 39:12 40:7 54:11 56:9 63:25 85:11
---	--	--	--

104:9 105:3 106:25 107:8 108:11,20 128:10,17 129:1,5,9 131:5,11,12,17,25 132:8 134:10 137:21,25 138:17 140:13 147:24 150:21 end-user 134:10 ended 92:2 engineer 128:10 132:5,9,10 engineering 131:9 engineers 169:5 English 142:13,14 enormous 76:11 enter 58:23 140:4 entered 141:22 entire 20:24 35:18 41:2 44:16 128:16 entities 177:23 entitled 27:21 36:21 37:7,12, 17 50:14 176:13 186:9 entity 21:16 entry 37:2 envisioned 144:5 envisioning 136:22 epidemiology 11:24 episodes 117:10 equal 148:21 equals 80:4 92:13	equation 59:1 equivalence 73:16 error 93:1 160:11 erudite 131:8 essentially 76:3 establish 172:12 estimate 165:12 168:15 estimated 136:4 estimates 132:17 evaluate 31:7 59:25 69:21 70:16 73:19 74:5 75:11,18 77:12 83:25 85:18 105:18 126:23 154:20 169:17 172:2,10,20 173:25 174:12 176:2 180:11 evaluated 29:13 172:8 evaluates 80:13 evaluating 27:11,22 38:15 43:19 47:14 51:21 65:25 68:4 76:22 77:1,5,6,10 80:12, 16,17 81:2,5,14,19 82:11,12 84:5 86:5 119:5 120:16,20 155:8 171:22 evaluation 28:16 77:13 83:18 119:17,21 120:9 172:2 event 16:20,24 17:12 24:14 100:4 events 16:19,24 17:11 30:17 31:24 everyday 78:4 137:3	evidently 95:16 139:5 exact 165:22 EXAMINATION 4:5 examined 4:3 examples 15:7 24:15 42:9 101:19 134:9 162:7 171:1 exceeds 162:4 170:13 187:1 excursion 29:8 excursions 28:19,22 29:11,18 excursions' 117:12 Excuse 158:6 exercise 75:5 Exhibit 5:14,18,21 8:14,23 9:5,13 10:1 14:2,11 18:11 26:3,9,12 27:20 33:25 34:2 49:10 51:8 52:19 61:13,14 65:20 91:12,13 95:21 96:23 106:9 138:4,8 161:14 existed 180:2 existing 106:21,22 expect 126:21 151:12 177:18 expectation 24:13 104:12 145:15 experience 9:22 173:17 experimental 148:12 explained 62:10,14 105:4 106:4 145:4 157:6 169:15 187:13,17	explanation 159:23 169:23 explicitly 29:17 58:13 88:11 expressed 174:22 expressing 88:18 174:17 expressly 143:15 extent 143:14 external 102:17 103:14 extrapolated 30:12,14,23 F fact 79:25 88:18 107:20 108:2 120:11 126:11 128:24 150:23 151:9 154:16 158:10 159:3 163:23 facto 88:8 factor 80:1 factors 58:19 facts 36:21 fail 184:15,18,21 failed 181:17 fairly 88:11 false 31:14 32:3,6 33:4 familiar 6:5,12 26:15 32:13 126:14 133:23 fancy 59:6 129:5 131:8 farfetched 126:25 130:24 fast 78:16 fatigue 32:14,16 33:9,10,11, 13,16
--	---	---	---

fault 116:10 feasible 118:15 feature 106:11 fiddling 132:7,13 field 25:4 106:7 figure 18:13,17,24 19:1,9, 13 20:4 69:4,7,14,16 70:12,22 72:7,8 74:9 75:7,10 132:13,14, 24 136:13 150:2,7 153:5,6 156:14 158:19,20,25 159:24 160:8 figures 136:2 153:20 156:19 filter 131:7 132:15 filters 133:18 filtration 131:20 find 62:4 107:7 fine 16:7 35:6 188:23 finger 22:6 finish 8:7 FIR 131:7 fit 138:22 fixed 132:11 133:11,14 147:9 flat 153:24 159:22 flow 18:17 19:13 69:7 fluid 116:5 132:19,20 162:17 164:18 165:16,18,22 166:1, 4	focus 115:24 168:23 focused 28:15 73:17 95:25 focusing 112:18 113:4,20 footnote 40:8,10,13,17 41:1, 7,13 46:12,24 47:8 footnotes 87:8 forget 32:23 form 13:6,21 16:2 17:4,25 20:11 23:20 27:6 28:1,24 29:25 34:16, 22 35:25 43:8 46:25 47:9 48:2,8 55:6,19 57:25 60:22 71:18 76:5 81:3 89:2 91:1 92:7 93:11 94:1,6,9, 21 95:10 96:2,13 98:1 99:14 100:21 103:25 105:14 106:1 108:25 111:20 112:21 113:23 115:1 117:24 119:15 120:1 121:19 123:7 129:13 133:15 136:20 138:1 143:4 144:16 145:17 147:5 155:6 156:21 157:11,20 158:3 163:19 164:25 171:10 175:25 179:21 180:21 181:18 183:4 184:17 formal 10:5 formula 79:14,16 formulas 79:15 formulation 20:8 77:18 FORTRAN 12:20 forward 30:24 found 32:2 115:17 170:16 fourth 136:6 183:16	Freestyle 24:25 frequently 131:25 fulfill 88:13 full 28:10 function 13:1,4,10,14,17,19 34:21 35:2,3,9,12, 15,20,23 36:5 38:16 40:4,11 41:11,18 42:22 43:20 45:8 46:11,23 47:7,14,20, 25 48:7,16 49:7,8, 18,22,25 50:4 51:22 52:16,17 58:22 60:1 68:5,20 69:22,24 70:25 71:8,10,13,16 72:7,8,16,21,25 73:13,20,25 74:10, 13,17,21,23 75:2,8, 12,24 76:2,8,10,13, 23 77:6,10,12 80:16, 24 81:11 82:1,25 83:19,25 84:5,10 85:19 86:6 87:21,22 88:13,21 108:22 119:6 134:6 140:10 169:18 171:23 172:21 174:13 180:12,24 function' 66:1 functionality 106:20,22,23 107:19 108:14,16 144:21 functions 35:4 fundamental 106:11 future 23:13 30:13 fuzzy 87:6 G gave 92:21 159:23 169:24 gears 129:8	general 12:13 35:19 88:4 126:11 generally 14:24 24:7 25:7 29:6 80:21 generic 154:1 geology 10:19 get-go 55:2 Giunta 4:10 give 5:1,11 16:11 24:15 56:7 78:4 86:19 89:1 91:8 96:21,22 134:10 151:10 155:23 161:13 162:11 168:17 182:17 giving 23:11 87:12 101:20 143:22 144:23 glucose 6:13,16 14:9 15:1 21:18 22:4,5,6 24:18 27:12,22 29:4,15,18 30:12,14,24 32:10 38:17 39:18,21,25 41:4 42:3,4,5,6,8,10, 19 43:21 44:3,4,5,6, 11 45:2 47:15 48:12 49:2 51:2,4,9,12,14, 17,18,23 52:2,6 53:1,2,11,20 54:4, 12,18 56:3,5,6,11, 14,15,18,20,21,23, 24 57:2,3,4,8,10,23 58:8,18,20 60:2,20, 25 61:5,18,20 62:16, 17 63:4,5,8,9 64:25 65:1,7,10,21,23 66:5,25 67:2,10,13, 19,25 68:1,6,12,21 76:24 77:2,7,11,14, 19,20,21,22,24 78:2, 5,11,19,24 79:12,13, 16,19,21,25 80:5,8, 10 81:6,15,19,21,22, 25 82:17,19 83:20 84:1,6,10,15,18
--	---	--	---

85:20,25 86:7,23 87:1,3,9 88:1,14,19, 20,24,25 89:1,4,5,8, 12,13,19,20,24 90:1, 2,3,4,9,11,15,25 91:21,22 92:1,6,12, 16,21,23 93:3 100:4, 21 102:8,10 104:5, 16 105:19 107:5,16 108:14,23 109:12,22 110:14,16,18,19,20 111:3,4,6,7,8,15,19 112:5 115:22 116:5 117:3,4,6,7,21 119:7,13 121:3,4,18 122:2,3,4,18,25 123:6,19 126:24 132:18,19 136:4 138:18 139:3 140:9, 11,12 141:3,5 145:12 147:14 148:17,21,22,24,25 150:19,20 151:3,11 154:9,10,15,20,21 155:2,8,10,16,21 156:15,17 158:16 159:8,9,13,18 162:8, 17,22 163:3,7,23 164:13,14,18,22,24 165:7,13,16,18,20, 23 166:1,2,6,9 167:4,25 168:7,10, 11,16 169:11,19 170:1,4,25 171:1,3, 7,8,9,13,17,24 172:11,12,16,18,23 173:3,4,7,11 174:10, 11,16 175:6 176:14 177:20 178:2,3,4,9 179:23,24 180:13 187:1,3,7 188:4 Glucowatch 30:22 31:22 106:8 glycemic 14:16 42:12 116:3 goal 117:9 145:2 goals 138:23 God-given 139:13 good 4:7,8 8:8 36:11	86:21 91:10 107:23 113:18 graduate 11:23 graph 91:20,21 92:1,5,13, 17,21 93:24 95:20 154:19 155:19 graphical 104:20 155:1 graphically 155:18 greater 31:14 62:14 94:4,24 147:17 greatest 159:4 ground 4:12 48:5 49:14 50:24,25 52:25 57:20 58:6 66:11,12 88:9 103:18,19 108:21 114:18,25 115:15 120:22 121:1 124:11,17 157:3,6 186:9,14,22 187:18 grounds 36:22,25 37:6,13,21 38:12 46:22 50:13, 18 114:23 115:13 124:7,13,20 170:23 GT 30:22 31:22 guardian 63:15,20 64:3 Guerra 77:18 79:1 guess 32:18 Guide 37:14 39:18 45:2 47:13 49:21,25 50:3, 23 51:2,12 57:24 58:9 64:14,20,24 65:3,22 66:4,10,19, 24 67:6,17 68:11,19 84:15 88:10,12 103:18,19 104:15 105:1,11,13,20,24, 25 106:17,18,22 107:6,17 108:17,22 109:16 111:22,23 112:23 115:22	116:2,14,23 117:7, 18,21 118:5 123:16 138:9,13 139:1,10, 24 141:9,18,20 175:11,22 176:18,24 177:4,8,15 Guide's 52:6 176:14 177:5 Guide/harper 109:20,21 120:22 121:1,12,13,25 122:7,21 123:14 Guides 117:8 175:6 178:22 184:2 guts 128:13 129:4 guy 132:14 guys 90:20 91:4 132:7 gynecology 11:13 H Hahnemann 11:15 halfway 62:8 146:5 hand 61:12 78:11 138:8 handed 5:17 8:18 26:7 27:4 handled 33:19 handwriting 91:19 happening 24:14 happy 61:11 150:4 153:8 Harborview 11:6 hard 137:1 harm 150:22 Harper 37:15 47:13 48:10, 25 49:12,17 50:25 52:10,24,25 53:7,10, 14,18 54:4,12 55:4,	8,11,14,17,18 56:10, 18 57:11,13,16,24 58:9 60:24 61:9,10, 11,13,22,23,24 62:6 66:12,19 103:20 104:15,25 105:11, 12,17,24,25 106:18, 23 107:5,16,20 108:13,16,23 110:1 111:23 112:3,4,6,18, 19,23 113:4,5,7,20, 21 116:15,22 117:1, 17,21,23 118:5,18 121:5,16 122:3,5 123:1,6,9,16,18 124:23 128:16,20 145:24 146:2,7 Harper's 42:3 44:3 45:1 56:3 57:22 58:8 60:19 109:11 115:21 116:1 Health 11:25 healthcare 55:1 63:6,14,19,23 64:2,4 112:15 114:1 148:3 168:2 169:14, 25 170:6 hear 32:24 81:6 heard 130:7 hell 140:20 high 33:3 78:7,21 110:18, 20 111:6,8,15,18 112:4 138:18 139:2 142:16 higher 78:14 highs 104:6 hinting 90:20 history 31:3 hits 133:4 Hold 110:3 hope 91:20
--	--	---	--

Hopkins 11:24		implemented 136:23	indication 171:20
horizon 102:9	I	implicitly 58:15	indicative 14:15 38:17 39:20, 25 41:4 42:6,19 43:21 44:6,11 47:15 51:23 52:2 56:6 60:2 68:6 76:24 77:14 84:17 86:7,15,19,23 87:5,13,25 88:19,25 89:1,4,8,12,16,23 90:1,5,23,25 119:7, 13 120:25 121:3,17 122:2,18,25 123:5, 19 169:18 171:2,8, 12 172:22 173:4,7 187:2,7 188:4
horizontal 150:12,13 159:7,16, 18	i.e 42:4 44:4 56:4	implied 114:18,19	indicator 54:5,18 56:11,14,18, 20,23 62:16,17 63:4, 5,9,10 97:7,19,23,24 98:4,7,8,9,10 99:8 102:5 104:18 118:24 120:10,18 121:15 122:11,24 123:18 172:4
Hospital 11:7,16	i.e. 126:6	implying 173:10	indicators 14:25 15:5,7 41:11 97:15 178:25 179:7, 13,15 180:18 184:5 185:15
hour 36:9 125:5	id 65:12 146:12,13 149:10	important 140:19 173:7	individual 118:12 127:9 139:18 173:21 184:23
hours 7:15,19,20 9:9	idea 8:8 78:23 103:3 140:14,15 163:7	impossible 168:2 169:13,25	individuals 142:15
Hygiene 11:24	identical 30:4 57:7 89:6 181:10	impression 35:19	infinite 99:18 131:6
hyper 167:21,22,23	identifies 164:6	improved 31:11	influence 104:21
hyperglycemia 99:5,8 150:14 162:10 166:23 167:8,10,17 168:8	identification 5:15 8:15 26:4 61:15 91:14 138:5 161:15	impulse 131:7	information 12:10 99:7 102:6 107:22 142:16
hyperglycemic 167:20	identified 118:17 122:25 123:18	inaccurate 23:19 24:1	informed 87:19
hypo 167:21,22,24 173:17	identifying 116:21	inappropriate 133:8	initial 131:3 139:25
hypo-avoidance 102:3	ignoring 73:24	include 77:17 89:13 100:12 101:13 102:5 136:11 161:6 167:6	initiating 99:4
hypoglycemia 31:9,11 53:5,12,21 99:4 109:15 116:17 143:16 145:10 166:22 167:8,9,17 168:8 172:20	IIR 131:7	included 9:22 10:18 11:12 154:16	inputs 13:15,20
hypoglycemia' 117:11	illustrated 106:8	includes 11:3 77:20 80:4 89:5 90:2,3 101:5,10 130:21 165:4	inside 22:5 163:9
hypoglycemic 41:11 97:7,15,19,23 98:4,7,8,9,10 102:2, 5 118:24 120:18 121:14 122:11,24 123:17 167:19 172:4 178:24,25 179:6,7, 13,15 180:17,18 181:7 182:4,5,8,14, 15,18,21 183:17,18 184:4,5 185:14,15	illustrating 18:17 19:13 69:8	including 7:16 14:13 22:17 55:1 87:2 90:8 97:6, 15 99:2,12 117:2 118:23 121:14 122:10,23 123:17 136:3	
hypothetical 82:24	imagine 167:18	incorporate 107:4,15	
hypothetically 147:15	immaterial 129:18	increase 116:16 170:12	
	immediately 15:18 165:7,21	increasing 153:23	
	impact 130:14	index 79:16	
	impending 53:5 109:15 166:22, 23 167:8,9,22,23,24 172:19 178:24 179:6,14,25 180:17 181:7 182:5,8,15,21 183:18 184:4 185:15	indicating 158:12 171:16 176:23	
	implement 108:10 181:4		

instance 90:17 99:24 101:4,8 104:4 147:19 148:10 150:7 164:16 instances 57:9 instant 108:3 instantaneous 155:10 instruction 100:8 101:15,16 instructions 70:17 71:3,5,9,11, 17,22,23 72:4,13,17, 20 73:2,3,5,8 74:6, 12,14,17,18,21,22, 24 75:1,19,24 76:4, 9,13 99:2,12,22 100:17 101:5,10,20 102:11,17,24 103:13,14 instructs 5:5 insulin 99:1,3,6,22 102:4,8 103:4,5 147:14 intelligently 18:18 19:5,14 69:9 intend 177:17 intended 31:7 124:5 intensive 12:17 interchangeably 74:14,15 interdisciplinary 10:18 interest 26:20 interested 164:12 173:15,16 interesting 177:7 interface 100:20 101:2 135:15,21 136:5,10, 17,24 144:6 interfaces 137:4	intermediary 153:25 internal 11:15,20 129:4,8 internship 11:6,10 interpolate 29:2 interpret 87:9 interpretation 49:11 52:23 64:17 87:1 98:12 142:10 interpreted 80:22 interrupted 16:6 interstitial 116:5 132:19,20 162:17 164:18 165:16,17,22 166:1, 3 interval 127:25 129:23 intuitive 78:4 invalidate 182:25 invention 22:14 investigation 28:12,15 29:14 invisible 59:10 involve 77:10 152:16,22 153:15 involves 51:18 58:19 65:22 68:1 81:2,14 82:10, 11 180:25 iphone 133:24 IPR 4:14,18 irrelevant 129:18 130:19 irrespective 33:1 issue 26:23 27:1,2,5,24	item 124:14 J January 26:23 27:2,5,25 job 91:3 Johns 11:24 jointly 184:19 journal 26:12,15,21 27:23 28:5 jumbo 89:21 K Kamath 27:23 keyboard 136:11,16,18,24 137:2 140:5 kind 20:1 33:8 39:11 43:16 59:6 61:17 78:5 89:13 104:21 126:21 129:4,21 134:10 135:3 139:12,19,25 144:9 148:20 151:12 163:8 174:25 175:1 kinds 33:7 90:8,10 King 11:6 knew 24:16 156:7 knowing 173:23 knowledge 29:3 Kovatchev 79:2,16 L labeled 9:23 19:2 69:16 158:24 159:7,10	labs 103:7 lag 131:20 132:18,23 language 20:1,18 39:25 40:11, 25 41:5,10,12,23 42:19,23 43:6 44:17, 20 45:9,24 46:23 47:7 48:1,7,16 60:9 72:7,18 86:16,25 89:16 90:7 91:5 122:17 127:3 130:20 142:13,14 149:21 157:17,25 187:8,22 188:4,7 languages 12:16,18 126:16 large 89:7,13 larger 92:22 93:19,22 95:1 96:6 161:22 late 106:7 lawyer 5:5 lead 33:8,16 leaders 25:4 learn 13:1 learned 12:12,15,19 left 26:11 117:22 left-hand 28:11 lesser 147:18 lets 135:21 140:2 letter 37:24 38:2,6 59:22 level 17:1,2,15,16,18,22 29:16 42:5,12 44:5 51:10 53:20 56:5,15, 21,24 58:20 67:10 91:21,22 92:6,12,17 93:3 100:3,4 108:15
---	---	---	--

132:18,19,22 151:4 154:9,20 156:15,18 163:7,10 164:5,6,12, 13,14 165:7,13 166:9 168:5,11,16 170:12 171:24 173:11 187:1 level' 39:19 84:16 levels 15:1 16:19,24 17:11 110:16,18,19,20 111:5,6,7,8,9,15 116:5,6 117:3 141:5, 6 150:16 162:8,22 163:3 164:22,24 166:14 167:18 168:11 life 137:4 Likewise 154:9 156:17 limit 147:19 limitation 38:11,14,21 40:1,4, 11 42:20 43:7,13,16 44:12,17 45:9 47:7 49:13,18 50:18 51:5 52:1,24 57:20 58:5 59:22,24 60:7,12,15 66:5,18 67:3 68:12 83:18 86:4,16 97:4, 5,18 122:9,17 123:4, 24 124:3,5,7,11,14, 16,20 169:23 180:10,19 181:9 182:1 183:3 187:8 188:5,7 limitations 97:22 limited 80:25 81:12 82:1,8, 15 83:1 154:1 limits 139:11 linear 173:13 linearly 111:2 lines 14:11,18 18:15 71:5 72:11,23 84:22	98:19 101:9 102:19 106:4 150:12,13,23, 24,25 160:19 161:19,21,22 list 47:19 99:21 114:4 listed 10:6 27:15,17 listing 76:15 83:15 97:3 118:21 lists 99:12,16 liter 67:11 138:20,22 literally 90:12 110:14 litigation 87:20 lock 54:17,21,24 55:4,13 locked 54:5,13 55:2 56:11 60:25 63:10 64:5 logic 59:6,12 78:5 145:24 149:1 logical 151:15 174:2 long 7:14 43:16 102:7 133:3 135:3 160:4 longer 33:21,22 62:2 looked 52:14 60:15 70:12, 22 103:12 loss 100:6 lot 103:18 140:21 148:8 loud 16:14 low 45:2 51:2,3,11,14,17 52:6 54:4,12 56:11, 14,18,20,23 57:2,3,8 58:20 60:25 64:25 65:10,21 66:25 67:2, 13,18,25 78:6,8 79:16 100:4 107:5, 16,21 108:3,4,6,7	110:18,19 111:6,7, 15,18 112:4 115:22 117:2,7 138:18 139:3 140:9,10,12 148:17,22,24,25 150:19,20 151:3 175:6 176:14 177:20 low-glucose 177:5,8 lower 62:16 63:4,8 65:23 78:12 139:11 140:18 lows 104:6 luck 113:18 lumping 20:5 lunch 83:6,11 125:5 M M-LAB 12:20 M.D. 4:2 made 14:3 38:21 48:21 88:8 113:12 114:12 115:11 magnitude 94:19,23,24,25 95:9, 18,21,22,25 96:1,5, 9,11,16 157:15,18 158:2,23 maintained 116:4 make 10:20 48:19 61:17 82:16 88:11 93:15 112:25 118:2 130:15 132:25 138:7 141:24 143:1,24 145:6,8,25 148:4,6,7 makes 16:12 making 48:11 49:1 54:20 58:18 63:23 89:24 143:10 145:11,12 164:15	manifested 104:19 manipulation 13:11 131:4 manner 16:16 25:8 172:1 manufacturer 54:25 135:10 137:20,25 139:4 144:2 146:17,19 147:4,10 148:6,15 149:4,12,18,23 manuscripts 25:3 map 188:7 mapping 68:18 187:25 mark 26:2 91:12 marked 5:15,17 8:15,19 26:4,7 27:4 37:23 61:15 91:14 96:23 138:5 161:15 market 160:5,6 material 22:24 mathematics 10:19 MATLAB 12:20 matter 4:17 58:16 120:12 142:13 148:5 154:3, 14 171:17 mature 148:13 maximum 155:20,21 MD 10:22 11:1 meaning 15:25 86:18 87:12 88:25 95:15 130:13 145:23 146:13 meaningful 93:7 means 19:23 23:11 34:13 71:21,24 79:10,24
--	--	---	--

87:6 90:12,13 111:18 129:25 137:19 140:14,24 141:14 142:5 153:23 158:13,15,25 159:2, 8,13,17,18 172:11 meant 39:14 70:3 128:21, 22 146:3,4 148:9 measure 21:17 90:13 165:13, 20,25 166:1,5 measured 29:4 132:19,21 measurement 163:16 measurements 93:2 162:18,21 164:19,21 170:24 measurements' 65:8 measures 21:22 90:14 measuring 22:6 90:13 104:15 163:10 165:15 166:6 mechanisms 105:18 145:24 medical 11:3 160:17 166:17 167:16 medicine 11:2,11,13,15,20 Medtronic 24:24 meet 7:9,12,14 122:21 123:15 152:17 179:19 180:19 181:8,16 182:1,16 183:12 184:16,18, 21,25 185:4,9,20 meeting 7:16,21 185:24 meets 38:17 43:21 47:16 49:17,21 51:23 60:2 66:4 68:6,11 76:25 83:20 84:1,6 85:20 86:7 119:7,14 121:12 122:18 123:1,19 152:23	153:16 169:19,22 172:23 174:14 180:13 184:13,14 memory 57:14 mention 85:24 mentioned 59:9 99:17 112:11 121:6 128:20 154:18 166:23 167:16 171:9 173:8 174:10 mentions 35:2 menu 63:7 110:13 111:2 message 99:1 messed 116:10 messing 144:10 met 7:13 64:20 66:18 69:23 73:21 75:13 97:9 119:1,21 121:16 122:13,16 145:22 meter 22:4 90:12 147:14 method 76:21 80:23 methods 14:14,24 21:9 22:13, 14,19 23:3 27:11,21 34:12,14 105:6 175:14 MG 31:14 174:17 microvolts 163:25 164:3,11 middle 27:10 127:14 152:11 mild 150:8 mildly 159:22 mile 128:17 milliamps 164:11	milligram 151:3 164:1 milligrams 51:20 52:6 53:22 65:11,12 67:1,10 68:3 88:16 138:19, 21 162:9 163:8,11, 15,17 164:2 174:19, 23 millimole 67:11 millimols 138:20,21 mind 9:7 16:18 32:25 89:5 152:25 Minimed 24:24 25:13 minimize 117:11 132:15,17 minimizing 99:5 133:1 minimum 114:18 minus 95:1,4,5,15 minute 53:22 78:13 79:19 minutes 30:13,24 31:15 34:5 52:14 91:8 102:13, 21 108:5,6,8 151:12 173:18 misleading 141:21 misquote 141:25 missed 15:10 123:11 mistaken 82:4 misunderstanding 158:7 mode 100:8,12 101:13 modeling 165:23 moderate 150:8 moderately 133:19	modification 176:25 modify 58:23 105:11 135:16,21 144:7 175:23 176:19 modifying 106:21 module 70:15 74:4,20,25 75:17,23 85:17 100:7 127:23 128:4 129:6 molecular 21:16 moment 22:7 78:8 104:8 107:23 momentary 155:9 monitor 27:12,22 166:13 monitoring 6:13,17 19:15 24:19 90:9 104:5 117:9 morning 4:7,8 mother 129:2 motivated 104:25 107:3 115:21 move 78:9 113:17 moving 153:23 mumbo 89:21 mysterious 89:22 N names 27:15 150:9 narrow 83:2 narrower 82:2 narrowing 82:21 nature 148:1
---	---	---	---

Navigator 24:25	140:10 182:5,14,19 183:18 184:7	147:5 155:6 156:21 157:11,20 158:3	opining 49:17
necessarily 16:4 18:7 23:22 36:6 127:4 150:25 171:23	187:16,22 188:6 nonutilize 54:21	163:19 164:25 171:10 175:25 179:21 180:21 181:18 183:4 184:17	opinion 39:18 49:12 50:23 52:24 64:14,20 66:4, 10,17 68:11 84:15 107:3 126:2 130:10, 22 143:18 151:23 152:6,14 153:13,19 160:21 172:15 173:2,9 174:7 181:22 186:19
needed 33:19 172:9	normal 155:22	obscure 166:25	opinions 36:21 37:5 38:11
needing 137:5	north 158:13,14 159:2	observe 156:17	opposed 148:12,17,20,24 151:4
negative 92:17,19 93:24 94:13,25 95:3	notice 150:2	obstetrics 11:12	optimized 133:10
neighborhood 78:18 79:9	notify 51:11 67:12	obtain 106:9	optimizing 131:19,24 132:6
nexus 104:3 130:25	nuances 148:9	obtained 162:20 164:20	option 83:3
NIH 12:9	number 9:7 12:9 25:18 28:8 76:11 92:2,3 99:18 130:5 139:22 141:16 148:21 163:15,16 164:10 168:9,10	obvious 37:14 89:9 103:23 109:10 113:9,10 114:9 115:10 130:12 134:25 135:6 142:21 143:1,18,23 144:18, 25 145:6,8 186:10 187:14	options 82:22 99:16 180:4
noise 131:19 132:15,16	numbered 36:20	obviousness 143:10 144:23	oranges 178:10
noisy 133:19	numbers 110:23 121:10 139:22 140:5	occur 23:13 28:16 165:5	order 55:8 121:11 154:24
noncontinuous 21:24 22:2	numeral 36:17,20 44:24	occurred 27:2	ordinarily 170:5
nonglucose 51:19	O	offer 64:19 66:17 130:22 145:14	ordinary 6:6,10
nonsensical 178:8	oath 4:1,3	offered 130:10	original 171:17 172:7
nonsettable 123:2 179:24	Object 27:6 120:1 143:4	offhand 59:18	orthopedics 11:13
nonuser 38:18 40:4 43:22 47:16 51:16,24 52:3, 7,10 54:8 58:22 60:3,8,20 61:21 67:20 68:2,7,16 77:13 84:6 86:8 88:15,22 97:8 111:24 113:1,12 114:12 115:12 118:7,10,11,25 119:8,14 122:12,19 123:20 126:6 135:8 142:24 143:3,7,12, 17,24 144:21 145:1, 6,9,12,13,21,22,25 156:1 169:19 172:23 174:14 175:12,17 179:2,8,12,14,16 180:1,18 181:8,11 182:22 185:16	objection 13:6,21 16:2 17:4,25 20:11 23:20 28:1,24 29:25 34:16,22 35:25 43:8 46:25 47:9 48:2,8 55:6,19 57:25 60:22 71:18 76:5 81:3 89:2 91:1 92:7 93:11 94:1,6,9, 21 95:10 96:2,13 98:1 99:14 103:25 105:14 106:1 108:25 111:20 112:21 113:23 115:1 117:24 119:15 121:19 123:7 129:13 133:15 134:4,13 136:20 138:1 144:16 145:17	on-skin 167:5	outpatient 11:13
nonuser-settable		on-the-job 12:17	output 22:10,11 97:6,13,18 98:7,25 99:11 101:2, 5,10 103:10,13 104:21 118:23 119:12,18,22 120:10,13 121:14 122:10,23 123:17 124:1
		one-and-a-half 102:19	oval 19:2,4
		operate 180:3	overnight 31:9
		operates 135:17 144:8	
		operation 135:21	
		opine 49:21 60:19	

owner 4:10 49:6 52:15 87:8,20 88:3 143:14 owner's 41:18 49:11,18,22 50:4 52:23 64:16 P p.m. 83:9 125:8 151:19 178:16 188:15,24 package 76:4 pages 22:24 pagination 116:10 para 90:12 paragraph 9:15,18 14:2,3,6,7, 21 15:5 28:11 38:10, 24,25 39:2,3,7,11, 17,24 40:5,6,7 41:2, 16,22,25 42:18,23 43:6,7,25 44:10,16, 21,23 45:6 46:24 47:2,12,19 49:4 50:21 52:5,9,13 53:14,25 56:1,9 57:15,20 58:6 59:13 60:12 62:6,8 64:12, 19,23 66:8,17,22 70:8,11,21 71:4 72:10 74:2 84:13,14, 21 85:7,11 104:23, 24 105:3 106:25 107:8 109:7 110:2,5, 11 112:8,9 115:19, 25 116:8,11,12 118:17 124:2,19 125:11,21 127:12 128:16 130:21 131:1 134:21 135:24 136:9 137:8,11 138:14 142:20,25 143:9,22 144:13,24 145:4,14 146:11 149:5,7,24 151:22 152:5,11 153:5,12 157:18,24 158:1 160:9,12,15 161:22,25 166:11,24	167:2,14 168:23,24 169:15 170:7 172:13 174:5 175:4 176:10 178:19 183:23 185:13 186:4,5,13, 17 187:6,10,12,21 188:1,3,5 paragraphs 38:22 45:10,19 46:7, 11 47:8 123:22,23 124:4,6,16,23 154:17 176:11,12,17 177:3 parallel 120:11 parameter 38:16 39:20,25 41:4 42:6,19 43:20 44:6, 11 47:15 51:22 52:2 56:5 60:1 68:5 76:24 77:14 84:17 86:6,15, 19,22 87:13,24,25 88:19,24 89:1,4,8, 12,16,23 90:1,5,6, 12,22,25 118:12 119:6,13 120:25 121:3,17 122:2,18, 24 123:5,19 169:18 171:2,8,12 172:22 173:4 174:14 parameters 73:11 90:6,9,10 112:24 118:8 147:8, 9 155:16 171:15 173:7 187:2,7 188:4 parent 63:14,19 64:3 parentheses 14:10 49:14 parenthetical 149:3 parlance 24:7,9 part 8:3 16:21 40:20,25 73:8 124:9,10 131:3 135:4 142:2 153:6 161:22 partial 124:13 particles 31:4	parts 40:3 46:4 passes 120:20 password 54:6,13,14,17,22,24 55:5 56:12 60:25 63:11 64:5 past 22:22 174:3 patent 4:10 5:23 6:2,3 7:2 14:8,23 15:9,12,16, 24 18:11,25 19:20 20:2,3,17,24 21:2,5 22:15 23:25 25:12, 18,20 29:23 34:1,14, 20 35:6,14 39:1 40:17,22 41:10,12, 15,17,22 42:12,16, 25 45:16,19 47:3,25 48:6,10,15,23,25 49:6,11,18,22 50:4 52:15,23 55:15 68:24 71:8,10,15 74:13 76:18 84:9,22 85:4 87:8,20 88:3 89:18 90:18 98:19 101:4,9 102:16 143:14 154:8 171:3 patent's 20:10 65:19 patented 22:18 patents 25:14 patient 29:16 63:22 78:13, 20 104:22 108:1 126:12,18 128:9 129:2,3,9 130:7 133:17 139:14 160:17 166:16 167:7,20 168:2,4 169:13 patient-selected 167:18 patients 28:18 29:5 128:11 131:5 pediatrics 25:5	people 25:1 26:20 27:17 32:17,25 103:7 106:13,18 113:10 114:4,5,10 115:10 128:18 132:23 137:3 139:14 144:10 147:12,13,14 154:12 169:3 173:23 perceived 101:20 percent 31:11,12,13,16 32:3, 6 perform 74:21 75:1,24 77:9 performance 140:20 168:17 period 92:22 93:9 95:5 96:10,11 112:13 154:4 167:25 178:5 permission 63:13,18 64:2,7 persist 33:22 person 6:5,10 33:21 78:7 101:6,11,18,21 102:20,25 103:14 108:1 126:21 151:10 154:13 173:16 person's 165:19 personal 138:23 petition 36:25 37:13 49:14 50:24,25 52:25 66:11,12 186:9 phenomenon 33:1 phone 16:14 134:18 phone's 100:19 101:2 phrase 22:13 115:7 161:18 physics 10:19 pick 168:9
--	---	--	---

picked 90:16,17	16,23 94:5,16,17	predictions 48:11 49:1	10 173:22 186:8
place 60:18 111:23 124:6, 15	possibilities 153:25 180:2 181:3, 5,16 182:4 183:15, 22 184:10,12,15	predictive 19:5 23:4,7,11,15,18 24:1,4,16,21,22 25:2,6,10,14 28:17 29:24 31:3 32:3 33:3 34:13,15 35:15,20, 23 36:7 49:9 50:1 52:18 80:25 81:1,12, 14,18,19,21,22,25 82:2,5,8,10,16,17, 18,19 83:1 85:20,21 87:4,9,23 88:1 89:19,20 90:17,21 91:5 106:10	previously 22:18 128:23 187:16
placeholder 139:19	185:7,14,20,23 186:1	prefer 25:12 87:9	principally 11:11
places 19:20 20:7,9 47:19 149:25 174:16	possibility 107:24 179:17,19 181:6,15 182:7,13 183:16	preference 154:13	prior 23:18,24 105:5 154:7 175:13
plain 15:25 86:25 89:16 106:6	possibly 9:12 55:1 87:2 107:19 118:3 144:11 172:1	preferred 88:2 127:15,22 130:5	priori 147:9,10
play 173:13	post-high 10:5	preparation 7:9 8:3	priority 23:25
plural 98:15	potentially 55:1 78:22 107:25 177:7	prepare 6:19	probability 107:23
point 5:8 47:12 48:20 59:13 109:5 120:16 132:23 151:16 155:14 156:14 185:11 187:21	power 131:21,24 133:1 134:3,11,19	present 21:9 22:13,14,19 23:2,9 34:11 100:2 118:6 168:1	problem 33:4,13,17 132:23 150:15
pointed 39:10 121:17	pre 133:20,21	presented 16:17	problematic 147:25
pointing 122:1 158:19 159:11,13	preceding 160:6	preset 79:14	problems 33:7
points 48:21	predetermined 100:3 127:25	pressing 100:5	proceedings 188:24
poor 148:4	predict 29:18 53:5 109:14 168:14 178:3	presume 22:16 29:8	process 18:18 19:14 69:8 133:21
population 142:14	predictable 105:7 109:5 175:15	presumptive 104:9	processing 14:8 21:10 128:4 131:20 162:3
portion 43:10 44:12,15 46:11	predicted 23:13 30:4 31:24 42:4,8 44:4 56:4 57:5,6,9 77:2,7,11, 19,24 78:1 81:6,15 90:25 102:8 105:19 108:15,24 113:11 114:11 115:11 126:24 143:16 145:10,12 167:25 168:5,7,8 169:11 170:1,3,4 172:11,12 177:19	pretty 113:9,10 114:9 126:17	processor 70:15 74:4,20,25 75:17,23 85:17 100:7 101:13 127:22 129:6
portions 48:4 103:9,11 105:18	predicting 31:9 53:21	prevent 54:6 63:11,25	produces 22:10
POSA 6:8	prediction 18:19 23:8 58:18 69:9 102:9 168:16	previous 96:22 123:12 169:7,	professional 9:18 63:6,14,19,23 64:3,5 148:4 166:17
POSITA 6:9 42:2 44:2,25 56:2 104:11,25 107:3 109:10 115:20 116:13 126:3 135:7 144:14,18,19 160:22 170:23 175:5 176:13 178:21 184:1			professional.' 160:18
positive 33:4 92:2,3 93:10,			professionals 169:4,6
			profile 45:1 107:4,16 115:21 116:1 117:1
			profiles 116:15
			program 10:16,18 11:23 12:5 127:9 129:24 135:16 137:8,15 140:25

141:13,18,22,23 142:5 144:7 145:20 156:2 164:8 programmable 127:23 128:2,8 130:21 131:14,15,18 132:10 133:13 160:16 166:16 169:2 programmed 125:19,25 126:4,10 127:2,3 135:7 137:19,24 139:3,8 140:13,16,17 141:6, 10,20 142:17,18 143:2,6 151:13 156:3 163:23 164:5, 12 168:6 programmers 126:13,14 142:15 169:5 programming 12:8,15,19 13:1,2,5 126:15,20,22 127:3 134:25 137:9,10 139:23 140:1,14,24 141:12 142:3,11,22 programs 10:20 12:10,12,23 129:23 135:11 144:3 progresses 110:14 111:2 projected 29:19,23 30:3,11,16, 21 42:3 44:3 53:2,11 56:3,24 57:4,23 58:8 60:19 61:5,18,20 109:12,22 110:19,20 111:7,8,15,18 112:4 117:2,21 121:4 122:3 properly 86:24 properties 173:24 proposed 41:18 64:16 87:21 88:3 108:21 109:19, 21 145:24 175:22 proposing 105:10 175:23 proposition 149:22	protect 54:18 protected 54:6,13,14 56:12 60:25 63:11 64:6 provide 19:5 38:11 55:14 82:10 88:6 102:1 116:17 117:9 119:12 124:7 151:22 152:6 provided 4:14 9:19 121:14 provider 55:2 112:15 114:1 168:3 169:14 170:1, 6 providing 18:19 23:3 34:12,14 35:23 69:9 80:25 81:1,12,13,18 82:2,8 83:1 97:6,13,18 98:6,25 117:12 118:23 122:10,23 123:17 134:24 169:23 proviso 99:17 proximity 100:13 Public 11:25 publication 26:19 published 27:4,23 purported 14:13 purpose 105:16 172:2 purposes 45:25 push 32:24 put 33:25 132:10 164:2 Q qualifications 9:19,22 qualifier 92:25	quantity 163:11 166:6 question 5:4 15:22,23 17:7 43:4 46:13,17,19 47:5 55:9 58:2 72:2, 6,15 73:15 81:7,11 82:7 87:17 93:14 94:16 101:7 105:22 113:16 115:15 118:2,14,16 121:22 123:12 153:11 169:9 177:10,11 182:25 questioning 6:1,8 questions 4:13,25 5:1,12 6:15 8:7 17:10 48:25 123:13 142:2 153:8 188:12,16 quick 4:23 quotation 149:14,16 quote 40:24 41:12 157:17 158:1 quoted 149:21 quotes 161:18 quoting 41:9,22 44:19 R range 29:9 54:7 65:9,24 155:12 range.' 65:2 ranges 29:7 rapidly 78:9 158:15 159:1, 14 rate 32:7 33:4 42:5,7 44:5 53:3,4,20 56:4, 15,21 79:11,12,20, 21 80:4,9 87:4 92:21,23 93:9,10,18, 19,22,23,24 94:3,4,	5,8,12,13,14,19,24 95:8 102:9 103:5 109:13,23 112:13 117:3 121:4,7,8 122:4 152:17,23 153:16,20,21 154:3, 20,23,25 155:1,4,11, 12,16,20,21,24 156:4,10,15,16,18 158:24 159:9,20 170:10,11,13,25 171:7,16,23 172:6, 16,17,18 173:3,11, 14,15,19 174:10,11, 21,22 175:1 177:4, 13,21 178:3 186:24, 25 rate-of-change 57:23 58:9 60:20 61:2 109:14,24 112:12,19 113:5,21 117:22 177:12 rates 112:10 132:16,17 173:2 raw 121:9 173:19 reach 151:15 reached 168:11 reaches 162:4 170:13 187:1 reactions 165:5 read 15:4 20:22,24 35:17 43:3 46:13 50:21 62:25 74:10 76:17 87:18 90:18 107:14 128:23 141:2 143:25 151:25 153:4 166:21 167:13 174:5 188:17 reading 16:21 29:11 30:10 32:10 66:22 68:19 110:4 114:7 174:5 readings 29:15 30:12,14 reads 112:17 real 33:1 93:2,6 134:9
---	--	---	--

147:22 realize 14:3 15:10 123:11 realized 50:9 realtime 28:17 30:21 32:10 57:2 65:7 66:5 68:12,21 83:20 84:1, 6,10 85:25 87:3 88:14,20,24 89:5,13 90:3,4 106:7 126:23 155:10 168:10 170:24 171:17 178:2 179:23 180:12,23 reason 5:11 20:6 117:16 126:14 130:25 reasonable 104:12 145:15 reasons 56:7 107:2,13 recall 12:18 17:12 49:2 142:7 receive 12:4 14:15 receiver 51:10 67:12 136:3 152:15 153:14 recess 36:12 83:8 125:7 151:18 178:15 188:14 recitation 35:8 recite 34:20 40:23 41:11 44:16 recited 98:9 119:14 124:3 recites 35:11 38:14 60:8 80:11 83:24 recognize 5:21 8:21 26:9 98:14 recommend 174:1 recommendations 169:5 recompose 146:7	record 5:2 36:9 120:14 158:18 reduce 102:7 134:17 reduction 155:21 reenforces 131:10 refer 4:17 6:1,8,15 22:14 30:9 98:3 137:8 157:4 reference 45:15,18 47:2 48:10 51:14 75:8 85:2 125:14 136:13 142:9 157:18 158:2 169:11 referenced 79:4 84:24 references 103:24 104:13 140:25 referred 71:11 72:3 104:5 referring 4:18 6:2,9,16 20:18 40:20 41:2,4,5 70:11,21 74:11 87:16 88:10 120:3 122:16 135:23 150:11 163:1 166:22 167:15 187:8,10 refers 29:24 36:24 70:24 71:2,5 77:5 157:13 162:25 166:20 167:14 refresh 57:13 regard 88:3 126:24 133:7 137:14 143:6 154:1 155:20,22 regarded 25:7 reiterate 96:6 relate 21:9 23:3 34:12,14 related 6:23,25 23:10 29:6	90:11,15 119:12 relates 14:8 87:1 relating 90:21 relationship 119:24 128:14 129:1 173:13 relevant 36:21 123:25 remember 76:12 Rendered 186:10 repeat 17:7 58:2 71:14 93:14,15 101:7 115:6 121:21 rephrase 17:16 121:24 replacement 182:24 reported 31:21 reporter 5:2 26:2,6 91:12 188:19 reporter's 8:6 reports 26:19 represent 4:10 16:18,23 17:10, 23 representation 154:11 155:1 representations 136:3 representative 171:18 represented 164:7,9,10 request 129:25 requesting 128:1 required 5:4 104:11 181:13 requires 23:8 52:1 83:18 170:4	research 103:6 resembles 19:25 Reserve 10:23 residency 11:15,19 respect 75:5 117:4,6 124:17 respond 32:23 108:11,12 responding 33:21 response 16:22 17:9 39:13 48:24 100:8 131:7 142:1 143:20 responsive 87:17 113:16 rest 7:23 result 118:4 165:5 178:23 184:3 resulting 144:11 results 105:7 144:12 175:15 retained 118:6 reused 76:4 review 7:3,6,25 152:25 reviewed 6:23 7:4 reviewing 7:23,24 reviews 15:20 39:5 43:1 45:13 47:10 58:11 59:16 61:25 71:19 87:14 110:7 114:20 115:4 125:1 127:17 137:12 152:1 153:2 158:4 168:21 170:19 176:8,20 Richard 4:10 right-hand 127:14
---	--	--	--

rigorously 185:24	28:6 29:10 30:5 34:19,25 36:3,8,14	scope 13:7,22 17:5 18:1 28:2,25 30:1 76:6 93:12 94:10 95:11 96:3,14 134:4 165:1	14:9 21:10,11,20,21 22:3,4,5,9,10 38:15 42:9 43:19 47:14 51:9,21 59:25 65:25 67:9 68:4 69:21 70:16 73:19 74:5 75:11,18 76:22 77:5 80:16 83:19,25 84:5 85:18 86:5 88:10,12 102:2 105:20 108:19 119:5 132:20,21 133:20 145:23 161:9 163:9,25 165:4,8,12, 17,21 166:2 167:5 169:17 171:22,23 172:20 173:25 174:13 176:24 180:11
ringing 101:12	39:9 43:5,12 45:17 46:15,18,20 47:4,18 48:3,13 55:10,25 58:3,14 59:19 61:1, 12,16 62:1 72:1 83:7,10 89:10 91:7, 11,17,18 92:11 93:17 94:2,7,18 95:6,19 96:8,18 97:1 99:20 104:10 105:21 106:15 109:3 110:10 112:1 113:2,15,19 114:2,24 115:8 119:19 120:5 121:23 123:10 125:4,9 127:20 129:19 133:22 134:8,20 137:7,16 138:6 143:8 144:22 146:8, 9 151:17,20 152:4 153:10 157:1,16,23 161:16 168:22 170:20 176:4,9 177:1 178:12,17 180:5 181:1,24 183:7 184:20 188:11,18,21	scores 150:6	sensors 21:25
rising 158:15 159:1		screen 63:7 110:15 111:3, 16	sentence 9:17 14:22 15:4 21:8 22:12,25 31:20 34:3 39:16 40:24 42:1 62:9,21,24 64:13 66:9 74:10 75:16 85:12,24 98:20 99:11 100:1 101:25 107:10,12,14 110:24 112:9 115:6,20 125:17 127:15 128:15 129:20 131:13 135:3 141:1 143:25 146:5,6,10 149:9 152:13 153:12 160:15 161:2,17 166:21 167:14 170:8 172:13 173:9 174:6 178:20 179:4 183:24,25 185:13
risk 77:1,6,10,17,19,21, 23 78:1,8,10,14,22, 23,24 79:6,7,8,10, 11,13,20,22,24 80:1, 2,3,7,12,13,17 81:2, 5,15,19,22,24 82:11, 12,18,20 83:2 102:10,11 146:18 147:2 148:14,16,18, 19 149:17 150:4,6,8, 9,16 151:4,5		sealed 144:10	sentences 28:14 115:24
Rodbard 4:2,7 8:18 26:6 36:15 83:11 91:9 125:10 133:23 151:21 178:18		Seattle 11:7	separate 51:3 67:1 76:13
Roman 36:17,20 44:24		seconds 129:7 130:4	series 30:17 72:23 73:5,6 170:4
room 11:12		section 10:3,6 11:22 21:5,8 36:20,24 37:7,11,12, 17,23 38:1,6,9,10,21 41:2 43:3,10 46:9,21 50:13,17 57:19,22 58:5,7 59:21 60:11, 15 66:16 71:2 156:24 175:5 176:12 177:3 186:9	session 173:22
rooms 132:7		secure 144:12	sessions 173:22
rough 188:19,23	satisfactory 25:7	select 110:16 111:4,14 141:16 167:20 168:16	set 51:3,19 59:5 65:9,24
routinely 55:3	satisfy 183:3,20 185:4	selectable 125:20 126:2	
rule 126:11	save 134:3,18	selected 29:16 112:14 113:25 141:11,23	
rules 4:12,24	Say's 160:16 172:15 175:6,23 176:3,5,14, 19,24 178:22 184:2	selecting 140:1 141:12	
S	scenario 81:17	send 102:11	
S-A-I-D-A-R-A 25:17	schematic 136:2	sending 102:16,20	
safe 155:20,22	school 10:5 11:3,24	sense 24:6 62:2 78:4 86:25 89:15 93:15 141:13 142:4	
safety 33:13,16	science 12:8 26:12,16,22 27:24 76:3	sensitivity 31:10,21,23	
Saidara 25:12,16,20	sciences 10:14,17 11:4 12:10	sensor	
Saraswat 4:6,9 5:16 8:16 13:13,25 15:21 16:5 17:8 18:5 20:16 23:23 26:1,5 27:9	scientist 128:11		

66:25 68:2 70:17 71:5,9,11,17,22,23 72:4,12,17 74:6,11, 14,17,20,22,24 75:1, 19,24 89:7,13 96:19 110:13 112:24 118:11 138:19 139:10 141:10,19 146:17,18,20 147:2, 3,8,9 148:15 149:4, 11,17,23 150:13,20, 23 151:1 167:18 168:3,4 169:3,14 170:1 173:25 settable 38:18 40:5 43:22 47:16 51:16,19,24 52:3,7,10 54:8,19 57:24 58:10,22 59:9 60:3,8,21 61:21 62:22 65:14 67:20 68:2,7,16 77:13 83:20 84:2,7 86:8 88:15,22 97:8 111:19,25 112:5,20 113:6,12,22 114:13 115:12 117:23 118:7,9,10,11,18,25 119:8,14 121:15 122:12,19 123:1,2, 20 126:5,6 135:1,9 140:8 142:23,24 143:3,12,17,24 144:15,19,21 145:1, 6,9,13,21,22 146:1 148:9 151:6,7,9 156:1 160:23 169:19 172:24 174:14 175:12,16,17 179:1, 2,7,8,12,14,16 180:1,14,19,25 181:8,12,25 182:15, 22 185:16,17 setting 14:25 15:24 31:25 33:2 137:9,14,24 139:25 140:9 178:7 settings 133:9 134:2,11 144:15 setup 113:1 143:7	severity 16:19,24 17:1,11,15, 16,18,22 share 91:15 Shariati 125:13,18,24 127:1, 10,12,13 128:7,21, 22,23 130:3 133:7 134:16 135:13,20 136:19,22 137:18 139:7 140:15 143:11,15 144:4,5, 14 146:3,4,6,13 147:1 149:2,14,16, 22 150:3 151:6,23 152:6,10 157:4,7,9, 17,25 158:20 186:11,15,20 187:15,25 188:8 Shariati's 148:10 sharply 158:14 sheet 18:25 shipped 137:20 short 188:13 shorthand 46:3 show 8:17 61:24 87:11 103:23 104:2,3,11 114:16 121:11,13 150:25 153:20,21 155:5 157:14,15 158:23 showed 92:1,5,13 95:21 showing 88:18 154:9,10,14 155:3 157:9 159:3,4 shown 100:19 101:1 side 33:25 sign 72:22 76:10 95:1,14 96:6 188:17 signal	165:6 166:2 signalling 104:17 signals 133:19 161:8 significantly 133:19 signify 100:6 similar 30:3 65:19 75:5 98:17 108:18 119:24 similarly 74:15 83:24 simpatico 184:25 simple 59:6 172:1 simply 77:17,21 78:23 122:6 simultaneously 79:11 single 13:14 sir 93:25 sitting 176:7 situation 33:15 126:20 131:4 147:24 178:10 182:17,18 situations 147:15,21 skill 6:6,10 slightly 73:7 89:22 slope 93:6,7 95:2,17,18, 22,23 154:21 sloppy 141:21 small 36:17 smaller 92:3 smart 100:19 101:1 smartphones 133:23 134:1	smoother 132:16 smoothing 133:18 so-called 32:5 160:6 soft 148:20 softer 140:19 software 12:14 solid 142:18 something's 142:17 sort 78:17 82:13 133:6 sorts 90:7 sound 16:15 29:15 30:15 108:9 110:17 111:6 sounded 24:11 33:20 120:7 sounds 16:15 south 159:13 spans 127:13 Sparacino 77:18 79:2 speak 15:17 24:7 29:2 184:25 speaker 136:11,24 special 126:15 139:12 specific 18:3 108:8 112:10 specifically 15:17 41:6 72:24 90:3 specification 20:8 35:14,22 38:25 39:11 40:14,15,18 41:1,14,21 44:20 45:19,23 46:3,6 47:24 48:6,14 71:12, 15 72:17 84:9 90:24
--	--	--	---

103:9,11,12 specifications 45:16,22 48:22 91:6 specificity 31:22,23 specifies 51:12 67:17 speculative 118:1 spell 25:16 spent 7:18,19,21,23 9:4 spirit 105:16 150:19 SR 80:4 stage 133:2,10 stamp 138:11 stand 170:2 standardized 165:10 stands 146:5 Stanford 25:5 start 4:11 8:11 85:5 110:11 135:4 started 92:2 starting 21:5 34:9 37:7 44:24 50:17 66:16 74:3 85:8 106:4 107:10 starts 10:1 28:11 34:3 36:17 37:20,24 38:2, 6,9 50:13 62:9 69:4 76:15 80:3 85:8,12 98:20 127:15 138:14 175:5 State 10:13 stated 65:6 115:7 117:8 120:8 169:16 statement 13:10 31:2 36:2	73:12 88:8 118:2 127:5 163:21 170:2 states 58:13,15 static 77:23 78:1,14,23 79:6,7,8,11 80:2,3, 13 81:19,21,22 82:12,18 stating 169:22 statis 102:10 status 19:15 81:24 steeper 93:7 94:15 step 172:3 step-by-step 100:17 stick 22:6 story 133:17 straight 159:4 street 133:4 147:11 stretch 128:18 strike 113:17 175:20 strong 24:13 strongest 159:5 strongly 158:15 159:21 STS 51:9,10 67:9,12 88:10,12,23 105:19 108:19 111:22 139:24 141:4 145:23 148:17 176:24 stuck 165:18 study 10:16,25 11:9,18 31:7 32:2 stuff 120:17	subject 103:6 subjects 173:23 submitted 8:1 subsection 44:23 45:5 subsequent 22:23 substance 83:12 substantively 90:4 success 104:12 145:15 successful 138:15 145:25 sugar 150:7 sugars 29:7 suggesting 158:8 suggests 160:21 suitable 182:24 summer 11:23 support 145:5 149:22 supports 142:10 supposed 32:21 surgery 11:12 surrounding 165:7 suspend 102:7,12,21 suspending 99:3 synonymous 185:1,2 system 32:19 59:3,7,12 102:3 117:9 118:9, 10 125:19 126:1,5, 10 127:2,8 129:9 130:9 131:6 132:5,6	133:3,5,11,14 135:1, 11,17 137:19,20 140:20 141:4 142:22 143:2,7 144:3,8,10, 12 145:2 148:1,11, 13 161:6 162:2,16 163:1,15 167:6 169:3,4 170:9 173:25 175:7,15 176:15 177:9 183:2 186:23 system' 135:8 systems 14:14,25 21:9 22:13, 14,19 23:2 24:15 34:12,14 135:12,13 144:4,5 180:3 T T1 91:23 92:23 93:19 94:4,14 95:23 96:7 T1-t2 96:10 T2 92:22,24 93:9,18,19 94:3,4,13,14 95:5, 22,23 96:6,7 T2-t3 96:10 T3 91:23 92:14,22 93:9, 18 94:3,13 95:5,22 96:6 table 36:16 50:8 157:5 tabs 100:21 takes 13:17 80:2 taking 13:20 79:24 105:16 154:3 talk 24:8 84:4 97:13 101:19 131:3 141:13 142:4 152:9 talked 99:13 103:9 106:7 133:9
---	--	--	--

talking 22:22 23:9,10 29:3,4 48:15 82:25 86:12 95:16,17 99:11 101:9 102:16,24 103:10,17 105:12 123:4 130:14 131:14 132:4,5 134:16 139:10 140:8,15 148:18 151:2 158:9 168:10 180:6 181:3, 6 186:13 187:6 talks 73:25 97:18 98:6 103:12 122:17 137:18 140:16 164:17 target 54:5,12,18 56:11,14, 18,20,23 62:16,17 63:4,5,8,10 65:2,9, 24 164:7 teach 47:13 teaches 49:12 52:24,25 55:12,18 125:24 169:1 170:9,17 172:20 186:20 teaching 169:16 teachings 116:14 176:3,5 178:22 184:2 tech 142:16 techniques 126:15 technology 26:13,16,20,22 27:24 142:17 telling 32:21 99:22 tells 79:8 ten-minute 178:12 tendered 96:24 tentatively 82:13 182:2 term	6:5,12 21:15 29:23 32:13 49:7 52:16 71:16 72:12 74:11, 13 86:19 87:13,21 88:4,7,17 89:4,8,23 90:5,23 130:13 141:9 terminology 141:18 terms 30:8 35:20 45:16 48:11 49:1 89:7 terrible 150:9 test 174:2 testified 4:4 testimony 83:12 text 70:24 124:3 Theoretically 33:14 theory 82:9 thing 16:17 20:3 30:9 33:11 35:18 71:12, 16 72:16 77:23 96:22 106:14 121:2 122:1 123:18 150:1 164:11 things 21:24 22:17 30:6 57:11,16 58:21,24, 25 59:2,8 72:16 88:20 90:8,11 99:12, 21 134:2,17 139:7 156:5 163:2 171:18 172:8 174:9 179:9 thinking 15:25 16:13 58:16 131:10 146:3 148:10 185:10 thinks 59:9 thought 106:13,19 128:25 129:16,17 130:12 186:3 threshold	29:14 30:15,16 31:12,16,23 32:7,9, 10 51:19 53:19 54:7, 15 55:13 56:15,21, 24 57:2,3,4,5,6,8,9 60:24 61:6,19,21 63:12,21 64:1 65:23 66:6 68:2,13,14,16, 21 78:6,7,18 79:9 84:11 88:15,22 104:16 107:24 108:15,24 110:15,16 111:3,5,16 113:5,22 114:5 125:18,25 126:4,10 134:25 135:7 137:9,14 142:22 143:6,17,24 144:19 145:10 147:3 148:21 151:2,4 160:16,22 161:5 162:4,7,15,25 163:2 164:7,15 166:14 168:3,5 169:14 170:1,13 172:18 174:21,25 175:1,12 177:5,8,14,22,25 178:9 187:2 thresholds 53:1,2,3 57:23 58:9 60:20 61:2 104:17 109:12,14,23,24 111:19 112:5,12,19, 25 117:2,22 126:22 143:2 145:6 146:16 149:4,11,23 150:17 162:11 168:7 169:1 174:17 175:24 176:19 181:8 time 7:17 9:4 13:18,19 22:7 23:13 32:20 78:8 79:13,21,22 90:7,8 91:22,23 92:22,23 93:9 96:10 107:23 108:8 110:13 112:13 116:18 117:5,6,13 127:24, 25 129:23,24,25 130:6,9 131:15,18, 20 132:18,22,25 133:14 154:4 155:13 160:4 165:14 167:25 168:1 175:1 178:6	181:21 188:12 timed 30:17 times 13:15 61:7 71:24 80:4 90:18 129:7 tired 32:22 tissue 165:7,19 today 4:13 5:12 today's 6:19 7:10 told 59:14 78:12,20 129:12 156:19 168:18 top 10:2 19:1 26:11 27:10 84:25 124:2 150:14 175:9 topics 10:16,25 11:9,18 total 7:17 totally 129:18 130:13 touch 59:3 104:21 TP 57:5 training 12:10,17,22 translated 164:13 transmitting 98:25 treating 20:10 trend 30:11,24 95:2 trending 92:6,9,14 trial 139:25 trials 133:5 trigger 53:12 150:18 164:16 triggered 19:16 162:2
--	---	--	---

trouble 181:20 true 18:7 27:21 29:6 82:23 144:9 156:12 truthful 5:11 turn 9:14,25 14:1,6 18:10,12,24 19:7 21:4 34:1 43:14 50:7 51:13 64:10 67:18 68:23 70:2 76:14 83:14 86:3 97:2 98:18 104:19 116:11 118:20 125:10 131:1 138:10 141:15 142:19 160:12 186:5 turning 103:3 tweak 137:6 two-day 188:19,23 type 104:7 131:4 137:5 types 165:24 typical 135:10 144:3 typically 173:17 typographical 160:11 U u-s-e-r 128:15 U.S. 5:23 6:3 ultimately 184:22 uncertainty 93:1,4,5 unclear 31:25 unconscious 100:18 underneath 26:21 27:15,17 36:24 37:2,17,23	understand 4:15,18 5:2,6 6:2,9, 16 21:1 45:21 56:17 58:4 71:23 77:17 87:18 88:2 90:19 94:17 105:10 110:22 116:3 134:23 140:23,24 144:14,20 153:18 163:6 understanding 13:4 23:24 24:20 25:9,11 31:3 74:12 86:22 87:8 103:22 180:24 181:20 185:6 understood 17:14 41:6 42:2 44:2 56:2 90:19 116:13 126:3 170:24 178:21 184:1 undesirable 28:18,22 107:25 unit 167:5 175:2 units 174:17,23 universal 139:17 University 10:13 11:16,24 25:5 unknown 99:18 unlock 54:21,24 55:5,13 unpatentability 36:22 37:6 unreasonable 147:22 unusual 136:25 upper 62:17 63:5,9 139:11 140:18 upstroke 159:1 upwards 158:25 usage 90:24 142:13,14 user 14:14 23:4 33:5 34:13,15 47:13 51:11,12,13 54:6,14,	17,18,20,23 55:12 57:24 58:10,23 59:3, 4,5,9 61:21 62:18, 22,23 63:8,11,20,25 64:9 65:9,24 67:13, 17 83:20 84:2 88:10, 12 100:13,18,19 101:2,16 104:9,15, 22 105:20 108:11 110:15 111:4,14,19, 22,23 112:5,15,20, 23 113:6,22 114:1,4 116:2 117:13,23 118:5,7,9,18 121:15 123:1,2 125:20 126:2,5,9,12,18 128:2,8,9,10,17 129:1,5,9,21,22 130:13,22 131:11,14 132:4,8 134:10 135:1,10,15,20,21 136:4,10,16,24 137:4,21,25 139:4,9, 24 140:1,8,13 141:10,19,22 142:23 144:3,7,15,19 146:20 147:2,24 148:9 149:19 150:21 151:1,6,7,8 156:17 160:23 169:2 170:5 175:16 176:24 179:1,7 180:13,25 181:12,25 182:15 185:16 user's 37:14 39:18 42:10, 11 45:2 50:23 51:1 64:14,24 65:14,22 66:10,24 67:17 84:15 107:6,17 109:16 115:22 116:2,14 117:7,8 175:6,11 176:14 178:22 184:2 user-settable 139:21 158:9 182:9 183:17 184:6 users 116:18 131:6,25 148:4 usual 155:20,22	Utility 27:11,22 utilize 54:21 176:23 177:9 utilized 12:14 57:9 utilizing 88:17 V vague 24:10 89:22 validated 79:18 value' 39:21 42:9 56:6 84:18 171:3 value,' 42:6 value...' 44:7 values 42:4,10 44:4 51:18 53:11 54:7 56:4 62:15,21 63:3,12 64:1 65:1,10,23 66:5 68:1 136:4 139:4,10, 15 161:5 162:7,15, 19,25 163:2 164:20 170:25 171:1,7 values' 42:8 variety 12:15 varying 110:16 111:4 159:19 verbal 5:1 versa 73:9 versus 17:2 31:24 vertically 158:25 vibrate 51:11 67:12 vibrator 136:12,25 vibratory 104:20 vice 73:9
--	--	---	---

view 37:15 86:23 137:18 140:23 145:20 186:10 views 136:2 vitae 9:23 volt 165:6 voltage 161:7 162:19 163:2, 13,16,24 164:20 165:11,17 166:7,8 Volume 26:23 27:4,24 W wait 8:7 183:24 wanted 74:16 wanting 137:5 warn 172:19 warning 116:18 117:13 warnings 53:13 116:17 warns 167:7 way.' 14:17 ways 76:11 77:9 78:3 81:18 82:9,14 165:9, 10 172:10 weakly 159:22 well-known 79:17 139:16 165:9 well-understood 90:23 Western 10:23 whatsoever 129:1 130:15 wheel 141:15 Whereabouts 69:2	widely 147:12 Williams 7:13,17,21 8:12 13:6,21 16:2 17:4,25 20:11 23:20 27:6 28:1,24 29:25 34:16, 22 35:25 43:8 46:13, 16,25 47:9 48:2,8 55:6,19 57:25 60:22 71:18 76:5 81:3 83:5 89:2 91:1 92:7 93:11 94:1,6,9,21 95:10 96:2,13 98:1 99:14 103:25 105:14 106:1 108:25 111:20 112:21 113:18,23 115:1 117:24 119:15 120:1 121:19 123:7 125:6 129:13 133:15 134:4,13 136:20 138:1 143:4 144:16 145:17 146:2 147:5 151:15 155:6 156:21 157:11,20 158:3 163:19 164:25 171:10 175:25 179:21 180:21 181:18 183:4 184:17 188:13,16,22 withdraw 15:22 46:16,18 169:8 withdrawn 20:22 103:10 109:20 111:13 122:8 word 15:11 21:14 62:9 85:12 90:16 92:10 120:10 123:12 128:15,25 130:16 133:8 141:11,18,20 142:10 155:13 words 15:25 18:13 19:9,21 20:15 28:12 29:11 34:4 37:24 38:2,6 44:14 50:17 59:8 69:4 70:9 85:8 102:21 127:15 130:21 131:14 138:14 148:15	work 9:22 24:11 142:16 183:10,11 worked 24:16 working 24:5 25:6 26:20 133:5 works 126:19 132:14 world 33:1 134:9 147:22 worldwide 103:7 worried 129:5 worries 133:18 worry 128:18 worse 32:6 write 12:23 writing 91:4 written 46:2 80:13 98:10 186:4 wrong 43:15 100:14 wrote 174:5 Y years 103:7 yield 105:7 175:14 York 10:13 Z zone 148:19 zones 146:18 147:2 148:15,16,19 149:17 150:4 151:5
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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 JANUARY 18, 2023
DEPOSITION OF DAVID RODBARD, M.D.**

I, David Rodbard, M.D., do hereby make the following corrections to my
January 18, 2023 deposition transcript:

PAGE	LINE	CHANGE/CORRECTION	REASON
32	25	"alarm alerts" to "alarm fatigue"	Transcription Error
72	22	"an algorithm" to "a logarithm"	Transcription Error
79	3	"Clark" to "Clarke"	Transcription Error
79	12-14	"of change of glucose or the rate of – if we know the – any time we know glucose, we can calculate the risk according to a preset formula" to "of change of glucose or the rate of risk. If we know the rate of change of glucose any time we know glucose, we can calculate the dynamic risk according to a preset formula"	Clarification/Misspoke
80	3	"risk, the DR, the dynamic risk" to "risk: The DR, the Dynamic Risk"	Transcription Error
81	24	"status" to "static"	Transcription Error
84	6	"realtime" to "real time"	Transcription Error
84	6	"nonuser" to "user"	Transcription Error/Misheard Question
95	1	"during" to "without"	Transcription Error
95	14	"direction plus" to "direction, 'plus'"	Transcription Error
95	15	"up and minus usually meaning down" to "'up' and 'minus' usually meaning 'down'"	Transcription Error

98	14	“the” to “the indicator”	Transcription Error
103	6	“215 that” to “215. That”	Transcription Error
104	2-3	“-- one anywhere” to “- - one anywhere --”	Transcription Error
108	5	“second” to “next”	Transcription Error
109	5	“predictable” to “predictive”	Transcription Error
118	11	“set” to “setup”	Transcription Error
131	8	“very what” to “what”	Transcription Error
136	25	“an unusual” to “unusual”	Transcription Error
147	10	“not a priori” to “ <i>a priori</i> ”	Transcription Error
155	12	“range” to “change”	Transcription Error
158	9	“215” to “215”	Transcription Error
160	4	“and” to “around”	Transcription Error
160	6	“215” to “215”	Transcription Error
160	11	“in the category” to “that’s in the category”	Transcription Error
165	5	“occur” to “occurring”	Transcription Error
167	23	“complicated because impending” to “complicated, because for impending”	Transcription Error
169	1	“C” to “Say”	Transcription Error
169	12-13	“whether parameter indicative of a glucose value” to “whether a	Transcription Error

		'parameter indicative of a glucose value'	
173	16-18	"interested in do we think this person is going to experience a hypo within the next -- and its typically 30 minutes." to "interested in: 'Do we think this person is going to experience a hypo within the next -- and it's typically 30 minutes.'"	Transcription Error
174	3	"past" to "passed"	Transcription Error
177	9	"or one of" to "for one or"	Transcription Error
178	4-6	"and then you could ask is that glucose likely to be at or below 55, for example, within a specified period of time" to "and then you could ask: 'Is that glucose likely to be at or below 55, for example, within a specified period of time.'"	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: January 25, 2023



David Rodbard, M.D.