

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE INC.,

Petitioner,

v.

Case IPR2022-00909

Patent 10,702,215

DEXCOM, INC.,

Patent Owner

DEPOSITION OF

DESMOND BARRY KEENAN, PH.D., MBA, PMP

WEDNESDAY, MARCH 29, 2023

9:12 A.M. - 6:28 P.M.

WOLF, GREENFIELD & SACKS

600 ATLANTIC AVENUE

BOSTON, MASSACHUSETTS

REPORTED BY: Sandra A. Deschaine, CSR, RPR,

CLR, RSA

Job No. SY006871

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EXHIBITS

(NO EXHIBITS MARKED.)

1 MARCH 29, 2023

2
3 9:12 a.m.

4
5 Deposition of Desmond Barry

6 KEENAN, PH.D., MBA, PMP, held at Wolf,
7 Greenfield & Sacks, PC, 600 Atlantic Avenue,
8 Boston, Massachusetts, pursuant to Notice,
9 before Sandra A. Deschaine, a Shorthand
10 Reporter, Registered Professional Reporter,
11 Certified LiveNote Reporter, and Notary
12 Public in and for the Commonwealth of
13 Massachusetts.

1 DESMOND BARRY KEENAN, PH.D.,
2 MBA, Deponent, having first been
3 satisfactorily identified by the production
4 of his driver's license and duly sworn by the
5 Notary Public, was examined and testified as
6 follows:

7 EXAMINATION

8 BY MR. WILLIAMS:

9 Q. Good morning, Dr. Keenan.

10 A. Good morning, sir.

11 Q. My name is Eliot Williams, and I
12 represent Abbott.

13 Can you state your name for the
14 record?

15 A. Full name is Desmond Barry Keenan.

16 Q. What city do you reside in?

17 A. Las Vegas.

18 Q. Las Vegas. Okay.

19 Have you been deposed before?

20 A. Not in a case like this. I've
21 been on a court stand before several times.
22 I've been in court before

23 Q. Okay. So you've given testimony
24 in court before. Is that what you're saying?

25 A. Yeah.

1 Q. And how many times?

2 A. Just once.

3 Q. Okay.

4 A. Mostly business related.

5 THE REPORTER: Okay. You got
6 to --

7 MR. WILLIAMS: She has to get what
8 you're saying.

9 THE REPORTER: You're going to
10 have to keep your voice up. You're
11 really soft, even with my volume up.

12 THE WITNESS: I know. I'll keep
13 my voice up.

14 THE REPORTER: Only because I have
15 to hear those words accurately.

16 BY MR. WILLIAMS:

17 Q. Okay. Have you ever given
18 testimony as an expert witness in a case?

19 A. I have not.

20 Q. So this is the first case you've
21 given expert testimony?

22 A. This is the first case.

23 Q. Okay. All right.

24 You understood you took an oath to
25 tell the truth today?

1 A. I understand that, yep.

2 Q. Okay. And is there any reason you
3 can't testify truthfully and accurately
4 today?

5 A. There's no reason why I can't.

6 Q. Okay. If you don't understand any
7 of my questions today, let me know, otherwise
8 I'm going to assume that you understood them.

9 Understand?

10 A. I understand.

11 Q. Okay. Great.

12 And just make sure you give verbal
13 answers so that the court reporter can take
14 down your testimony. Okay?

15 A. I got it.

16 Q. Okay. I see in front of you you
17 have a document.

18 Can you identify that for me?

19 A. This is the declaration that was
20 prepared on behalf of Dexcom for -- in the
21 case against Abbott for this inter partes
22 review.

23 Q. Can you turn to the last page?
24 Maybe the very last page.

25 Is that your signature?

1 A. This is my signature.

2 Q. Okay. And this document, then,
3 refuses your written testimony in this case?

4 A. It does.

5 Q. Is that correct?

6 Just back to the cover and ask you
7 a few things just so we can establish some
8 terminology here.

9 You understand that you submitted
10 this testimony in connection with an inter
11 partes review of Patent Number 10,702,215?

12 A. I do.

13 Q. Okay. Great.

14 And then I'm going to occasionally
15 use the '215 patent to describe that patent.

16 Will you understand my question if
17 I use that terminology?

18 A. I will.

19 Q. Okay. Great.

20 When did you first learn of this
21 patent, the '215 patent?

22 A. It was when I was contacted by --
23 by attorneys here regarding this case. I
24 believe. I mean, it's -- I review a lot of
25 patents, so it's not impossible that, you

1 know -- but I certainly don't recall ever
2 seeing it before.

3 Q. Approximately when was it that you
4 were first contacted by the attorneys?

5 A. I mean, I'd have to check my email
6 to give you an exact answer, but it's got to
7 be four or five months ago.

8 Q. How were you contacted? How were
9 you first contacted about this matter?

10 MR. SARASWAT: I'm just going to
11 caution the witness, in answering
12 questions about communications with
13 attorneys, not to reveal the details of
14 any communications with attorneys.

15 A. I was contacted by the law office
16 and asked if I'd been an expert witness
17 before.

18 BY MR. WILLIAMS:

19 Q. Okay. Were you contacted by email
20 or by phone, the first time?

21 A. It was by email, I believe.

22 Q. Okay. And the attorneys that
23 contacted you, were they attorneys from Wolf
24 Greenfield, or do you recall?

25 A. I don't think it was Wolf

1 Greenfield. It was -- I think originally it
2 was another -- another law firm or attorney.
3 I'm not a hundred -- I'm not sure.

4 Q. Okay. Turning -- the document in
5 front of you, that declaration, it bears
6 Exhibit Number 2008, is that right, at the
7 bottom?

8 A. Exhibit 2008, correct.

9 Q. 2008?

10 A. Yeah.

11 Q. Yeah, okay.

12 Can you explain the process you
13 used to create this document?

14 MR. SARASWAT: And, again, I'm
15 just going to caution the witness not to
16 reveal any communications with
17 attorneys.

18 A. So when I -- well, I became aware
19 of the case, of course, and discussed the
20 details of the case. I was provided a lot of
21 materials to review, which are various -- you
22 know, a number of patents to review to begin
23 with.

24 BY MR. WILLIAMS:

25 Q. Okay. And what happened after you

1 were provided those materials? Did you
2 review the materials?

3 A. I did, yeah.

4 Q. Okay. How did you go about
5 putting together this document 2008?

6 A. Well, I -- well, so I reviewed the
7 materials, and we looked at arguments from
8 Dr. Rodbard and looked to see where, you
9 know, they were inaccurate based on -- based
10 on the material.

11 Q. Okay. And did you then draft this
12 document yourself, or was a draft provided to
13 you?

14 A. It was a back-and-forth process.
15 I didn't draft it. I reviewed it in detail,
16 made comments, suggestions, you know, based
17 on material I had read and also, you know, my
18 technical opinion from -- my technical
19 opinion on technical details that are -- you
20 know, that were in here.

21 Actually, beyond technical. I
22 mean, I'd say more -- a lot of it was general
23 related to diabetes and diabetes technology.

24 Q. Okay. Had you had any
25 conversations with counsel about the case

1 before you received the initial draft of the
2 document?

3 MR. SARASWAT: You can answer yes
4 or no.

5 A. Yes.

6 BY MR. WILLIAMS:

7 Q. How many such conversations do you
8 recall? Again, this is prior to receiving
9 the first draft of the declaration.

10 MR. SARASWAT: You can answer with
11 a number, if you remember.

12 A. I don't remember a number. There
13 was certainly, you know, not a lot of phone
14 calls but maybe two or three. And -- well,
15 sorry, they would have been, like, meetings,
16 I guess, you know. Two or three phone calls,
17 and then various emails back and forward.

18 BY MR. WILLIAMS:

19 Q. Any in-person meetings?

20 A. No.

21 Q. During that time, do you remember
22 what attorneys you were having phone calls
23 with?

24 A. In regard to the case, it's
25 been -- it's been mostly Anant.

1 Q. You said "mostly."

2 Were there any other attorneys
3 involved in your conversations prior to
4 receiving the original draft of your
5 testimony?

6 A. Not really. I mean, there was --
7 another attorney was on a call, but that
8 was -- I don't know if it was Anant's boss,
9 maybe, but she's the person, you know, that
10 asked me what my consulting rate would be,
11 for instance.

12 MR. SARASWAT: And, again, I just
13 caution the witness not to reveal any
14 conversations with attorneys.

15 BY MR. WILLIAMS:

16 Q. Let me switch gears for a second.
17 Prior to getting involved in this
18 case, had you ever interacted with anyone at
19 Dexcom?

20 A. Yes. I know a lot of people at
21 Dexcom because I worked at Medtronic, and
22 people left Medtronic and went to Dexcom.

23 Q. And since becoming involved in
24 this proceeding, have you interacted with
25 anyone at Dexcom?

1 A. No.

2 Q. When would you say would be the
3 last time you interacted directly with
4 someone employed by Dexcom?

5 MR. SARASWAT: Objection, scope.

6 A. It's been quite a while, actually.
7 Some of the people I interacted with at
8 Dexcom are ex-Dexcom and have been for a
9 while.

10 BY MR. WILLIAMS:

11 Q. So it's -- would you say it's been
12 a number of years since you interacted with
13 anyone from Dexcom?

14 A. Definitely.

15 MR. SARASWAT: Objection, scope.

16 Dr. Keenan, please just give me
17 time to interpose an objection if I need
18 to.

19 BY MR. WILLIAMS:

20 Q. Okay. Do you have an
21 understanding of how counsel for Dexcom
22 learned of your availability to be an expert
23 witness in this case?

24 MR. SARASWAT: Objection, scope.

25 A. I do not know that. I just know

1 that I -- attorneys on that side, legal from
2 these attorneys contacted me, but --

3 BY MR. WILLIAMS:

4 Q. Okay. And then -- at that time
5 you had never acted as an expert witness in
6 any litigation, correct?

7 A. I had not.

8 Q. Okay. All right. Just going back
9 to then the process that led to Exhibit 2008.

10 So after you were provided with an
11 initial draft, did you make any changes?

12 A. Yeah, there were -- there were
13 several changes at different points that --
14 that changes were made to it, yeah.

15 Q. Okay. Does the -- when is the
16 last time you read this document,
17 Exhibit 2008?

18 A. Yesterday.

19 Q. Okay. Does it -- do you still
20 stand behind everything in here as being
21 correct and accurate?

22 A. I do.

23 Q. And it reflects your opinions,
24 correct?

25 A. It does.

1 Q. Okay. I should talk briefly about
2 preparation for today.

3 When did you begin to prepare for
4 today's deposition?

5 A. I began to prepare at the end of
6 last week.

7 Q. And how -- I don't want to know
8 the conversations you had with counsel, but,
9 just generally, how did you go about
10 preparing for today's deposition?

11 A. I reviewed the -- the declaration,
12 looking at the points.

13 Q. The declaration meaning
14 Exhibit 2008?

15 A. Correct.

16 Q. Did you review any other documents
17 to prepare for the deposition?

18 A. I looked at the patent or the --
19 the exhibits that Dr. Rodbard discusses, I
20 looked at them.

21 Q. So paragraph 1 of your declaration
22 says you're being compensated at your
23 standard rate of \$250 per hour.

24 A. Yeah.

25 Q. Do you see that?

1 A. I see it.

2 Q. Okay. And that's correct, right,
3 that's the hourly rate you're charging in
4 this case?

5 A. That's correct.

6 Q. When you say that's your standard
7 rate, what do you mean by that? Standard for
8 what?

9 A. If I'm consulting, it's roundabout
10 what -- what I charge --

11 Q. Okay.

12 A. -- on an hourly basis. If I'm
13 consulting for a company or a client, that's
14 what I would charge on an hourly rate.

15 BY MR. WILLIAMS:

16 Q. Are you compensated in this case
17 in any way other than your -- by your hourly
18 rate?

19 A. I am not.

20 Q. Do you have an estimate of how
21 many hours you spent preparing the
22 declaration in this matter?

23 A. Probably -- probably close to 40
24 hours.

25 Q. And in preparation for today's

1 deposition, do you have an estimate of how
2 many hours you spent preparing?

3 A. Probably -- probably 50 hours.

4 Q. Okay. In terms of the preparation
5 for today's deposition, did you have any
6 meetings with counsel?

7 MR. SARASWAT: And, again, you can
8 answer yes or no but don't reveal the
9 details of any meetings.

10 A. Yes.

11 BY MR. WILLIAMS:

12 Q. Okay. How many meetings did you
13 have?

14 A. Two.

15 Q. What days did those take place?

16 A. Monday and Tuesday.

17 Q. Who was present for those
18 meetings?

19 A. Anant and Rich here.

20 Q. So it was just the three of you?

21 A. Correct.

22 Q. Okay. Was there anyone on the
23 phone listening in to the meeting?

24 A. There -- occasionally.

25 Q. Do you know who was -- who else

1 was listening in to the meeting?

2 A. Yeah. Occasionally on Zoom,
3 Shirin at -- I believe she's Dexcom's
4 counsel.

5 Q. Okay. And have you had any other
6 meetings with Dexcom's counsel besides that
7 one?

8 A. No. No.

9 Q. Okay. Let me just hand you what's
10 been previously marked as Exhibit 2009.

11 Do you recognize this document?

12 A. I do.

13 Q. What is it?

14 A. It's my current resumé.

15 Q. Okay. Is everything on here
16 accurate?

17 A. I believe so.

18 Q. Okay. So my understanding is that
19 you're giving expert testimony in this case,
20 correct?

21 A. Correct.

22 Q. Can you give me your understanding
23 of what you believe yourself to be an expert
24 in?

25 A. Well, I'd say medical devices in

1 general, as you can see based on the resume.
2 As it relates to the case, I spent
3 approximately ten years working on diabetes
4 at Medtronic in various roles.

5 Q. And what years were those?

6 A. I started Medtronic in January of
7 2005, and I left just under ten years there,
8 I think -- it says exactly here -- I think
9 August 2014. Yep, or September 2014. It was
10 September 2014.

11 Q. Okay. And we will come back to
12 that in a minute.

13 But other than Medtronic, did you
14 have any other expertise related to
15 diabetes?

16 A. Not really, not really.

17 Q. Okay. What about any other
18 experience relating to medical biosensors?

19 A. Yeah. I mean, 25 years. My Ph.D.
20 is in -- in signal processing of -- my Ph.D.
21 is related to signal processing of biomedical
22 signals, so I've worked with many, many
23 sensors, biosensors.

24 BY MR. WILLIAMS:

25 Q. Did your Ph.D. focus on a

1 particular type of biomedical system?

2 A. It did. It focused on cardiac
3 ultrasound.

4 Q. Okay. So according to your
5 resumé, you have a bachelor's of engineering
6 degree in electronic systems; is that right?

7 A. That's correct.

8 Q. Okay. And then a Ph.D. in
9 biomechanical engineering; is that correct?

10 A. Correct.

11 Q. Okay. Was there any master's in
12 there, or did you go straight to a Ph.D.?

13 A. I went straight to the Ph.D.

14 Q. Okay. Did you have in the --
15 either the -- in any of your educational
16 background, did you have any expertise in
17 analytical -- do you have any expertise in
18 analytical chemistry?

19 A. Very little.

20 Q. Okay. So I want to understand now
21 more -- I guess more about your time at
22 Medtronic and the devices that you worked on
23 there.

24 Can you just summarize for me the
25 types of devices you worked on while at

1 Medtronic?

2 A. Medtronic, my time at Medtronic, I
3 started out as a principal scientist. I
4 always worked in the -- I worked in R&D,
5 mostly sensor R&D.

6 For the first two years, I was
7 working directly with -- throughout my ten
8 years, I was working with CGM data all the
9 time. For the first two years, I was a
10 principal scientist developing the algorithms
11 for CGM devices. Devices like the Guardian
12 REAL-time, you know, the pumps -- you know,
13 the insulin delivery pumps that had -- the
14 sensor-augmented pumps.

15 While there, I developed a lot of
16 algorithms. I developed the, you know, the
17 calibration algorithm, which I believe is
18 still used today. I developed protective
19 algorithms, filtering algorithms, all kinds
20 of algorithms to clean up the signals.

21 They were originally looking at
22 artificial intelligence to see if we could
23 perform therapy management well with all the
24 CGM data we collected. That was for about
25 the first two years.

1 After that, I moved over to -- to
2 manage the artificial pancreas group, called
3 the closed loop development group. That was
4 a group of scientists who really developed
5 all the -- you know, most of the algorithms
6 in Medtronic Diabetes. We were developing
7 the artificial pancreas. We were developing
8 the closed loop glycemic control algorithms,
9 and we also developed all the algorithms for
10 the products. And those -- the artificial
11 pancreas was the first artificial pancreas to
12 hit the market that we developed.

13 BY MR. WILLIAMS:

14 Q. I don't want to cut you off. That
15 was the end of your answer?

16 A. I can elaborate, certainly.

17 Q. Well, I'm going to ask you
18 follow-up questions.

19 But were there any other devices
20 you worked on at Medtronics besides -- I
21 think you mentioned Guardian and the
22 artificial pancreas?

23 A. I'm trying to get the names right.

24 Guardian RT was already out. I
25 was working on the Guardian REAL-time

1 algorithms. I believe that's where the
2 calibration algorithm went; I think so. And
3 the low glucose suspend pump. I'm trying to
4 remember the -- well, there's a name inside
5 Medtronic, then there's the commercial name.
6 The glucose suspend pump, it might have been
7 530G, but I can't remember exactly.

8 I worked on the retrospective
9 device, the iPro. I did some of the
10 algorithms in there for -- you know, for
11 filtering, some signal-processing routines.

12 Often you write reports,
13 engineering reports, file patents, whatever,
14 but, you know, it's -- don't always know
15 exactly what went into the devices. We don't
16 always know exactly, you know, what goes in
17 the devices. I didn't actually correct the
18 system spec for it. I handed over my
19 algorithm, which would have been implemented.

20 I worked on the CareLink system,
21 the therapy management system. It had all
22 the -- where all the CGM data is uploaded to.

23 BY MR. WILLIAMS:

24 Q. Can you spell that?

25 A. CareLink, C-a-r-e-L-i-n-k. It's a

1 therapy management system that -- that, you
2 know, records all of -- you know, all of this
3 data. And I was working on, you know, doing
4 artificial intelligence type work.

5 Actually, I can give you the names
6 here. I apologize.

7 So 670G was the artificial
8 pancreas that was launched.

9 As a principal scientist, I worked
10 on iPro2 -- sorry -- Paradigm VEO, that was
11 the low glucose suspend pump.

12 THE REPORTER: The what?

13 THE WITNESS: Sorry.

14 A. In relation to the devices I
15 worked on at Medtronic, I worked on the CGMS
16 iPro2 glucose monitor. I developed
17 algorithms for the Paradigm VEO. It's a
18 little glucose suspend pump. And also the
19 670G artificial pancreas.

20 BY MR. WILLIAMS:

21 Q. I missed the name of that low
22 glucose suspend pump.

23 A. VEO, V-E-O.

24 Q. V-E-O, I see.

25 All right. What was SmartGuard?

1 A. SmartGuard was -- SmartGuard was
2 the -- I guess the marketing name which --
3 which had predictive alerts.

4 Q. And what product would that have
5 been incorporated into?

6 A. So it would have -- I believe the
7 Guardian REAL-time, it would have went into
8 that.

9 This -- what I'm talking about
10 here, the GMED submission was based on a
11 clinical study where the algorithms were --
12 it would go with the sensor-augmented pump
13 platform. I'm not sure what the -- what
14 the -- what pumps that are on the market that
15 it's in, but it would have been the evolution
16 of the Paradigm VEO. It -- this technology
17 would probably be in 670G and onwards.

18 BY MR. WILLIAMS:

19 Q. Okay. Let me just back up and
20 make sure I have the picture here.

21 What kind of a product was
22 Guardian REAL-time?

23 A. Guardian REAL-time was CGM only.
24 It didn't do pump. It didn't have an insulin
25 pump.

1 Q. Was SmartGuard integrated into
2 Guardian REAL-time?

3 A. I think so. If not -- if not
4 right away -- you know, I don't know what
5 marketing called it, the genre. I haven't
6 kept up with what the next generations are
7 called.

8 But, yes, it was a -- SmartGuard
9 was really intelligent, intelligent alarms,
10 you know, predicting highs and lows. And
11 that would be in all of the -- it would be in
12 all of the -- actually all of the products --
13 and I'm not sure about 670G. Probably not in
14 670G, because 670G is mostly just automation.

15 But sensor -- any sensor -- any
16 Medtronic pump with a sensor would likely
17 have these -- these algorithms.

18 Q. And when did you start working on
19 this SmartGuard predictive alert technology?

20 A. It's hard to -- it wasn't -- you
21 know, there's a project SmartGuard that's
22 start -- that's finished. We've always been
23 developing algorithms and always trying to
24 improve them based on the CareLink database.
25 So we're always testing predictive alerts to

1 figure out false-positive sensitivity
2 specificity. And as you -- I guess as
3 marketing releases new products, they will
4 put the latest and greatest algorithm that --
5 that exists.

6 So I think SmartGuard is more of a
7 marketing kind of term, but it's really
8 the -- it's predictive alerts that evolve
9 over time.

10 Q. So when did you first start
11 working on predictive alerts from?

12 A. Very early. Probably -- I mean,
13 in 2005. Well, yes -- I mean, yeah. We
14 started with -- we started with all the
15 calibration and -- yeah, 2005 is when we
16 started looking at them.

17 Q. Okay. At that time, in 2005,
18 were -- what was the state of the glucose
19 monitoring work, and who had products on the
20 market at that time?

21 MR. SARASWAT: Objection, scope.

22 A. CGM products?

23 BY MR. WILLIAMS:

24 Q. You know what -- okay. Let's
25 withdraw the question and back up.

1 What's a CGM?

2 A. CGM is a continuous glucose
3 monitoring device.

4 Q. And were there CGM products
5 available on the product when you joined
6 Medtronic in 2005?

7 A. There was three, at least three
8 companies developing products that had
9 products on the market.

10 Q. Do you remember the names of those
11 companies?

12 MR. SARASWAT: Objection, scope.

13 A. Medtronic -- Medtronic Diabetes
14 had their -- had their devices. Abbott
15 Diabetes and Dexcom.

16 BY MR. WILLIAMS:

17 Q. Do you draw a distinction between
18 Abbott and TheraSense in your mind?

19 THE REPORTER: And what?

20 MR. WILLIAMS: TheraSense.

21 MR. SARASWAT: Objection, scope.

22 A. I mean, I know -- I know Abbott
23 acquired TheraSense.

24 BY MR. WILLIAMS:

25 Q. Okay. In 2005, had Abbott already

1 acquired TheraSense?

2 A. I think they had.

3 Q. I'm just trying to figure out, in
4 your last answer when you said Abbott
5 products were on the market in 2005, would
6 that include TheraSense products?

7 A. Well, yeah. Well, certainly they
8 had the meters. But for CGM, Abbott's CGM
9 was the navigator.

10 I think Abbott had -- I'm not a
11 hundred percent, but I think Abbott had
12 acquired TheraSense, and the navigator was an
13 Abbott product.

14 Q. Okay. That's fine. Just thinking
15 back now to this time period -- let me ask
16 another question about CGM.

17 When you use that term "CGM," what
18 do you mean by "continuous"?

19 A. Unlike a finger stick measurement,
20 which was one measurement in time, continuous
21 is acquiring samples from the patient at a --
22 continuously, you know, all the time pretty
23 much at a uniform rate.

24 Q. And in -- so just thinking back
25 now to when you joined Medtronic in 2005, you

1 indicated that you thought there were three
2 companies that were developing or had
3 marketed CGM products as of that date; is
4 that right?

5 MR. SARASWAT: Objection, scope.

6 THE REPORTER: I'm sorry? You're
7 nodding your head, sir.

8 BY MR. WILLIAMS:

9 Q. Yeah, I need an answer.

10 A. Oh. I believe so.

11 Q. Okay. Did any of those products
12 in your -- at that time have predictive
13 alerts?

14 A. I don't think so.

15 Q. What is the first product
16 you're aware of -- first CGM product you're
17 aware of with predictive alerts?

18 MR. SARASWAT: Objection, scope.

19 A. I don't know. I know certainly
20 with Medtronic predictive alerts were much
21 later.

22 BY MR. WILLIAMS:

23 Q. Okay. So while at Medtronic, you
24 were developing predictive alert algorithms,
25 correct?

1 A. I was analyzing, yeah. We were
2 doing everything, looking at artificial
3 intelligence, you name it.

4 Q. Okay. But did -- okay, so let me
5 reask that question, then.

6 Did you -- did you develop a
7 predictive alert algorithm while at
8 Medtronic?

9 A. I worked with predictive alerts,
10 yeah. I worked on predictive algorithms,
11 right.

12 Q. Okay. And did those algorithms
13 wind up in a Medtronic product?

14 A. Eventually.

15 Q. When?

16 A. I don't -- I don't know when these
17 products got launched. I'm not sure.

18 Q. Would it have been before 2011?

19 A. No, I don't think so.

20 I'm trying to remember the name of
21 it. I believe it went into a
22 sensor-augmented pump first. I'm trying to
23 remember the name of the pump.

24 There was a predictor pump -- I'm
25 really looking back and trying to think. It

1 would have been the first time these
2 indicators appeared -- or not indicators,
3 they -- the first time they were implemented.

4 I didn't work in marketing on
5 launching the products, so I -- I don't have
6 a good memory when they got on the market.

7 BY MR. WILLIAMS:

8 Q. What's a predictive pump? I'm
9 sorry, withdrawn.

10 What's a sensor-augmented pump?

11 A. Oh, it's a CGM with an insulin
12 pump.

13 Q. So to the best of your
14 recollection, Medtronic wouldn't have had a
15 product with predictive alerts in it before
16 2011?

17 MR. SARASWAT: Objection, scope.

18 A. I don't recall if they had a
19 product on the market with predictive alerts
20 at that time. I don't think so, but I -- I
21 don't know the dates that, you know, products
22 got launched.

23 Certainly there is a -- there is a
24 very long time difference between working
25 on -- working on the technology and

1 launching. You go through a very long
2 regulatory process and development process.
3 So I don't -- I don't think so, but I don't
4 know what got launched when. I believe
5 predictive alerts were much later.

6 Yeah, SmartGuard was a study in
7 Europe.

8 (Reporter clarification.)

9 THE WITNESS: Oh.

10 A. The SmartGuard, the GMED
11 submission, that was -- that was a clinical
12 study we looked at in Europe.

13 BY MR. WILLIAMS:

14 Q. Turn to -- in your declaration,
15 turn to paragraph 53, please.

16 Let me know when you got there.

17 A. I'm here.

18 Q. Can you read that paragraph to
19 yourself, and let me know when you're done.

20 A. Yep. I'm done.

21 Q. Okay. What is the user guide that
22 is being discussed in that paragraph?

23 A. Guardian REAL-time.

24 Q. And when was -- in your
25 understanding, when was that product

1 commercially available?

2 A. Probably -- probably when the
3 manual was published.

4 Q. And do you recall -- you say in
5 your third sentence in paragraph 53 that it
6 bears a copy -- a 2006 copyright date.

7 Do you see that?

8 A. I do.

9 Q. So do you think that product would
10 have been available by 2006?

11 A. I do not.

12 Q. So what is the meaning of the 2006
13 copyright date?

14 A. The date it was copyrighted.

15 Q. When do you think that product
16 became commercially available?

17 A. It was certainly much later. I
18 recall there was products 2005-2006 that --
19 that we worked on that we decided not to
20 launch.

21 And I don't want to get confused.
22 I worked on predictive alerts which went into
23 both the pump product and a CGM alone
24 product.

25 A. To be honest, I have no idea to

1 give you a date when they got launched.

2 Q. Okay. You say, about the middle
3 to the end of that paragraph, "I believe that
4 Exhibit 2015 is an accurate copy of a
5 Medtronic Guardian REAL-time User Manual
6 published prior to 2012."

7 Do you see that?

8 A. I do.

9 Q. What's the basis for your belief
10 it was published prior to 2012?

11 A. It was copyrighted 2006.

12 Q. Okay. Any other basis for your
13 belief that it was published prior to 2012?

14 A. The copyright 2006, so it was six
15 years, you know, prior to 2012 when it was
16 copyrighted.

17 Q. Let me hand you what has been
18 marked as 2015 just so you have a copy. So
19 feel free to take a look at the document and
20 familiarize yourself with it.

21 But my question is, is this the
22 document that you're referring to in
23 paragraph 53 of your declaration?

24 A. I believe so.

25 Q. And your testimony earlier was you

1 believe this product that's described here
2 was not available on the market in 2006; is
3 that correct?

4 A. No, there's no way it was on the
5 market. I don't believe it was on the market
6 in 2006.

7 Q. Okay. And when you say "there's
8 no way," why were you saying "there's no way?"

9 A. Oh. It's a long time ago. I'm
10 trying to recall, you know, when I joined
11 Medtronic and what I worked on, so I should
12 know what was on the market at the time.

13 I worked in research. I wasn't
14 working directly, you know, knowing what
15 product was on the market.

16 I think -- I might get my dates
17 wrong, but I think Guardian RT was maybe just
18 getting launched and not REAL-time. I know
19 that REAL-time certainly came, you know, much
20 later than RT. I don't think so, but --

21 Q. What's the difference between
22 Real-time and RT, Guardian REAL-time and
23 Guardian RT?

24 A. Guardian RT was -- I'm trying to
25 remember. Guardian RT was definitely an

1 earlier version. I don't -- I believe
2 Guardian RT -- if I can -- maybe this will
3 help explain.

4 What you're looking at -- the
5 monitor you're looking at on the cover page
6 is -- is -- it looks like the pump. It's got
7 a display.

8 The Guardian RT was an earlier
9 device that didn't have -- had a different
10 form fac- -- didn't have the display and
11 whatnot, and the sensor was much less
12 accurate.

13 But, of course, sensors are -- are
14 evolving, and whatever ends up in a product
15 is likely whatever is best at that time, when
16 the clinical study is started.

17 Q. So the form factor that's is shown
18 on the cover of 2015, do you recognize that
19 device?

20 A. I do.

21 Q. What is that device?

22 A. Guardian REAL-time. It's -- it
23 actually looks like a pump.

24 Q. When you say it looks like -- what
25 do you mean "it looks like a pump"?

1 A. The monitor is very, very similar
2 to the -- to the pump monitor.

3 Q. Okay. But this product, the
4 Guardian REAL-time, was just a standalone
5 CGM?

6 A. That's correct.

7 Q. All right. And so -- so the fact
8 that there's a copyright date of 2006 on
9 page 3 doesn't mean that that was when this
10 product was available on the market, correct?

11 A. I believe so. I mean, I don't
12 know when -- you know, when this got
13 launched.

14 Q. Okay. And do you know the date
15 that this document that you're looking at was
16 first published?

17 A. I don't. Copyright 2006, but I
18 don't know when it got published.

19 Q. Okay. On the last page of the
20 document there's a code on the bottom right.

21 Do you have any -- sorry. The
22 very last page, yeah.

23 You see the code on the bottom
24 right? Do you have any idea of what any of
25 those digits mean?

1 MR. SARASWAT: Objection, scope.

2 A. I don't know exactly, but
3 obviously it relates to -- I'm speculating.

4 BY MR. WILLIAMS:

5 Q. Are you familiar with the
6 Medtronic user guide format?

7 A. I don't know if there's a standard
8 format. I mean, I -- it looks reasonable. I
9 mean, you mean format in how the document is
10 laid out or -- or just having the logo and --
11 I think it's a standard document.

12 Q. Okay. Do you think this is the
13 Medtronic REAL-time user guide as published
14 by Medtronic?

15 A. I believe it must be. I mean, I
16 don't -- yeah, I don't imagine -- it looks
17 like it -- it looks like the Guardian
18 REAL-time, as it says.

19 Q. Okay. Did you ever see this
20 document when you were working at Medtronic?

21 A. I didn't sit down and review
22 document -- you know, sit down and review
23 manuals. I did things more on a smaller
24 basis.

25 For example, I may have -- you

1 know, I may have been sent something from
2 marketing with a couple of pages maybe in the
3 document, and I would, you know, review it
4 for, you know, accuracy or -- or edit some
5 things, but that was -- but not knowing
6 where -- exactly where it's going in all the
7 time.

8 I mean, I open the page. You
9 know, the area under the curve, you know -- I
10 open the page that says -- just says area
11 under the curve. For me, I would look at
12 that and make sure it's correct.

13 Q. Okay. Did the -- did the
14 Guardian REAL -- okay, let me ask you a
15 different question.

16 Were you familiar with the
17 Guardian REAL-time product that was
18 commercialized by Medtronic?

19 A. At a high level.

20 Q. Okay. And did that product
21 include predictive alerts?

22 A. I believe predictive alerts within
23 the -- I believe so --

24 THE REPORTER: Within the what?
25 When I ask you, all I need to know

1 is what you said.

2 So you said, "I believe the
3 predictive alerts with the lots"?

4 THE WITNESS: Oh, sorry.

5 I believe predictive alerts were
6 part of the Guardian REAL-time. I think so.
7 I -- yeah.

8 BY MR. WILLIAMS:

9 Q. Did you download this document,
10 the Guardian REAL-time user guide, for this
11 case?

12 A. I did.

13 Q. Where did you get it?

14 A. There's a link where you can get
15 all -- all kinds of documents. Sorry.

16 Q. So you have a link in paragraph 53
17 of your declaration.

18 A. Pardon?

19 Q. If you turn to paragraph 53 of
20 your declaration, you have a link there.

21 Is that the link where you got
22 this document?

23 A. Yep, that is where it came from.

24 Q. This website "ManualsLib" where
25 you obtained the document, does it tell you

1 when the document was published?

2 MR. SARASWAT: Objection, scope.

3 A. I don't recall.

4 BY MR. WILLIAMS:

5 Q. And the very last sentence of
6 paragraph 53, you say, "based on my
7 familiarity with Medtronic's documentation
8 and business practices, it is my opinion that
9 Exhibit 2015, exhibit, accurately describes
10 the operation of the version of the Guardian
11 REAL-time product that was commercially
12 available at the time the exhibit was
13 published."

14 Do you see that?

15 A. I see it.

16 Q. Okay. So what time period would
17 that have been? When was this exhibit
18 published, in your opinion?

19 A. I'd be hazard -- I'd be providing
20 a -- kind of an educated guess.

21 It would have been -- well, I
22 mean -- I would assume anyway, I could be
23 wrong, that it was published around the time
24 of launch, unless they published it earlier
25 for some reason. I don't know the marketing

1 perspective, but intuitively I would assume
2 that.

3 Q. Uh-huh.

4 And was that prior to 2012?

5 A. I believe so.

6 Q. Okay.

7 MR. WILLIAMS: You know what,
8 we've been going about an hour. Why
9 don't we take a short break.

10 MR. SARASWAT: I was going to say
11 the same thing.

12 (Recess taken at 10:12 a.m. 10:25 a.m.)

13 BY MR. WILLIAMS:

14 Q. This website "ManualsLib" that you
15 used to obtain Exhibit 2015, is that a
16 website you've used before in your work?

17 A. Yeah. I have -- I've downloaded
18 manuals there before.

19 Q. You've done what?

20 A. I've downloaded manuals there
21 before.

22 Q. You researched product manuals on
23 that website before. Is that what you mean?

24 A. I've looked for manuals, yeah.
25 That's one of the places where, you know,

1 you -- you can do a Google search and see if
2 you can find it first, and that's one way of
3 looking for manuals that don't pop up in
4 Google searches.

5 (Off-the-record discussion.)

6 BY MR. WILLIAMS:

7 Q. Do the product manufacturers post
8 product manuals as well on their websites?

9 A. I don't know that Medtronic did,
10 but I know that some do. I've downloaded
11 stuff from archives in China before, I
12 recall, recently.

13 Q. Okay. Just referring back to
14 Exhibit 2015 for a moment, which is the
15 Guardian REAL-time manual.

16 You mentioned there was an earlier
17 version called Guardian RT, right?

18 A. Yes. I'm trying to remember the
19 names. Guardian RT was the first -- I think
20 it was the first real-time CGM from Medtronic
21 after CGMS, but they worked on different
22 products that -- you know, some didn't
23 even -- some didn't get launched, you know.

24 Guardian RT, of course, was -- I
25 believe was the first real-time CGM from

1 Medtronic, so it would predate REAL-time. It
2 would predate the Guardian REAL-time.

3 Q. I think earlier you said that the
4 Guardian RT used a different sensor than was
5 in Guardian REAL-time; is that correct?

6 A. If I said that, it would have been
7 incorrect. Generally, I think -- I think I
8 should have articulated it better.

9 It would have used -- generally
10 the sensors are evolving, and obviously the
11 monitors on the market use the best sensors
12 at that time. So I'm trying to -- I'm trying
13 to -- I'm trying to think about that more
14 clearly.

15 Because you can only use a
16 sensor -- even if you have better sensors --
17 (Reporter clarification.)

18 A. When you make sensor improvements,
19 and you have better sensors, you cannot put
20 them in a product until they go through FDA.

21 BY MR. WILLIAMS:

22 Q. So do you believe the Guardian
23 REAL-time used the same sensor as was in
24 Guardian RT?

25 MR. SARASWAT: Objection, scope.

1 A. Sensor -- the same technology. I
2 don't recall if Guardian REAL-time -- if a
3 new sensor was -- went through the FDA with
4 the CGM.

5 I guess, if you could define
6 different sensor.

7 BY MR. WILLIAMS:

8 Q. When you say that sensors are
9 evolving, what did you mean?

10 A. Well, technology improves over
11 time, manufacturing processes improve over
12 time.

13 Q. While at Medtronic, were you
14 familiar with the sensor technology being
15 used in Medtronic's CGM devices?

16 A. Could you rephrase that?

17 MR. WILLIAMS: I'll have the court
18 reporter repeat it.

19 THE REPORTER: "While at
20 Medtronic, were you familiar with the
21 sensor technology being used in
22 Medtronic's CGM devices?"

23 I was familiar at a high level.

24 As we discussed earlier, I didn't work
25 on the chemistry side, I worked on

1 the -- on the data side.

2 BY MR. WILLIAMS:

3 Q. Okay. Fine.

4 Let me put in front of you a
5 document previously marked as Exhibit 2014.

6 Do you recognize this document?

7 A. Yep. I recognize this as a
8 Freestyle Navigator User's Guide.

9 Q. How did you obtain this document?

10 A. Can I go back to my declaration
11 and find it?

12 Q. Sure.

13 A. I don't recall exactly where all
14 the documentation came from.

15 Q. And if you want to look at
16 paragraph 54 to help refresh your
17 recollection, that would be one place you
18 might find helpful information.

19 A. Yep, this document came from the
20 same website. This document came from the
21 same website.

22 Q. Do you have an understanding of
23 when this document was published?

24 A. I think I saw a copyright 2008. I
25 would imagine around that time.

1 I should be careful because I
2 don't know when, you know, it gets
3 copyrighted or when something is actually
4 published. I don't know the publication
5 date. Assuming -- I'm assuming it's close to
6 the copyright date.

7 Q. Are you familiar with this
8 product?

9 A. I'm familiar with the product in
10 terms of -- somewhat familiar. I mean, I
11 never wore it. I've read many, many
12 manuscripts talking about this data,
13 scientific manuscripts. So that would be
14 data from the product.

15 Q. And were you aware of this product
16 at the time you worked at Medtronic?

17 MR. SARASWAT: Objection, scope.

18 A. We were aware -- well, I was aware
19 that -- well, we always knew TheraSense was
20 developing a CGM. Abbott acquired -- Abbott
21 acquired TheraSense. I was -- certainly in
22 the early days, yeah, I was aware that -- you
23 know, lots of talk about what's the
24 performance of high accuracy, yep.
25 /

1 BY MR. WILLIAMS:

2 Q. And do you believe that the
3 product was commercially available by 2011?

4 A. I believe so.

5 Q. Okay. And so do you believe this
6 document, then, accurately describes the
7 operation of the device as it existed in that
8 pre-2011 time period?

9 A. I believe -- yeah, I believe it
10 would have to. Generally there's not many
11 errors in this. There's generally not
12 many -- there shouldn't be too many errors in
13 a user guide. They get proofread so many
14 times, I believe so.

15 BY MR. WILLIAMS:

16 Q. Did this device have predictive
17 alarms?

18 A. It had projected alarms here, as
19 described starting at page 70.

20 THE REPORTER: You did say
21 predictive, right?

22 THE WITNESS: It's -- it had --
23 here it's called projective. Projective
24 or predictive, I guess.

25 /

1 BY MR. WILLIAMS:

2 Q. Do you think those are the same
3 things, describing the same things,
4 projective and predictive alarms?

5 Well, let me ask a different
6 question.

7 What's your understanding of what
8 a predictive alarm is, in a CGM context?

9 A. For CGM context for predictive,
10 you're -- you're predicting ahead. You're
11 predicting where your glucose is going to be
12 in a -- in a certain time duration. Let's
13 say 20 minutes, you're predicting where it's
14 going to be in 20 minutes. I guess
15 predicted, projected, it should be the same
16 thing here.

17 Q. And this device, the Freestyle
18 Navigator device, also had a threshold alarm
19 based on a real-time value glucose, right?

20 A. It had a threshold alarm and a
21 projected alarm.

22 Q. And the threshold alarm, in your
23 understanding, was based on a current blood
24 glucose value?

25 A. Correct.

1 Q. And going back to the Medtronic
2 Guardian REAL-time Exhibit 2015.

3 I don't recall if I asked you
4 about this earlier, but did this device have
5 a predictive alarm?

6 A. Yep. Page 33, it discusses the
7 projective -- predictive alarm. They say
8 predictive there, predicitive alerts.

9 Q. And did this device also have a
10 threshold alert based on the actual glucose
11 levels?

12 A. It did.

13 Q. Did the -- this Guardian REAL-time
14 product, did it incorporate any of the
15 predictive algorithms that you had been
16 working on at Medtronic?

17 A. It's -- I believe it would have
18 components of the algorithm. The predictive
19 alert, there were various components to the
20 algorithm, and they involved different
21 processing blocks, for example, filtering and
22 things like this. I can't say for sure
23 something didn't change in things that I had
24 developed. It -- I believe this version, I
25 believe it did. Some of the things I did may

1 have come in later. I don't recall when --
2 you know, what calibration algorithm issues
3 and things like that.

4 The projected alert was really
5 based on a -- on a filter.

6 Q. Can you explain what you mean by
7 that? Based on a filter how?

8 A. So you have your CGM signals,
9 which, of course, are filtered because of the
10 noise and artifact.

11 Then there's a -- it's a rate of
12 change filter, a filter that tells you the
13 rate of change of glucose, and they're not
14 issues to project.

15 BY MR. WILLIAMS:

16 Q. I'll hand you what's been marked
17 as Exhibit 2006.

18 Are you familiar with this
19 document?

20 A. A little bit. I've -- some time
21 ago I would have read it very, very, very,
22 very fine detail. Right now I am somewhat
23 familiar at a high level.

24 Q. Okay. Do you remember making
25 citation to it in your testimony?

1 A. Can you direct me to where --

2 Q. Sure. One place I noticed is in
3 paragraph 46.

4 A. Thank you.

5 Yep, I do.

6 Q. And what were you using this
7 document for -- withdraw the question.

8 How are you using this document to
9 support your opinions in this case?

10 A. To -- to -- sorry.

11 I guess to characterize the -- the
12 state of the art at the time with -- during
13 that time period with alerts, the performance
14 of alerts.

15 Q. And the time period here, this
16 document -- this paper was published in 2010;
17 is that right?

18 A. Correct.

19 Q. Are you familiar with the journal,
20 the Journal of Diabetes Science and
21 Technology?

22 A. I am.

23 Q. How are you familiar with it?

24 A. I've published in it before. I've
25 reviewed articles for publication of it. I

1 have reviewed articles for the editorial
2 board, and I have published in the journal.

3 BY MR. WILLIAMS:

4 Q. Okay. Do you know if you received
5 this -- if you received the journal at this
6 time, in January of 2010?

7 MR. SARASWAT: Objection, scope.

8 A. Are you asking if I -- if I had
9 read this paper when it was published?

10 BY MR. WILLIAMS:

11 Q. Around the time it was published,
12 yeah, that's right.

13 A. I don't recall. I -- I don't
14 recall the papers, but I do read a certain
15 amount. If I did, I didn't -- I didn't spend
16 a lot of time off it that was -- that I
17 remember.

18 Q. Do you know these authors? Any of
19 these authors, I should say?

20 MR. SARASWAT: Sorry. Objection,
21 scope.

22 A. I do not know them personally. I
23 recognize one name.

24 BY MR. WILLIAMS:

25 Q. Which name do you recognize?

1 A. James #Brooker. I've seen him
2 present. I may have talked to him before.
3 He's got patents there and --

4 THE REPORTER: He's got patents?

5 THE WITNESS: I apologize.

6 THE REPORTER: You're dying out at
7 the end of every answer. He's got
8 patents what?

9 THE WITNESS: I've seen -- I've
10 seen his name on patents.

11 BY MR. WILLIAMS:

12 Q. What about the name Kamath, the
13 first name, Kamath?

14 A. I don't know Kamath.

15 Q. Let me ask you, you referred to, I
16 guess -- is it page 65, is that the first
17 citation you have there in paragraph 46?

18 A. That's correct.

19 Q. I'm just trying to find which page
20 that is. I don't see page numbers actually
21 on the document.

22 Oh, I see 61. Some of them are
23 here.

24 A. Is it the last page?

25 MR. SARASWAT: Counsel, if you

1 were looking at the PDF, it's PDF page
2 9, if that helps.

3 BY MR. WILLIAMS:

4 Q. Okay. So I think page 65 is the
5 one that has conclusions on it; is that
6 correct?

7 A. That's correct.

8 Q. Okay. Great.

9 You cite that page for the
10 principle that -- by the way, I'm looking at
11 paragraph 46 of your declaration.

12 Do you see that paragraph?

13 A. I do.

14 Q. Okay. You say, "Furthermore a
15 POSA" -- let's stop there.

16 What's a POSA?

17 A. A person of skill in the art.

18 Q. Okay. And this is -- in your
19 view, this would have been someone around
20 2011; is that correct?

21 A. Correct.

22 Q. So you say, "A POSA would have
23 understood that the prevailing view in the
24 art was that predictive alarms were
25 inaccurate and caused high incidences of

1 false alarms."

2 Correct, that was your -- that's
3 your testimony?

4 A. Correct.

5 Q. And you're basing that off of
6 what? Is it page 65 of this document, among
7 other things, correct?

8 A. Correct, among other things.

9 Q. Okay. So where in the Kamath
10 paper do you see support for the principle?

11 A. Where else or --

12 Q. Where in this document -- yeah,
13 show me on page 65 here where you think he
14 says something that supports that premise.

15 A. So paragraph 46 references the 65
16 percent of down false alerts.

17 THE REPORTER: Of what false
18 alerts.

19 Q. D-o-w-n; is that right? Down,
20 d-o-w-n?

21 A. Correct.

22 Q. Okay. So let me see.

23 I see that here in the middle of
24 that left column on page 65, and that seems
25 to be talking about a study of the GlucoWatch

1 G2 Biographer device; is that correct?

2 A. That's correct.

3 Q. Are you familiar with that device?

4 A. A little bit.

5 Q. How did you become familiar with
6 it?

7 A. I hadn't heard of it until I
8 joined Medtronic in 2005. Then I was
9 familiar -- I can't remember what stage it
10 was at. I know that -- I can't remember if
11 it had already been taken off the market.
12 What I know is it's a -- it was a CGM, and it
13 caused rashes; it was a watch.

14 Q. Did it have an implantable sensor?

15 A. I'm trying to remember the sensor.
16 It was -- it wasn't implanted in the body. I
17 believe it was percutaneous, though. It
18 penetrated the skin. It wasn't noninvasive,
19 to my recollection.

20 Q. And your recollection -- so you
21 believe at some point it was taken off the
22 market?

23 A. Yeah. I mean, I don't know when,
24 but I -- because of the rashes, I don't think
25 it was well received. But I do know that

1 Animas acquired the technology.

2 (Reporter clarification.)

3 THE WITNESS: Animas at Johnson &
4 Johnson, Animas.

5 BY MR. WILLIAMS:

6 Q. Okay. Did you read -- this study
7 that is being referred to in this section of
8 the Kamath paper is referenced by footnote
9 reference number 18, I believe, correct?

10 A. Correct.

11 MR. SARASWAT: Objection, scope.

12 BY MR. WILLIAMS:

13 Q. Did you read that paper?

14 MR. SARASWAT: Objection, scope.

15 A. I don't recall but not recently.

16 BY MR. WILLIAMS:

17 Q. And that study -- the date of that
18 paper appears to be in 2004, correct?

19 MR. SARASWAT: Objection, scope.

20 A. The publication was 2004.

21 BY MR. WILLIAMS:

22 Q. So referring back into the Kamath
23 paper, he describes that study as "the study
24 intended to evaluate the effectiveness of the
25 down alert."

1 Do you see that?

2 A. I do.

3 Q. What's your understanding of what
4 the down alert was in this device?

5 A. I believe the down alert is likely
6 the hypoglycemic alarm. Here it says
7 real-time projective alert. Down being
8 hypoglycemia.

9 Q. So it was a -- so your
10 understanding is -- of the down alert, was
11 that it was a projective alert, correct?

12 A. Based on what it says here, the
13 first available real-time projective alert
14 was the GlucoWatch G2 Biographer, quotes,
15 "down alert."

16 That's not -- it's not very clear
17 by that statement, though. Down alert could
18 simply mean it's hypoglycemia, up alert could
19 be hyperglycemia.

20 Q. Okay. Do you -- are you familiar
21 with how the down alert in the GlucoWatch G2
22 worked?

23 A. I'm not very familiar with exactly
24 how it worked.

25 Q. It says here, "In a study intended

1 to evaluate the effectiveness of the down
2 alert at predicting overnight hypoglycemia,
3 although the sensitivity to detect
4 hypoglycemia was improved from 8 percent with
5 the threshold alert to 77 percent with a down
6 alert, 65 percent of down alerts were false
7 (blood glucose greater than 70 milligrams per
8 deciliter within plus or minus 30 minutes
9 from the alert) compared to 16 percent for
10 the threshold alert."

11 Do you see that sentence I just
12 read?

13 A. I do.

14 Q. What's your understanding of what
15 "sensitivity to detect hypoglycemia" means
16 there?

17 A. Sensitivity, I believe, would mean
18 accuracy.

19 Q. So when they say it was -- when
20 they say that -- that measure "was improved
21 from 8 percent with the threshold alert to 77
22 percent with a down alert," does that mean
23 that with only the threshold alert the device
24 was only detecting hypoglycemia 8 percent of
25 the time?

1 MR. SARASWAT: Objection, scope.

2 A. No. These -- these alert
3 thresholds are not hypoglycemic.

4 BY MR. WILLIAMS:

5 Q. So let me just ask a different
6 question.

7 What did the 8 percent there
8 reflect?

9 MR. SARASWAT: Objection, scope.

10 A. Sorry. You're asking me what the
11 8 percent means?

12 BY MR. WILLIAMS:

13 Q. Yeah.

14 What is your understanding of what
15 that 8 percent is measuring?

16 MR. SARASWAT: Objection, scope.

17 A. I believe it's -- it's predicting
18 you're going to pass a threshold, you know,
19 by between 8 percent to 77 percent.

20 BY MR. WILLIAMS:

21 Q. I don't think I understood your
22 answer.

23 What does that mean, pass a
24 threshold between 8 percent and 77 percent?

25 A. "In a study intended to evaluate

1 the effectiveness of" --

2 THE REPORTER: Sir, if you're
3 reading, you need to be clearer.

4 THE WITNESS: I apologize.

5 A. "In a study intended to evaluate
6 the effectiveness of the down alert at
7 predicting overnight hypoglycemia, although
8 the sensitivity to detect hypoglycemia was
9 improved from 8 percent with the threshold
10 alert to 77 percent with the down alert, 65
11 down alerts were false."

12 That would tell me that the
13 percentage of events detected by the
14 algorithm went from 8 percent with a
15 threshold alert to a -- to a performance of
16 77 percent with -- with the down alert?

17 BY MR. WILLIAMS:

18 Q. I see.

19 So then without the down alert,
20 the device was only detecting these events
21 8 percent of the time; is that right?

22 MR. SARASWAT: Objection, scope.

23 A. I assume it means it's -- it was
24 only detecting 8 percent based on the
25 threshold of 70 milligrams per deciliter.

1 BY MR. WILLIAMS:

2 Q. So what is the threshold you're
3 referring to there? I'm sorry, I don't think
4 I understood what you said.

5 A. I'm looking for a definition of
6 their -- of what they call hypoglycemia.

7 Based on what I'm reading is
8 the -- the threshold alert alone was
9 detecting 8 percent and with the down alert
10 that's increased to -- with a combination
11 increased to 77 percent, with 65 percent of
12 alerts being false-positives, greater than
13 70.

14 Q. So, yeah, and -- so Kamath
15 describes that as an improvement or that the
16 sensitivity to detect hypoglycemia improved
17 when the down alerts were used, correct?

18 MR. SARASWAT: Objection, scope.

19 A. I don't agree.

20 BY MR. WILLIAMS:

21 Q. He doesn't say that?

22 A. I think what he's describing is
23 you give up -- you give up specificity for
24 sensitivity. So, you know, if you want to
25 improve detecting hypoglycemia, you're going

1 to increase your false alarm rate.

2 Q. I think I understand what you're
3 saying, but let me just make sure I unpack
4 that.

5 You said you give up specificity
6 for sensitivity. What do you mean by
7 specificity?

8 A. Your false-positive rate, I should
9 say, would be more accurate.

10 Q. Okay. And sensitivity would mean
11 what?

12 A. True positives.

13 Q. And, in this case, a positive
14 would mean entering a hypoglycemic state?

15 A. Or a threshold. You know, being
16 able to detect a threshold, where you have
17 your threshold.

18 If I recall, hypoglycemia is below
19 70 milliliters a deciliter, 70 milligrams a
20 deciliter is the threshold.

21 Q. Okay. So why do you -- what's
22 your understanding of what a person of skill
23 in the art would have thought the word
24 "improved" meant in this sentence?

25 A. I think if you take the -- the

1 text in its entirety, the improved would mean
2 increased. So by just looking at the -- you
3 know, the sensitivity to detecting events, in
4 that case on its own, the sensitivity
5 increased.

6 Q. Meaning it was detecting more
7 hypoglycemic events than it was without the
8 down alert, right?

9 A. Correct.

10 Q. Now, you mentioned also in
11 paragraph 46 of your declaration a -- another
12 reference to Navigator, which I think is
13 Exhibit 2014 that you should have already.

14 Do you have Exhibit 2014?

15 A. I do.

16 Q. Okay. So what is it about
17 Exhibit 2014 that you think supports your
18 opinions in paragraph 46?

19 A. Well, the guide states that --
20 that projective alarms cannot be relied on
21 exclusively for notification of --
22 (Reporter clarification.)

23 A. Predictive alerts cannot be relied
24 on exclusively for notification of low or
25 high glucose.

1 BY MR. WILLIAMS:

2 Q. Do you have page 68 of
3 Exhibit 2014 in front of you?

4 A. I do.

5 Q. Right in the middle of the page
6 there's a graph showing high threshold 180 mg
7 per deciliter with an alarm icon and then an
8 up arrow.

9 Do you see that?

10 A. I do.

11 Q. And next to it there's a sentence
12 that says, "These alarms are designed to help
13 you take action as soon as you're notified."

14 Do you see that?

15 A. I do.

16 Q. Could you read the next sentence
17 out loud for us?

18 A. "Projected low and projected high
19 glucose alarms increase the overall ability
20 to detect a condition of low or high glucose.
21 However, they cannot be relied on exclusively
22 for notification of all low and high glucose
23 conditions."

24 Q. Okay. So a person of ordinary
25 skill in the art reading this paragraph would

1 have understood that projected alarms
2 increase the ability to detect a low glucose
3 condition, correct?

4 A. A person of skill in the art would
5 increase the sensitivity to detecting low and
6 high conditions.

7 Q. They would understand that by
8 using a projected low alarm, you would
9 increase the sensitivity to detect a low
10 glucose condition?

11 MR. SARASWAT: Objection, scope.

12 A. I believe they would understand
13 that it would detect more events.

14 BY MR. WILLIAMS:

15 Q. Okay. Is there anything in this
16 document that suggests the predictive alerts
17 would cause a high incidence of false alarms?

18 MR. SARASWAT: Objection, scope.

19 A. I believe the next page alludes to
20 that when it says when the detection rate is
21 maximum, you look at the greatest number of
22 alarms. When the detection rate is minimum,
23 you would get the fewest number of alarms.

24 BY MR. WILLIAMS:

25 Q. Does it say that those alarms are

1 going to be false alarms?

2 A. I believe it's implied.

3 Q. Why?

4 A. Well, if you get more alarms, a
5 person -- if you get more alarms, a person of
6 skill in the art would understand that with
7 more alarms you get more false-positive
8 alarms.

9 Q. Go back to page 68 for a moment,
10 under the paragraph I had you read earlier.

11 Can you read the next paragraph
12 that begins "High" or "High and low."

13 Just read that out loud for us.

14 A. The whole paragraph?

15 Q. The first sentence.

16 A. "High and low glucose threshold
17 alarms can detect a low or high glucose
18 condition more often than projected and
19 projected low glucose alarms."

20 Q. And it has a parenthetical
21 referring the reader to the performance
22 characteristics section.

23 Do you see that?

24 A. I do.

25 Q. So that sentence that you just

1 read suggests that the threshold alarms
2 detect a low glucose state more often than a
3 projected low alarm, correct?

4 MR. SARASWAT: Objection, scope.

5 A. I need to look at the performance
6 characteristics to get the details.

7 I'm trying to find the performance
8 section, but I do think the line is somewhat
9 ambiguous. I mean, more detail is -- is
10 required. I can give you an example, if
11 you'd like.

12 BY MR. WILLIAMS:

13 Q. Sure.

14 A. If we said hypoglycemia -- let's
15 say hypoglycemia is 70. I can probably
16 detect 100 percent of the events below 70 by
17 setting the threshold at 120, but you will
18 get false alarms -- you will get false
19 alarms.

20 Q. So you're not able to tell whether
21 the threshold alarms detect low glucose state
22 more often than projected alarms. Is that
23 what you're saying?

24 MR. SARASWAT: Objection, scope.

25 A. I'd need more details. I need to

1 know what is the -- what is the parameter
2 values for the threshold alarms, what is the
3 parameter values for the high and low glucose
4 predictions.

5 BY MR. WILLIAMS:

6 Q. So you wouldn't take -- you
7 wouldn't take these are manual suggestion at
8 face value, then, is that what you're saying?

9 MR. SARASWAT: Objection, scope.

10 A. Yeah, I'd need to find the
11 performance characteristics to make -- to
12 give an informed answer.

13 (Pause in proceeding.)

14 BY MR. WILLIAMS:

15 Q. We had a little interruption.

16 But do you remember the question?

17 A. Yeah, I do.

18 Your question was in relation
19 to -- your question was in relation to the
20 line "High and low glucose threshold alarms
21 can detect a low or high glucose condition
22 more often than projected high and projected
23 low glucose alarms"?

24 Q. Correct.

25 A. Yeah, so I -- I mean, my first

1 answer was I need more details because it's
2 too ambiguous. You know, a threshold alarm
3 could be set higher and you'd have to do the
4 analysis to determine which was -- which was
5 detecting more there. So I want to see the
6 alarm performance to understand -- I want to
7 see the numbers where it shows that.

8 In the appendix and the
9 specification, it says, "The threshold alarm,
10 as characterized below, the projected alarm
11 performance has not been established."

12 So I don't understand -- I don't
13 understand this. I mean, they're referencing
14 something that -- the reference says it
15 hasn't been established.

16 So -- and all I can say is, you
17 know, it wouldn't be clear to a person of
18 skill in the art. You need more information,
19 ideally data results.

20 Q. Okay. So it's possible that the
21 authors of this user guide were inaccurate
22 when they said that high and low glucose
23 threshold alarms can detect a high -- a low
24 or high glucose condition more often than
25 projected high and projected low glucose

1 alarms?

2 MR. SARASWAT: Objection, scope.

3 A. Not necessarily inaccurate. They
4 didn't provide enough information.

5 BY MR. WILLIAMS:

6 Q. I see.

7 MR. SARASWAT: Sorry.

8 MR. WILLIAMS: Yeah, you're not
9 going to have the whole transcript. Is that
10 what you're asking?

11 MR. SARASWAT: No, I'm asking
12 about the real-time.

13 MR. WILLIAMS: Yeah. Let's go off
14 the record for a second.
15 (Off-the-record discussion.)

16 BY MR. WILLIAMS:

17 Q. Okay. Does that Navigator guide
18 say that predictive alarms were inaccurate?

19 A. I'd have to look, have a really
20 close look. Certainly -- certainly they
21 didn't include -- certainly they didn't
22 provide the predictive results from their --
23 from their study, which doesn't really make
24 sense because they have the data.

25 Q. Sorry.

1 When you say they have the data,
2 what data are you talking about?

3 A. That they've -- they have data in
4 the performance section for threshold alerts,
5 but it could have been reprocessed for
6 predictive or -- it could have been -- the
7 data could have been retrospectively analyzed
8 for predictive alerts.

9 BY MR. WILLIAMS:

10 Q. What does that mean, a
11 retrospective analysis?

12 A. You already have the data, so you
13 don't have to detect it in a -- what's the
14 best way to put it? You don't have to take a
15 predictive study as in you don't have to
16 do -- you have to run the study beforehand.
17 You have data, you can run the algorithms
18 through your -- you can run the data through
19 your algorithms and simulate what the answers
20 would have been.

21 Q. I see.

22 But they don't report the results
23 of the projected alerts in the appendix that
24 you're reviewing, correct?

25 A. No, they do not.

1 MR. SARASWAT: Objection, scope.

2 BY MR. WILLIAMS:

3 Q. All right. Just going back to the
4 Kamath paper for a moment. That's
5 Exhibit 2006.

6 Do you have that?

7 A. Yep.

8 Q. In the introduction section -- did
9 you misplace something?

10 A. I'm looking for my pen. Here it
11 is.

12 Q. I was going to ask you about the
13 introduction section to this paper.

14 A. Yep.

15 Q. The first sentence says, "Low and
16 high glucose alerts are standard features on
17 every continuous glucose monitors CGM."

18 Do you see that?

19 A. I do.

20 Q. Do you agree with that?

21 MR. SARASWAT: Objection, scope.

22 A. I would say it's certainly true.

23 Now, you know, the monitors on the market now
24 certainly all have -- the monitors on the
25 market now all have the real-time features,

1 the real-time predictive features.

2 BY MR. WILLIAMS:

3 Q. I'm sorry. Yeah, I was asking a
4 totally different question.

5 Do you agree that, as of 2010,
6 that low and high glucose alerts were
7 standard features on every CGM?

8 MR. SARASWAT: Objection, scope.

9 A. I -- I'm not honestly sure. I
10 don't know exact, you know, when products
11 with these features were launched.

12 BY MR. WILLIAMS:

13 Q. Do you think, in that sentence,
14 he's referring to predictive alerts?

15 A. Oh, I apologize.

16 MR. SARASWAT: Objection, scope.

17 A. It doesn't state if it's threshold
18 or predictive.

19 BY MR. WILLIAMS:

20 Q. Right.

21 So what would you have assumed, as
22 a person of ordinary skill in the art reading
23 that sentence, that he was talking about? Is
24 it predictive or threshold alerts?

25 MR. SARASWAT: Objection, scope.

1 BY MR. WILLIAMS:

2 Q. Or both?

3 MR. SARASWAT: Same objection.

4 A. I mean, it is -- it's lacking
5 specificity because you don't have alerts on
6 every CGM, certainly not the retrospective
7 ones. You know, alerts are really a
8 real-time feature. But certainly the CGM
9 devices, real-time CGM devices have threshold
10 alerts.

11 BY MR. WILLIAMS:

12 Q. And that was true as of 2010?

13 MR. SARASWAT: Objection, scope.

14 A. The -- as I said, you know, I'm
15 not sure of when these particular products
16 were launched.

17 BY MR. WILLIAMS:

18 Q. If you turn to the page that has
19 Table 3 on it. It's page 61.

20 You see that table?

21 A. Yes.

22 Q. Okay. I'm actually going to ask
23 you about something below that. So at the
24 bottom of the right column there's a
25 paragraph that begins "There is a tradeoff."

1 Do you see that sentence?

2 A. I do.

3 Q. Okay. And it reads, "There is a
4 tradeoff in the setting CGM alerts between
5 increased safety with higher TA rates (lower
6 MA rates) and increase nuisance with higher
7 FA rates."

8 Do you understand what that
9 sentence means?

10 A. Sorry. I'm just confirming that
11 TA is true alerts, and MA is missed alerts.

12 Q. Yeah, that's one of the things I
13 wanted to ask you about.

14 So that's your understanding of
15 what those acronyms mean?

16 A. People use different acronyms. I
17 don't know that I would have used the -- you
18 know, the TA, FA myself, but -- So true
19 alerts, missed alerts. Okay. So true
20 alerts, missed alerts.

21 So there's a tradeoff in setting
22 CGM alerts between increased 50 with higher
23 true alert rates. There's a tradeoff in
24 setting CGM alerts between increased 50 with
25 higher true alert rates (lower missed --

1 lower missed alert rates) and increased
2 nuisance with higher false alert rates.

3 I would agree with that sentence.

4 Q. Okay. And that was your
5 understanding of the art at the time as well,
6 correct?

7 A. Correct.

8 Q. All right. And he referenced --
9 and at the end -- if you go to the next page
10 where he finishes that sentence, he refers to
11 Figure 5, which is a few pages later.

12 Do you see Figure 5?

13 A. Yeah.

14 Q. Okay. And this Figure 5 is
15 labeled a "Receiver-operator characteristic
16 curve."

17 Are you familiar with this kind of
18 curve?

19 A. I am.

20 Q. Can you kind of explain what's
21 being shown here?

22 MR. SARASWAT: Objection, scope.

23 A. A receiver-operator curve is a way
24 to set parameters optimally by -- by plotting
25 the -- the true-positive and false-positive

1 rates against each other, and looking for
2 optimal thresholds to give the best -- to
3 give the best results.

4 Or not necessarily the best
5 results, the results that you like the best.

6 BY MR. WILLIAMS:

7 Q. Okay. And when you say "like the
8 best," what do you mean? How would you
9 decide which results you like the best?

10 A. It's -- it actually -- there's not
11 always -- you can't always point to a place
12 on the line and say that's the -- that's is
13 the fast- -- that's the objective.

14 It could be -- it could be that,
15 you know, somebody rather would have lots of
16 false alarms to ensure they detect more of
17 the true alarms; whereas someone else might
18 hit false alarms, we call them nuisance
19 alarms, and, therefore, detect less true
20 alarms to reduce false-positives.

21 BY MR. WILLIAMS:

22 Q. Are you saying nuisance alarms are
23 synonymous with false alarms?

24 A. Not necessarily. Nuisance alarms
25 are alarms you get that you don't want.

1 Certainly false-positive alarms would -- can
2 be described as a nuisance.

3 Q. Would a true alarm be described as
4 a nuisance, in your view?

5 A. I don't think so, not in the terms
6 of CGM. You know, I -- yeah.

7 Q. Okay. So when Kamath talks about
8 this tradeoff in setting CGM alerts, do you
9 have a sense of how he was controlling that
10 tradeoff, what settings he had available to
11 him?

12 MR. SARASWAT: Objection, scope.

13 A. Could you repeat the question?

14 BY MR. WILLIAMS:

15 Q. When Kamath talks about this
16 tradeoff in getting CGM alerts, what settings
17 was he talking about controlling?

18 MR. SARASWAT: Objection, scope
19 and form.

20 A. He's not -- I think he's just
21 showing an analysis of, you know, the
22 true-positive rate against the false-positive
23 rate.

24 BY MR. WILLIAMS:

25 Q. Okay. At the top of page 62,

1 which is above Figure 3, it says, "As actual
2 alert settings are adjusted to increase
3 the" -- sorry -- "TA rate (the vertical
4 position on the grid), the FA rate (the
5 horizontal distance from the left extreme of
6 the grid) also increases (Figure 5)."

7 Do you see that?

8 A. I do.

9 Q. Okay. Does that suggest to you
10 that he was adjusting the alert settings?

11 MR. SARASWAT: Objection, scope.

12 A. What he's showing is as you adjust
13 the -- as -- with this retrospective
14 analysis, he's showing that, you know,
15 with -- with more true alerts, you get more
16 false alerts.

17 BY MR. WILLIAMS:

18 Q. So maybe it's easier if I just ask
19 you about Figure 5A.

20 Do you have that figure?

21 A. I do.

22 Q. Okay. It looks, from the caption
23 there for 5A, that he's got three different
24 alert settings graphed, 70, 80, or 90
25 milligrams per deciliter.

1 Have I interpreted that
2 correctly?

3 MR. SARASWAT: Objection, form and
4 scope.

5 A. Figure 3A?

6 BY MR. WILLIAMS:

7 Q. Sorry. Figure 5A.

8 A. So he's showing that the false
9 alerts, as a function of true alerts, to
10 detect the target level of 70 with settings
11 of 70, 80 and 90.

12 Q. Okay. And at the setting of 70,
13 he had a false alert rate of something less
14 than 10 percent, and a true alert rate of
15 between 60 and 70 percent; is that right?

16 MR. SARASWAT: Objection, scope.

17 A. So by -- based on the analysis of
18 this characteristic, with a threshold setting
19 of 70 milligrams a deciliter, you would have
20 detected approximately between 60 and 70
21 percent of events with a false alert rate of
22 less than 10 percent.

23 BY MR. WILLIAMS:

24 Q. And, similarly, at a threshold
25 setting of 90, you would have detected false

1 alerts between 20 and 30 percent of the time
2 and true alerts a little over 90 percent of
3 the time; is that right?

4 MR. SARASWAT: Objection, scope.

5 A. Based on analysis of this very
6 particular data set, it shows that setting
7 of -- with a setting of -- with the threshold
8 of 90 milligrams a deciliter, you would have
9 got a false alert rate between 20 and 30
10 percent.

11 BY MR. WILLIAMS:

12 Q. And what would the true alert rate
13 have been?

14 A. True alert rate would have been
15 above 90 percent.

16 Q. When he talks -- going back to
17 page 61, which is under Table 3, he talks
18 about increased safety.

19 What's your understanding of what
20 that means? Page 61 has Table 3 on it.

21 A. You said just under Table 3?

22 Q. At the very bottom of the page on
23 the right, he talks about increased safety
24 with higher TA rates.

25 What's your understanding of what

1 he means by "increased safety" there?

2 A. In this context, if you are --
3 you're getting a lot of false-positives based
4 on your settings, and you're willing to
5 accept that, that you will get more true
6 positives. In that sense, it is -- that's
7 what I believe -- in that sense, it's safer
8 because you're going to be alerted to the
9 hypoglycemia more often if you follow the
10 alerts, every alert, but it comes with the
11 nuisance factor --

12 Q. Okay.

13 MR. WILLIAMS: This may be a good
14 time to take a break for lunch.

15 MR. SARASWAT: Yeah, and lunch is
16 here.

17 MR. WILLIAMS: Okay.

18 (Recess taken at 12:09 p.m. to 12:44 p.m.)

19 BY MR. WILLIAMS:

20 Q. Welcome back.

21 A. Thanks.

22 Q. Have you discussed the substance
23 of your testimony from this morning with
24 anyone else?

25 A. No one.

1 Q. Okay. Let me ask you -- back in
2 your declaration on paragraph 46 again. It's
3 on page -- I think it's page 23.

4 I want to ask you about paragraph
5 46 and your statement that "the prevailing
6 view in the art was that predictive alarms
7 were inaccurate..." Okay?

8 If that's true, why did Medtronic
9 use predictive alarms in the Guardian
10 REAL-time device?

11 MR. SARASWAT: Objection, scope.

12 A. Yeah I -- I can't really -- I
13 can't really speak for, you know, Medtronic
14 and their marketing department.

15 I think -- I think predictive
16 alerts do have their place. A lot of it --
17 it certainly can be a nuisance, but it's user
18 preference as well. Everybody is different.
19 Some people are extremely regimented and
20 would -- could accept false-positives and
21 more.

22 BY MR. WILLIAMS:

23 Q. Okay. And a person of ordinary
24 skill in the art would have understood that
25 at the time?

1 A. Correct, yeah. They are
2 certainly -- I mean, the term came about
3 "nuisance alerts," but they have a place.

4 Q. Okay. Let me just put the patent
5 in front of you. This is a document
6 previously marked as Exhibit 1001.

7 Let me switch copies with you just
8 in case there's a marking in there.

9 Do you recognize this document?

10 A. I do.

11 Q. What is it?

12 A. It's the '215 Dexcom patent.

13 Q. Okay. You reviewed this document
14 before?

15 A. I have.

16 THE REPORTER: Keep your voice up,
17 sir.

18 A. I have.

19 BY MR. WILLIAMS:

20 Q. Okay. I'm going to turn to the
21 claim, Claim 1, which is in Column 48.

22 Do you have that in front of
23 you?

24 A. I do.

25 Q. You've reviewed this claim before

1 as well, correct?

2 A. I have.

3 Q. What is your understanding of a
4 hypoglycemic indicator as used in this claim?

5 A. So in this claim, I see a
6 hypoglycemic indicator can be an alert or an
7 alarm.

8 Q. Is there a difference between an
9 alert or an alarm, in your view?

10 A. In this context, alert, alarms,
11 no. They -- alert, alarms -- certainly in
12 this context, they're all used
13 interchangeably, but I see no real specific
14 difference.

15 Q. Could an indicator be something
16 other than an alert or an alarm?

17 MR. SARASWAT: Objection, scope.

18 A. In the context here, the indicator
19 is taken as an alert and an alarm.

20 BY MR. WILLIAMS:

21 Q. So what -- can you give me an
22 example as something that would qualify as an
23 alert in the context of this patent? For
24 instance, would displaying a glucose value be
25 considered an alert?

1 A. Well, an alert would be something
2 that's -- that -- that alerts the user. In
3 the example of a hypoglycemic alert, it would
4 alert the user to hypoglycemia or impending
5 hypoglycemia. Something just flashing on the
6 screen wouldn't -- I wouldn't see as an alert
7 unless it was flashing alert. You know, it
8 would really depend on what's being flashed.
9 Ultimately, it's still -- it's to inform
10 the -- the patient.

11 Q. Just looking at the language of
12 Claim 1, for instance, the last element talks
13 about "providing an output including a first
14 hypoglycemic indicator."

15 Do you see that?

16 A. I do.

17 Q. An indicator in that context,
18 could that include displaying a glucose
19 value?

20 A. I -- I don't think so, not just a
21 glucose value. It must alert the patient
22 to -- to what you want to alert the patient
23 to.

24 Q. Do you see the word "alert" in
25 Claim 1?

1 A. I do not.

2 Q. So is it your opinion that Claim 1
3 requires an alert?

4 A. No, as I mentioned, indicator,
5 alert, alarm are used interchangeably
6 throughout this.

7 Q. Okay. So, in your view, would
8 displaying a glucose value constitute a
9 hypo- -- an output including a first
10 hypoglycemia indicator if that glucose value
11 was in a hypoglycemic range?

12 MR. SARASWAT: Objection, form.

13 A. In the context of the claim, an
14 indicator is -- can be used interchangeably
15 with alarm and alert.

16 BY MR. WILLIAMS:

17 Q. Okay. So would displaying a
18 glucose value be an indicator?

19 MR. SARASWAT: Objection, scope.

20 A. I don't see how glucose value
21 would be an indicator.

22 BY MR. WILLIAMS:

23 Q. What if it was flashing, would it
24 be an indicator then?

25 A. I don't see -- I don't see how it

1 would be an alert or an alarm.

2 Q. What would it need to do to be an
3 alert or an alarm?

4 A. It could buzz; it could sound. It
5 really needs to indicate that you're quite
6 hypoglycemic. If that's your -- if it's a
7 hypoglycemic indicator.

8 BY MR. WILLIAMS:

9 Q. Why doesn't -- why isn't a
10 glucose -- well, for instance, what if it was
11 a glucose value of 40, why wouldn't that
12 indicate that you're in a hypoglycemic state?

13 MR. SARASWAT: Objection, scope.

14 A. Well, the -- the algorithm
15 determines if you're in a hypoglycemic state.

16 BY MR. WILLIAMS:

17 Q. Sorry, what algorithm are you
18 talking about?

19 A. Well, I mean, you cannot just say
20 a number is -- the claim discusses, you know,
21 when an alert, an alert, an alarm would be --
22 would be executed.

23 Q. Do you see the word "alert" or
24 "alarm" in this claim somewhere?

25 A. I see the term "indicator."

1 Q. Okay. So that's what I'm trying
2 to understand.

3 Is there a difference between
4 indicator or alert, or does an indicator have
5 to be an alarm?

6 MR. SARASWAT: Objection, form.

7 A. In the context here, indicator,
8 alert, alarm are used throughout the spec.

9 BY MR. WILLIAMS:

10 Q. Right.

11 And in the claim, they used the
12 word "indicator," correct?

13 A. Correct.

14 Q. Okay. So to a person of ordinary
15 skill in the art, I'm trying to understand
16 what would -- how would you know if you had
17 an indicator? What is the criteria you would
18 use to determine that what you're seeing on
19 the display is an indicator as opposed to
20 your glucose value?

21 MR. SARASWAT: Objection, scope.

22 A. A person of skill in the art
23 would -- would, you know, see an indicator as
24 an alert or an alarm. And certainly in the
25 context of the specifications and exhibits,

1 it's used similarly together.

2 BY MR. WILLIAMS:

3 Q. So, then, is it the case that a
4 continuous glucose monitor that does not
5 vibrate or make a sound could not practice
6 this claim?

7 MR. SARASWAT: Objection, scope.

8 A. I mean, if the -- the claim has to
9 be implemented in the device.

10 MR. WILLIAMS: Move to strike.

11 BY MR. WILLIAMS:

12 Q. Did you understand my question?

13 A. I think so.

14 MR. WILLIAMS: Can you read back
15 the last question?

16 THE REPORTER: "So, then, is it
17 the case that a continuous glucose monitor
18 that does not vibrate or make a sound could
19 not practice this claim?"

20 MR. SARASWAT: Objection, scope.

21 A. So Figure 4A in the patent shows
22 a -- shows a low alert screen that could be
23 displayed responsive to a host's
24 concentration falling below a lower boundary.

25 THE REPORTER: Were you reading

1 something, sir, there? Because I didn't
2 quite get it.

3 THE WITNESS: I'm so sorry. I
4 was -- I'll speak up.

5 THE REPORTER: Shows a low rate?

6 A. Figure -- yeah, shows a low alert
7 screen that could be displayed responsive to
8 a host's analytic concentration falling below
9 a lower boundary.

10 BY MR. WILLIAMS:

11 Q. So is 4A a example of an indicator
12 that would satisfy the claim?

13 A. It is.

14 Q. Okay.

15 MR. SARASWAT: Objection, scope.

16 BY MR. WILLIAMS:

17 Q. And 4A, can you explain what it is
18 that is shown on Figure 4A?

19 MR. SARASWAT: Objection, scope.

20 A. To satisfy aspects of the claim...

21 So Figures 4A to F illustrate the
22 difference between a large generator based
23 on -- based on the first function.

24 So what you're looking at in
25 Figure 4A is -- well, we can take a look.

1 THE REPORTER: I have to hear you
2 sir.

3 A. Okay. So Figure 4A is an
4 illustration of an LCD screen showing
5 continuous and single glucose information in
6 the form of a trend graph in a single
7 numerical value.

8 BY MR. WILLIAMS:

9 Q. And so the trend graph is shown on
10 the left side and the value is shown on the
11 right side, correct?

12 MR. SARASWAT: Objection, scope.

13 A. And so Figure 4 is an illustration
14 of an LCD screen showing continuous and
15 single point glucose information in the form
16 of a trend graph that is 184. We can see the
17 trend graph in the middle, and the single
18 numerical value, 186, which is top right, at
19 283 milligrams a deciliter.

20 BY MR. WILLIAMS:

21 Q. And it was your testimony before
22 that Figure 4A is an example of an indicator
23 that would satisfy the claim, correct?

24 MR. SARASWAT: Objection, scope,
25 and form.

1 (Off-the-record discussion.)

2 MR. SARASWAT: Well, it only
3 caught one of my objections. It just says
4 "Objection, scope."

5 (Off-the-record discussion.)

6 A. So here at Figure 4A -- so Figure
7 4A shows an example of a -- of a threshold
8 alert. Yes, it's an alert, because it's
9 below the -- it's below the threshold.

10 BY MR. WILLIAMS:

11 Q. Okay. Back to the claim language
12 for a moment.

13 "The element evaluating sensor
14 data using a first function to determine
15 whether a real-time glucose value meets one
16 or more user settable first criteria" is the
17 first -- that's the first element after
18 comprising.

19 Do you see that?

20 A. I do.

21 Q. Okay. What's your understanding
22 of what "one or more user settable first
23 criteria" is meant to indicate there?

24 A. So for -- for Claim 1, I would say
25 evaluating sensor data using a first function

1 to determine whether a real-time glucose
2 value meets one or more user settable first
3 criteria."

4 So -- what was the question again?

5 I think it says --

6 BY MR. WILLIAMS:

7 Q. What -- what user settable first
8 criteria are being referred to there?

9 MR. SARASWAT: Objection, form.

10 A. So a continuous -- hypoglycemic
11 indicator is based on continuous glucose
12 sensor data, so that the settable criteria
13 here would be a threshold.

14 Q. Okay. And in the specification,
15 there is a -- sorry, I should back up.

16 Do you know what I mean by the
17 word "specification" here?

18 A. Yes.

19 Q. Okay. That's the written part of
20 the patent?

21 A. Yeah.

22 Q. This is in the claims, I should
23 say?

24 A. Yep.

25 Q. That's what I mean by that word,

1 if I use it.

2 There is a term in the
3 specification called TV2.

4 Do you remember that?

5 MR. SARASWAT: Objection,
6 foundation.

7 A. Can you point me to it in the
8 specification?

9 BY MR. WILLIAMS:

10 Q. Well, why don't you turn to your
11 declaration on paragraph 34 first. Maybe
12 that will help you.

13 A. Okay. I'm here.

14 Q. Do you see there a reference to
15 TV2?

16 A. I do.

17 Q. And you call that a threshold; is
18 that right?

19 A. Yeah, here it's threshold TV2.

20 Q. And you have a citation in the
21 patent to that, I believe, somewhere, right,
22 starting Column 21, line 55?

23 A. Okay.

24 Q. This part of the specification is
25 talking about Figure 5, correct?

1 A. Correct.

2 Q. And have you looked at Figure 5?

3 A. I have.

4 Q. So can you explain your
5 understanding of what's shown in Figure 5?

6 MR. SARASWAT: Objection, scope.

7 A. So Figure 5 illustrates a
8 continuous trace of glucose values over a
9 24-hour period.

10 BY MR. WILLIAMS:

11 Q. Okay. What's TV1?

12 A. So TV1 is a -- is a upper
13 threshold that may be settable by the user.

14 Q. Okay. And a glucose value
15 exceeding that would indicate then what, a
16 hyperglycemic state?

17 A. If you're defining hyperglycemia
18 as above a threshold of 180.

19 Q. Okay. And then TV2 you indicated
20 was a -- well, I don't remember what you
21 said.

22 What is TV2?

23 A. Similarly TV2 may be settable and
24 generally defines the lower limit of glucose.

25 Q. Okay. All right.

1 And then do you have an
2 understanding of what TVP is?

3 A. TVP is the predictive threshold,
4 the threshold against which a predicted value
5 is compared.

6 BY MR. WILLIAMS:

7 Q. Do you have the patent, Column 22,
8 in front of you?

9 A. I do.

10 Q. So at the top of Column 22, it
11 says "in some embodiments TVP may represent a
12 value at or around 55 milligrams per
13 deciliter."

14 Do you see that?

15 A. Column 22, that would be line 9?

16 Q. Line 2.

17 A. Sorry, line 2?

18 Oh, yeah. "TVP may represent a
19 value at or around 55 milligrams per
20 deciliter." I do see it.

21 Q. So TVP is a threshold value of
22 glucose, but it may not be set by the user.

23 Is that your understanding?

24 MR. SARASWAT: Objection, form.

25 A. TVP may not be settable by the

1 user.

2 It may be a fixed value or a
3 permanent value set during factory settings.

4 BY MR. WILLIAMS:

5 Q. You're reading there from the
6 bottom of Column 21; is that right?

7 A. I was reading from the -- from the
8 declaration.

9 But, yeah, it says TVP may not be
10 settable by the user.

11 Q. Okay. Is it your understanding
12 that any of those values we just talked
13 about -- TV1, TV2, TVP -- would correspond to
14 the user settable first criteria?

15 MR. SARASWAT: Objection, form and
16 scope.

17 A. In the context of the claim,
18 the -- the indicator would be -- TV2 would be
19 the threshold for that piece of the claim.

20 BY MR. WILLIAMS:

21 Q. Which -- I missed which TV you
22 said.

23 A. Oh. The -- the user settable
24 hypoglycemic threshold.

25 Q. That would be TV2? Which TV? I

1 just didn't hear your answer.

2 A. That would be TV2 in Figure 5.

3 Q. Okay. Thank you.

4 Now, by 2011, other devices had
5 user settable threshold criteria, correct?

6 MR. SARASWAT: Objection,
7 foundation.

8 A. In 2011, there were -- there were
9 monitors on the market that had threshold
10 alerts.

11 BY MR. WILLIAMS:

12 Q. Okay. And we've looked at two
13 examples so far, the Abbott device and
14 the Guardian REAL-time device; is that right?

15 A. Correct.

16 Q. Both of those had user settable
17 threshold values, correct?

18 A. Correct.

19 Q. Okay. You know what, let's look
20 at one other one while we're on that topic.
21 I'll show you what's been previously marked
22 as Exhibit 1004.

23 Are you familiar with this
24 document?

25 A. I am.

1 Q. What is it?

2 A. It's the Dexcom STS CGM System
3 User's Guide.

4 Q. Okay. And were you aware of
5 this -- were you aware of this device during
6 your time at Medtronic?

7 MR. SARASWAT: Objection, scope.

8 A. I was -- I was aware of Dexcom
9 monitors. I know that they've had a number
10 of iterations, so I was aware Dexcom had a
11 CGM.

12 BY MR. WILLIAMS:

13 Q. Okay. And you were aware that
14 Dexcom had a CGM that was available by 2011,
15 correct?

16 A. Correct.

17 Q. Okay. Do you remember knowing
18 that that device was called the Dexcom STS?

19 MR. SARASWAT: Objection, scope.

20 A. I know Dexcom had a monitor STS.
21 In terms of timeline, you know, the platinum
22 and seven, I -- I don't know, you know, which
23 was which and which was launched, basically.

24 BY MR. WILLIAMS:

25 Q. Okay. Have you yourself checked

1 to see if this Dexcom STS manual was
2 available on Dexcom's website before 2011?

3 MR. SARASWAT: Objection, scope.

4 A. I -- it was a long time ago. I
5 didn't download -- I don't recall, you know,
6 having looked for it back then. I may have.
7 I don't know.

8 BY MR. WILLIAMS:

9 Q. Do you recall looking for the
10 manual, the STS manual back in that time
11 frame and not being able to find it?

12 MR. SARASWAT: Objection, scope.

13 A. I -- back in that time frame, I
14 don't recall.

15 BY MR. WILLIAMS:

16 Q. Okay. Are you familiar with the
17 operation of this -- have you reviewed this
18 manual recently?

19 A. Yes, I've reviewed it.

20 Q. Okay. And, in your opinion, did
21 this device have a user settable threshold
22 for hypoglycemic indicators?

23 A. Yeah. Section 7.3 of the STS CGM
24 guide discusses how to -- how a user can
25 change the threshold settings.

1 BY MR. WILLIAMS:

2 Q. Okay. And that -- the STS manual
3 called that setting that you just referred to
4 a glucose alert, correct?

5 MR. SARASWAT: Objection,
6 foundation.

7 A. The user guide refers to glucose
8 alert settings.

9 BY MR. WILLIAMS:

10 Q. The heading 7.3 is "Changing Your
11 Glucose Alert Settings," correct?

12 A. Correct.

13 Q. Okay. And that's the section that
14 you were just pointing to as disclosing
15 threshold -- glucose threshold, correct?

16 A. The user settable glucose
17 threshold.

18 Q. Okay. Now, there's also a
19 Section 4.3 called "Low Glucose Alarm."

20 Are you familiar with that
21 section?

22 MR. SARASWAT: Objection, scope.

23 A. I'm familiar with this section.

24 BY MR. WILLIAMS:

25 Q. Okay. And this is a separate

1 functionality from the alert that we just
2 looked at in Section 7.3, correct?

3 MR. SARASWAT: Objection,
4 foundation.

5 A. This section discusses a glucose
6 alarm.

7 BY MR. WILLIAMS:

8 Q. And can the user turn this alarm
9 off?

10 A. Could you explain "turn off"?

11 Q. Let me read to you the third line
12 of the -- Section 4.3. "You cannot change or
13 turn off the low glucose alarm."

14 Do you see that?

15 A. I see it.

16 Q. Okay. Do you have an
17 understanding of what that means?

18 A. I do.

19 Q. And do you agree with me that it
20 means that the user cannot turn off the low
21 glucose alarm?

22 A. So this particular alarm cannot be
23 deactivated.

24 Q. Okay. This alarm is triggered by
25 a threshold set at 55 milligrams per

1 deciliter, correct?

2 A. That is correct.

3 Q. And that threshold cannot be
4 changed by the user, correct?

5 A. That's correct.

6 Q. Okay. Now, going back to
7 Section 7.3, this low glucose alert threshold
8 can be changed by the user, correct?

9 A. So Section 7.3 discusses how the
10 user can change their glucose alert settings.

11 Q. Okay. And Section 7.3.2 explains
12 how to do that, correct?

13 A. That is correct.

14 Q. Okay. And on the right column,
15 the top right of that section, there's a
16 bullet that reads, "You may select low
17 glucose alert values from 60 milligrams per
18 deciliter to 90 milligrams per deciliter."

19 Do you see that?

20 A. Sorry. Yeah, I was looking at
21 the -- on the right side, yeah, it says you
22 may select low glucose alert values from 60
23 to 90 milligrams a deciliter.

24 Q. Okay. So that's a different range
25 than a low glucose alarm, correct?

1 A. The known user settable threshold
2 was 55, so the 60 to 90 is a different range.

3 Q. Okay. So is it fair to say this
4 device had two different thresholds for a low
5 glucose indication, one was user settable,
6 and one was not user settable?

7 MR. SARASWAT: Objection, form and
8 scope.

9 A. So the STS system has a known user
10 settable threshold of 55, then it has a low
11 user settable range.

12 BY MR. WILLIAMS:

13 Q. That starts at 60?

14 A. From 60 to 90.

15 Q. Okay. Thank you.

16 Okay. Now --

17 MR. WILLIAMS: By the way, I've
18 lost track of time, so you'll have to let me
19 know when we hit the hour or --

20 MR. SARASWAT: By my count, we're
21 a bit over an hour. We started at 12:45.

22 MR. WILLIAMS: Okay. We can take
23 a break now.

24 (Recess taken at 1:49 p.m. to 1:59 p.m.)

25 MR. WILLIAMS: Back on.

1 BY MR. WILLIAMS:

2 Q. Can you turn to paragraph 38 of
3 your declaration.

4 You see that first sentence
5 there?

6 A. I do.

7 Q. You say, "The '215 patent states
8 that the 'processor module may be configured
9 to evaluate sensor data using a second
10 function,' which is a parameter indicative of
11 glucose value..."

12 I didn't understand what you mean
13 here. When you say "which is a parameter,"
14 what are you referring to? What is a
15 "parameter indicative of glucose value"?

16 A. So I understand the parameter
17 indicative of glucose value to be a predicted
18 glucose value.
19 (Reporter clarification.)

20 A. -- to be a predicted glucose
21 value.

22 BY MR. WILLIAMS:

23 Q. And is that what you mean in this
24 sentence when you say "which is a parameter"?

25 So is it the -- is it the sensor

1 data that is the parameter indicative of
2 glucose value, is it the function that is
3 indicative of glucose value, or is it
4 something else?

5 A. A parameter indicative of glucose
6 value is predicted glucose value.

7 Q. But the sentence reads, "The '215
8 patent states that the processor module may
9 be configured to evaluate sensor data using a
10 second function, which is a parameter
11 indicative of glucose value."

12 So I'm trying to figure out in
13 that sentence, when you say "which is a
14 parameter indicative of glucose value," what
15 are you referring to? What is the parameter
16 indicative of glucose value in that
17 sentence?

18 A. The parameter is the predicted
19 glucose value.

20 Q. Okay. But the sentence doesn't
21 talk about predicted glucose value. That's
22 what's confusing me.

23 A. Well, the next --

24 MR. SARASWAT: Objection,
25 foundation.

1 THE REPORTER: What was your --
2 sir?

3 BY MR. SARASWAT:

4 Q. I didn't get your answer.

5 A. Oh, I apologize.

6 The next sentence talks about a
7 predicted glucose value.

8 Q. Okay. What is the "which"
9 referring to in this sentence that I just
10 read?

11 A. Well, by evaluating sensor data
12 using a prediction algorithm, you produce a
13 predicted glucose value.

14 Q. Is that something performed by the
15 second function?

16 A. The second function -- well, I can
17 go back to...

18 MR. SARASWAT: Objection,
19 foundation.

20 A. So it says "evaluate sensor data
21 using a second function, ' which is a
22 parameter indicative of glucose value, ' to
23 determine whether a predicted glucose value
24 meets one or more predictive alarm criteria.

25 Q. Does it create a predictive

1 glucose value?

2 MR. SARASWAT: Objection,
3 foundation, asked and answered.

4 A. So it's using a second parameter
5 indicative of a glucose value. So the
6 predicted glucose meets one or more of the
7 user settable criteria.

8 BY MR. WILLIAMS:

9 Q. Okay. Do you know if the second
10 function creates the predicted glucose value?

11 MR. SARASWAT: Objection, scope
12 and foundation.

13 A. So the second function comprises
14 of an algorithm to determine the predicted
15 glucose value.

16 BY MR. WILLIAMS:

17 Q. And are you reading from
18 somewhere?

19 A. Well, I mean, it's -- I am. I'm
20 reading from -- it's kind of all over the
21 specification.

22 Just as examples of what the
23 second function does, there's common filters,
24 neuro networks, auto regressive models.

25 THE REPORTER: And networks what?

1 THE WITNESS: Pardon?

2 BY MR. WILLIAMS:

3 Q. Auto regressive, is that what you
4 said?

5 A. Sorry. Auto regressive.

6 Q. Modes? What was the last thing
7 you said?

8 A. Neuro networks, auto regressive
9 models.

10 Q. "Models," that was the word she
11 couldn't understand.

12 A. Oh, sorry.

13 Q. Okay. Let me ask you a broader
14 question.

15 If you turn to paragraph 58 of
16 your declaration, your conclusion -- sorry --
17 your opinion there is that a person of
18 ordinary skill in the art reading the
19 specification of the '215 patent would have
20 understood the specification to limit the
21 second function to being predictive.

22 Have I got that right?

23 A. At paragraph 58?

24 Q. Yes. I'm just asking if that's
25 your opinion here.

1 Is that your opinion in this case,
2 that a person of ordinary skill in the art
3 reading the specification would have
4 understood it to limit the second function to
5 being predictive?

6 A. I can -- I could give my
7 explanation.

8 Q. No, we'll get there. I'm just
9 asking if that's your opinion.

10 A. My opinion?

11 Q. Do you have an opinion in this
12 case as to whether or not a person of
13 ordinary skill in the art reading the patent
14 would have understood the second function had
15 to be predictive?

16 A. I believe someone with -- with
17 skill in the art would have -- would have
18 understood that a parameter indicative of
19 glucose would have been predictive.

20 Q. Okay. Let me ask you about the
21 second function before we get there.

22 What about the second function,
23 does the second function have to be
24 predictive?

25 A. Sorry. Your question was does the

1 second function have to be predictive?

2 Q. Yeah.

3 The way I'm reading your -- the
4 way I'm reading this sentence that you wrote
5 in paragraph 58 is that a person of ordinary
6 skill in the art would have understood the
7 specification to limit the second function to
8 being predictive. That's the words you
9 wrote, and I'm trying to make sure I
10 understand them.

11 Is that your opinion, that a
12 person of ordinary skill in the art would
13 have understood that the second function must
14 be predictive?

15 A. Yes, that's my opinion.

16 Q. Okay. Why?

17 A. It's -- it's stated in the -- in
18 the specification where it says that the
19 present system and methods relate to
20 providing accurate -- accurate, predictive
21 alarms to the user.

22 Q. Okay. I need to know where you're
23 reading from.

24 A. Oh, I apologize. This is
25 paragraph 59 of the declaration.

1 Q. Of your declaration, okay. And
2 that's -- okay.

3 You're quoting there, though, from
4 the specification at Column 1, line 30; is
5 that right?

6 A. Sorry, line 30? I -- oh, from the
7 specification?

8 Q. Yes.

9 A. That's -- I believe so. Let me
10 look.

11 Q. Okay. So I'm in that -- you want
12 to turn to that part of the specification?

13 MR. SARASWAT: Hold on a second.
14 Were you done with your answer?

15 THE WITNESS: I was -- I can
16 elaborate further, but I was -- well, that
17 was part of the answer. I mean, I have --
18 BY MR. WILLIAMS:

19 Q. Okay. If you have a longer
20 answer, I'm happy to take it.

21 A. So I understood the statement, the
22 methods related to providing accurate
23 predictive alarms to a user limits the
24 invention by limiting the second function.

25 I reviewed the specification. It

1 only describes predictive alerts and alarms
2 provided by the second function on its --
3 there's a lot of examples of that.

4 Q. Are you done? Is that the end of
5 your answer?

6 A. It is.

7 Q. Okay. The specification has a
8 first function which is not predictive,
9 correct?

10 A. The -- the first function is not
11 predictive.

12 Q. Okay. All right.

13 Now, just turning back to this
14 Column 1, line 30 language that you had
15 started reading from earlier.

16 Do you have the patent in front of
17 you?

18 So this section is in -- under the
19 heading "Background," right?

20 A. Yes.

21 Q. And it reads -- it's two
22 sentences, correct, in that "Background"
23 section?

24 A. Yeah, it's two sentences.

25 Q. Okay. And the first sentence

1 reads, "The present systems and methods
2 relate to processing analyte sensor data from
3 a continuous analyte sensor."

4 Correct?

5 A. Correct.

6 Q. And the second sentence reads,
7 "More particularly, the present systems and
8 methods relate to providing accurate
9 predictive alarms to a user," correct?

10 A. Correct.

11 Q. So why -- so why do you think a
12 person of ordinary skill in the art reading
13 those two sentences would conclude that the
14 claims are limited to predictive alarms?

15 A. The -- as I understand from --
16 from talking with attorneys, when it's --
17 when the invention is specified like that,
18 it -- it can limit the claims.

19 Q. Like -- when you say "like that,"
20 what do you mean? Like what?

21 A. Well, the specification has stated
22 what the invention is about.

23 Q. Okay. Do you see the word
24 "invention" in that -- in either of those two
25 sentences?

1 A. Maybe I should have said in the
2 body -- in the invention. I mean, it's --
3 it's very clear language saying that this --
4 this present systems and methods relate to
5 providing accurate predictive alarms to a
6 user.

7 Q. Okay. Are the claims limited to
8 accurate alarms?

9 MR. SARASWAT: Objection, scope.

10 A. I think it's subjective what
11 accurate is. I'd have to -- accurate would
12 have to be defined before I can say what
13 accurate is. Accurate is subjective.

14 BY MR. WILLIAMS:

15 Q. You don't know what "accurate"
16 means in that sentence, correct?

17 MR. SARASWAT: Objection,
18 foundation.

19 A. I see it as improving accuracy, to
20 make it -- this is -- I can go back.

21 I think the word "accurate" in
22 this sentence is to make accurate.

23 BY MR. WILLIAMS:

24 Q. Okay. And you agree that a person
25 of ordinary skill in the art reading this

1 section of the specification would conclude
2 that the claims are limited to providing
3 accurate alarms, correct?

4 MR. SARASWAT: Objection,
5 foundation and scope.

6 A. The person of ordinary skill in
7 the art would -- would read this as
8 understanding that a parameter indicative of
9 glucose would be predictive -- would be a
10 predictive alert. And that's the only --
11 only predictive alarms that are put here.

12 And when looking, again, through
13 the specification, it's really about
14 prediction with the examples I mentioned
15 earlier, common filter, auto regressive, you
16 know, networks.

17 BY MR. WILLIAMS:

18 Q. Okay. So then you're saying that
19 the claims are not limited to providing an
20 accurate alarm; is that right?

21 MR. SARASWAT: Objection,
22 foundation and scope.

23 A. That is not correct.

24 Accurate hasn't been defined
25 there, but, as I mentioned, it's -- it is to

1 provide accurate alarms.

2 BY MR. WILLIAMS:

3 Q. Okay. Is there a way a person of
4 ordinary skill in the art would know whether
5 they were providing accurate alarms or not?

6 MR. SARASWAT: Objection, scope.

7 A. Through analysis. You have data,
8 you analyze it, and you assess the results to
9 make a judgment on accuracy.

10 BY MR. WILLIAMS:

11 Q. Okay. And was there an understood
12 way to do that as of 2011?

13 MR. SARASWAT: Objection, scope.

14 A. As of 2011, there were prediction
15 algorithms. Prediction algorithms have been
16 around for quite some time, particularly the
17 ones cited.

18 BY MR. WILLIAMS:

19 Q. The ones cited in the
20 specification, you're saying?

21 A. As -- as an example.

22 Q. Okay. And those were known to be
23 accurate?

24 MR. SARASWAT: Objection, scope.

25 A. I believe -- there's a range

1 prediction algorithms. Some are better than
2 others. Some are better at different
3 circumstances. Some may be better than
4 others in certain circumstances.

5 BY MR. WILLIAMS:

6 Q. That section in the background
7 talks about predictive alarms.

8 Do you see that?

9 A. I do.

10 Q. So do you -- is it your opinion
11 that the claims are limited to predictive
12 alarms?

13 MR. SARASWAT: Objection, scope.

14 A. It is my view that a parameter
15 indicative of glucose is limited to
16 predictive alerts.

17 BY MR. WILLIAMS:

18 Q. And is -- what's your basis for
19 that conclusion? Does it have anything to do
20 with Column 1, line 30 to 35 of the patent?

21 MR. SARASWAT: Objection, form.

22 A. To the best of my review of the
23 specification, the specification only
24 describes predictive alerts as being provided
25 by the second function. There are a number

1 of examples.

2 Evaluating sensor data using the
3 second function to determine whether a
4 predicted value meets one or more second
5 criteria.

6 Using a second function to
7 determine whether a predicted glucose --

8 THE REPORTER: Sir, if you're
9 reading, you need to try to be clearer.

10 A. Using a second function to
11 determine whether the predicted glucose value
12 meets one or more second criteria comprising
13 a (inaudible) risk predicted glucose value.

14 An embodiment of the first aspect,
15 the second function comprises a common filter
16 to determine the predicted glucose value.

17 A second -- and then, an
18 embodiment of the second aspect, evaluating
19 sensor data using a second function to
20 determine whether the predicted glucose value
21 meets one or more second criteria.

22 And then, an embodiment of the
23 second aspect, the second function comprises
24 a common filter to determine a predicted
25 value using an estimate.

1 (Reporter clarification.)

2 THE WITNESS: Sorry, I stopped
3 there.

4 A. -- using an impetus -- estimate
5 derivative change of blood glucose.

6 Yeah, there's some more examples.

7 BY MR. WILLIAMS:

8 Q. Okay. So those are examples
9 you're reading from your declaration,
10 correct?

11 A. Yeah, they're -- they're quotes
12 from the specification.

13 Q. Right.

14 And what is it about these
15 examples that have led you conclude that the
16 claim is limited to predictive alerts?

17 MR. SARASWAT: Objection,
18 foundation.

19 A. Well, the specification only
20 describes predictive alerts as being provided
21 by the second function. The limitation comes
22 from the sentence under "Background" where it
23 states that "The present systems and methods
24 relate to providing accurate predictive
25 alarms to a user."

1 I'm not -- I'm not a lawyer, but I
2 understand that if -- if -- if it's plainly
3 stated in the specification what the -- what
4 the invention is about, it can limit the
5 claims.

6 BY MR. WILLIAMS:

7 Q. Okay. The claim language itself
8 doesn't use predictive, right, in Claim 1?

9 A. The word "predictive" is not in
10 Claim 1.

11 Q. Okay. Did you, in forming your
12 opinion, consider the fact that predictive
13 doesn't appear in Claim 1?

14 A. From -- I mean, I think it's clear
15 in -- in -- when you look at Claim 1 with
16 respect to a specification that it's -- it's,
17 you know, really only talking about
18 prediction.

19 Q. I didn't understand your answer.
20 You said it's clear from looking
21 at Claim 1 --

22 A. Oh, sorry.

23 Q. -- that it's talking about
24 prediction?

25 A. No, I --

1 MR. SARASWAT: Objection,
2 foundation.

3 A. When looking at the second
4 function of Claim 1, when we discuss a
5 parameter indicative of glucose, when the
6 second function is described in the
7 specification, it only describes predictive
8 alerts.

9 BY MR. WILLIAMS:

10 Q. Okay. Could the inventor have
11 inserted "predicted glucose value" instead of
12 "parameter indicative of glucose value" into
13 the claim? Is that something they could have
14 done?

15 MR. SARASWAT: Objection,
16 foundation and scope.

17 A. I can't really speak to what the
18 inventor was thinking or who -- who wrote it.

19 BY MR. WILLIAMS:

20 Q. Did you review the history of the
21 patent applications that led up to this
22 patent in the course of your work in this
23 matter?

24 A. I saw there was a history. I
25 didn't -- I didn't -- I didn't review it in

1 any detail.

2 Q. If you go to the front page of the
3 patent. This is Exhibit 1001.

4 I should have asked, by the way,
5 before you got -- before you worked in this
6 case, had you had any familiarity with
7 patents?

8 A. Yes. I've filed some patents.

9 Q. You filed some patents, okay.
10 So on the first page of
11 Exhibit 1001, on the left column, about the
12 middle of the page there's something that
13 says "Related U.S. Application Data."

14 Do you see that?

15 A. I do.

16 Q. Okay. And it -- the section
17 begins there, and then it continues on to the
18 top of the next page.

19 Do you see that?

20 A. I do.

21 Q. Did you look at any of these
22 related U.S. applications in the course of
23 forming your opinion in this matter?

24 MR. SARASWAT: Objection, form.

25 A. I did not.

1 BY MR. WILLIAMS:

2 Q. Okay. And the very last one
3 listed there is Application Number 13/742694
4 filed on January 16th, 2013, now Patent
5 Number 9,119,528.

6 Do you see that?

7 MR. SARASWAT: Objection, form and
8 foundation.

9 A. I'm sorry, where was that?

10 BY MR. WILLIAMS:

11 Q. Okay. It's at the -- if you go to
12 the next column -- or the next page at the
13 top of Column 2 --

14 A. Uh-huh.

15 Q. -- there's a list there --

16 A. Yes.

17 Q. -- of continuation applications.

18 Do you see that list?

19 A. I do.

20 Q. Okay. So the last one of the list
21 is Application Number 13/742694 filed on
22 January 16, 2013, now Patent Number
23 9,119,528.

24 MR. SARASWAT: Objection.

25 /

1 BY MR. WILLIAMS:

2 Q. Do you see that?

3 MR. SARASWAT: Sorry. Objection,
4 foundation.

5 Counsel, did you say Column --
6 never mind.

7 A. I'm not seeing it.

8 BY MR. WILLIAMS:

9 Q. Sorry. It's the next page.
10 That's probably why you're struggling.

11 A. Oh, sorry about that. I
12 apologize. I'm sorry.

13 Q. No. Maybe I wasn't clear about
14 that.

15 All right. So at the top of the
16 second page, do you see the related U.S.
17 application data that I was referring to?

18 A. Yeah, the continuation of parts.

19 Q. Yeah, okay.

20 So now I wanted to talk about the
21 last one on that list, which is -- it ends
22 with Patent Number 9,119,528.

23 A. Yeah, I found it.

24 Q. Do you see that?

25 A. I see it.

1 Q. Okay.

2 And so that application -- that
3 patent you didn't review, correct?

4 A. I don't believe so.

5 Q. Well, let me put it in front of
6 you and double-check.

7 MR. WILLIAMS: This is a document
8 that's been marked Exhibit 1031.

9 MR. SARASWAT: I'm going to object
10 to this as outside the scope because the
11 witness said he hasn't reviewed it.

12 BY MR. WILLIAMS:

13 Q. So take -- take your time to look
14 at Exhibit 1031. And the question is, have
15 you reviewed this before?

16 A. I recognize some of the figures, I
17 guess, because it's -- it's from the
18 continuation, but -- but...

19 The '215 is the one I reviewed.
20 While I recognize figures, et cetera, but I
21 can't say that I've reviewed this one.

22 Q. Okay. And you said a moment -- in
23 one of your prior answers that it was a
24 continuation.

25 What's your understanding of what

1 "continuation" means?

2 MR. SARASWAT: Objection,
3 foundation and scope.

4 A. I -- I understand the
5 continuation, in part, to -- a way to add on
6 to another patent with further claims, but
7 you keep the original priority date.

8 Q. Okay. Okay. I don't think we
9 need to go any further down that rabbit hole,
10 then.

11 Let's return to your list of
12 excerpts from the specification that you're
13 relying on to interpret the claims.

14 You were reading earlier, I think,
15 from the section of your declaration starting
16 around page 27 through 33; is that correct?

17 MR. SARASWAT: Objection,
18 compound.

19 A. I read -- I read a couple of
20 paragraphs describing the prediction
21 algorithms that were quoted in the
22 specification.

23 BY MR. WILLIAMS:

24 Q. Okay. And do you believe that the
25 claim requires that the second function be

1 different from the first function?

2 A. I don't think it would make sense
3 if the first function and second function
4 were the same.

5 Q. Why not?

6 A. Because you've got the first
7 function. Why have function one and function
8 one?

9 Q. You mean why recite a claim like
10 that? What do you mean "Why have function
11 one and function one?"

12 A. Well, you've got a function with a
13 certain functionality to do one thing. And
14 if you continue inventing, you want to have
15 another value. You wouldn't -- why would you
16 have the same function twice? I don't
17 understand, I guess.

18 Q. On page 18 of your declaration,
19 you talk about block 530 of Figure 6. And it
20 starts there and goes to the next page.

21 Do you see that?

22 A. I do.

23 Q. All right. And then you quote
24 there on page 18 from the patent.

25 You say, quote, "'In block 530,

1 the second set of instructions or criteria
2 may include any algorithm or algorithms
3 suitable for evaluating sensor data to
4 determine whether a glycemic state (hyper or
5 hypoglycemia) is predicted," and then it goes
6 on.

7 Do you see that?

8 A. I do.

9 Q. Okay. And so are these
10 instructions executed by a processor?

11 MR. SARASWAT: Objection, scope.

12 A. So the second set of instructions
13 criteria are the algorithms for evaluating
14 the sensor data to determine whether a
15 glycemic state is predicted.

16 Q. Do you have the patent in front of
17 you?

18 A. Pardon?

19 Q. Why don't you get the patent in
20 front of you. Turn to Column 25, if you
21 would.

22 Okay. In that section of your
23 declaration we were just looking at, you were
24 quoting from the patent starting at line --
25 Column 25, line 8 and going through Column

1 26, correct?

2 A. Well, I was actually quoting from
3 the -- from the -- the declaration, which was
4 referencing, yeah.

5 Q. Referencing that section of the
6 patent?

7 A. Yes.

8 Q. Yeah, okay.

9 So at Column 25, line 3, it says,
10 "At block 530, processor module 214 may be
11 configured to evaluate the sensor data using
12 a second set of instructions or criteria."

13 Correct?

14 A. Correct.

15 Q. Okay. So the processor would be
16 executing the second set of instructions
17 here, right?

18 A. Could be. I mean, it depends. I
19 mean, processing -- you're processing it as
20 well. This is a -- you know, you're
21 processing a function.

22 I mean, ultimately everything has
23 to be implemented in -- in a device.

24 Q. Yeah, I guess that's what I'm
25 trying to understand.

1 How do you interpret the patent
2 here when it talks about a "second set of
3 instructions related to Block 530"? Is
4 that -- is that part of the second function
5 which is shown in Block 530 of Figure 6?

6 A. Well, Block 530 is, to repeat, I
7 mean, evaluate sensor data using the second
8 function to determine one or more second
9 criteria are met. So this is the -- you
10 know, the function -- this is a, you know,
11 function being executed.

12 Q. Uh-huh.

13 And what's your understanding
14 of -- in Column 25, line 4, what the second
15 set of instructions is referring to there?

16 A. So the second set of instructions
17 is related to the second function. The
18 second set of instructions is the function.

19 Q. Okay. Got it.

20 And the next sentence says, "In
21 some embodiments, the first set of
22 instructions from Block 520 is different than
23 the second set of instructions from Block
24 530," correct?

25 Did you see that sentence?

1 A. I did. I did. Sorry.

2 Q. Okay. In 520 -- and Block 520 in
3 Figure 6 is -- corresponds to the first
4 function, correct?

5 A. Correct.

6 MR. SARASWAT: Objection,
7 foundation, scope.

8 BY MR. WILLIAMS:

9 Q. Okay. So at least here in the
10 specification it's suggesting that the first
11 set of instructions doesn't have to be
12 different from the second set of
13 instructions, correct?

14 MR. SARASWAT: Objection, form.

15 A. I read it as two different
16 functions. I mean, it's first set of
17 instructions and second set of instructions.

18 BY MR. WILLIAMS:

19 Q. So you read that as they may be
20 different?

21 MR. SARASWAT: Objection, form.

22 A. I do read them as being different.
23 Although I don't know why -- why they could
24 be the same.

25 Q. I guess I'm just asking, do you

1 think that word "may" there means that they
2 can be the same or not?

3 MR. SARASWAT: Objection, form.

4 BY MR. WILLIAMS:

5 Q. Actually, let me withdraw the
6 question. That was a terrible question.

7 When it says "In some embodiments
8 they are different," do you think that means
9 in all embodiments they must be different?

10 MR. SARASWAT: Objection, form,
11 scope.

12 A. Yeah, I believe it says they're
13 different.

14 BY MR. WILLIAMS:

15 Q. Okay. Turn to Column 48 for me.
16 Do you have that column?

17 A. Sorry.

18 Q. Column 48?

19 A. Yeah.

20 Q. Okay. And then line 27. It
21 begins "therefore"?

22 A. I got it.

23 Q. Okay. It says, "Therefore, the
24 description and examples should not be
25 construed as limiting the scope of the

1 disclosure to the specific embodiments and
2 examples described herein, but rather to also
3 cover all modifications and alternatives
4 coming with the true scope and spirit of the
5 disclosure."

6 Do you see that sentence?

7 A. I do.

8 Q. Did you consider that sentence in
9 forming your opinions in this case?

10 MR. SARASWAT: Objection, form and
11 scope.

12 A. I'm just trying to recall reading
13 it. I know I read through this.

14 But still, I mean, the algorithms,
15 for instance, should not limit the -- the
16 disclosure. Just because column and filters
17 are in there and auto regressive are in
18 there, it should be broad enough to use any
19 prediction algorithm, for instance.

20 BY MR. WILLIAMS:

21 Q. Okay. But it still -- but, in
22 your view, the claim is limited to a
23 prediction algorithm?

24 A. I -- I think so. I think, you
25 know, based on -- based on the earlier

1 statement in the specification.

2 But, I mean, this -- I think
3 that's kind of a -- that's kind of a legal
4 thing. I'm not really qualified, you know,
5 to -- I can speak to what I think it's
6 saying, but whether it truly limits the
7 claims or not, I -- that's -- I don't have
8 the legal background, I think, to answer
9 that.

10 MR. SARASWAT: Counsel, it looks
11 like we've been going for a bit over an hour.

12 MR. WILLIAMS: Sure. Yeah, let's
13 take a break.

14 (Recess taken at 3:03 p.m. to 3:16 p.m)

15 BY MR. WILLIAMS:

16 Q. Okay. So what would you say are
17 the ways that Claim 1 of that patent differs
18 from prior art?

19 MR. SARASWAT: Objection, scope,
20 form.

21 A. In terms of the prior art,
22 everything that has been cited. One
23 instance, the second function that provides a
24 predictive alert or alarm, the guide does not
25 disclose predictive alerts.

1 You want me to go through these?

2 BY MR. WILLIAMS:

3 Q. What are you reading from?

4 A. Oh, just the -- from the
5 declaration. The -- where I've pointed out,
6 you know, where -- where, for example, the
7 guide doesn't meet the claim.

8 Q. I see. Okay. So the guide --
9 right.

10 In your view, the claim requires
11 predictive, and the guide doesn't have that;
12 is that correct?

13 A. The -- one example is that the --
14 the -- you know, the claim -- if the claim is
15 limited to predictive, the guide doesn't have
16 predictive.

17 Q. Okay. Have you read Harper?

18 A. I have.

19 Q. Okay. Do you agree Harper has
20 predictive alarms?

21 MR. SARASWAT: Objection, form,
22 scope.

23 A. Correct, Harper has predictions.

24 BY MR. WILLIAMS:

25 Q. Okay. Just going back to your

1 answer a minute ago about the guide.

2 Have you -- do you have an opinion
3 in this case about whether the guide would
4 invalidate the patent if the claim did not
5 require predictive?

6 In other words, have you formed an
7 opinion about that hypothetical, so assuming
8 the claim does not provide predictive alarms,
9 would the guide invalidate the claim?

10 MR. SARASWAT: Objection, form.

11 A. Well, I mean, the guide doesn't
12 have predictive alerts; therefore, it can't
13 meet the claim -- it cannot meet the limit of
14 the claim.

15 BY MR. WILLIAMS:

16 Q. So if the board -- sorry. Go
17 ahead.

18 A. No, please. Sorry. I apologize.

19 Q. I was just going to ask, if the
20 board disagrees with your view of what the
21 claim requires, and they say it doesn't
22 require predictive --

23 A. Uh-huh.

24 Q. -- do you have an opinion then
25 about whether the guide would meet the

1 elements of the claim?

2 MR. SARASWAT: Objection, form.

3 A. I still believe it wouldn't reach
4 the limit of the claim, as the -- the second
5 function parameter indicative of glucose
6 cannot be glucose, a real-time glucose value.

7 BY MR. WILLIAMS:

8 Q. Okay. What does parameter
9 indicative of glucose value mean in the
10 claim?

11 MR. SARASWAT: Objection, form.

12 A. I've taken it to mean that it's a
13 predictive value.

14 BY MR. WILLIAMS:

15 Q. I see. Okay.

16 A. But -- sorry.

17 Q. And is that why you -- okay.
18 Let's say the board disagrees and says it's
19 doesn't have to be predictive. Do you have
20 an opinion that the user guide still wouldn't
21 satisfy the claim?

22 A. I still think it --

23 MR. SARASWAT: Objection, form --
24 sorry. Objection, form.

25 Go ahead.

1 A. I still think it wouldn't satisfy
2 the claim.

3 BY MR. WILLIAMS:

4 Q. And why is that?

5 A. The claim is specific. It --
6 well, first of all, as I mentioned, it would
7 have -- it would have to be real-time
8 sensored glucose, and I don't see how it can
9 be. Because a real-time sensor glucose value
10 cannot be indicative of a real-time sensor
11 glucose value; it is a real-time sensor
12 glucose value.

13 And then the fact that there's two
14 functions. One has the real-time sensor
15 glucose value. It doesn't make any sense to
16 have two functions doing the same thing.

17 Q. Are you talking about the STS --
18 is it your opinion the STS User Guide has two
19 functions doing the same thing?

20 A. No, no, I'm talking about --
21 talking about the claim.

22 If the second function was to meet
23 the guide, it would have to do what the first
24 function is doing, which is a real-time
25 sensor glucose value.

1 Q. Okay. In the -- in the STS User
2 Guide, the low glucose alert is different
3 from a low glucose alarm, correct?

4 MR. SARASWAT: Objection, form.

5 A. Certainly in the specification
6 they're treated the same.

7 BY MR. WILLIAMS:

8 Q. Can you explain what you mean by
9 that?

10 A. Oh, that they alert, alarm. It's
11 just in general, they -- they're used
12 interchangeably quite a bit.

13 Q. Okay. Can you show me where?

14 A. I mean, just in -- just meaning in
15 general. Well, actually, on both. I can
16 find some examples, I'm sure.

17 Yeah, actually the specification
18 treats alert and alarm the same. They do
19 often get -- I find them all the time get --
20 be taken the same way, alert/alarm,
21 alarm/alert, you know.

22 But looking at the programming
23 guide, it's -- it looks like there's a
24 glucose alarm and then -- it looks like
25 there's a -- Section 4.3 has a low glucose

1 alarm, and then 4.2 has high and low glucose
2 alerts.

3 Q. Okay. So you're looking at
4 Exhibit 2 -- I'm sorry -- Exhibit 1004?

5 A. Yeah, the User Guide.

6 THE REPORTER: And what page were
7 you reading from, sir?

8 THE WITNESS: Page 54 and 56.

9 BY MR. WILLIAMS:

10 Q. All right. So I'm just not sure
11 what your answer meant.

12 Are you -- are you saying that you
13 believe the STS User Guide uses alert and
14 alarm interchangeably, or are you saying that
15 they're two different things?

16 MR. SARASWAT: Objection, form.

17 BY MR. WILLIAMS:

18 Q. Maybe I should be more clear.

19 Are you saying that the user guide
20 uses low glucose alert and low glucose alarm
21 interchangeably, or are you saying those are
22 two different things in the STS User Guide?

23 MR. SARASWAT: Objection to
24 form.

25 A. The user guide has high and low

1 glucose alerts, then a different section
2 called "Low Glucose Alarm," which first alarm
3 that cannot be -- cannot be turned off and
4 cannot be changed.

5 I'd have to go through the whole
6 document partly to check for -- to check if
7 there was -- if there is somewhere where it's
8 interchangeable, but...

9 BY MR. WILLIAMS:

10 Q. Okay. At least that section you
11 just looked at, they appear to be different,
12 correct?

13 MR. SARASWAT: Objection, form.

14 A. In this -- in those two sections,
15 they use alert in one and alarm in the other,
16 and their sections talk about different
17 things.

18 BY MR. WILLIAMS:

19 Q. Okay. And the outputs to the
20 display are different, correct?

21 MR. SARASWAT: Objection, form.

22 BY MR. WILLIAMS:

23 Q. I guess I should be more clear.

24 The outputs to the display between
25 a low glucose alert and a low glucose alarm

1 are different, correct?

2 A. The --

3 MR. SARASWAT: Objection, form.

4 A. The outputs are different. One
5 has 80 milligrams a deciliter low, and the
6 other one has 5 milligrams a deciliter low.

7 BY MR. WILLIAMS:

8 Q. Okay. And the font on the -- the
9 font color for the low glucose alert for the
10 glucose value is white on a black background,
11 correct?

12 MR. SARASWAT: Objection,
13 founda- -- withdrawn.

14 A. The low glucose alarm is black on
15 a white background, and the low glucose alert
16 is black on a white background also.

17 BY MR. WILLIAMS:

18 Q. Where are you looking?

19 A. Page 54 and 56.

20 Q. So my copy of page 54, I'm looking
21 at the low glucose alert screen, and it
22 appears to me that that 80 is in white font
23 on a black background.

24 Is that what yours shows?

25 A. Oh, sorry. I was looking at the

1 whole background.

2 The 80 is white with a black
3 background, and the alarm is black with a
4 white background.

5 Q. All right. Just going back to
6 parameter indicative of glucose in the -- in
7 the patent.

8 So it's your view that when that
9 term appears in the claims, it means a
10 predictive value; is that right?

11 MR. SARASWAT: Objection, form.

12 A. Based on my understanding of the
13 spec and the claims, a parameter indicative
14 of glucose I take to be predicted glucose and
15 limited to predicted glucose in this;
16 otherwise, unless the board disagrees or
17 something.

18 (Reporter clarification.)

19 THE WITNESS: -- if the board
20 disagrees as -- as was mentioned earlier.

21 BY MR. WILLIAMS:

22 Q. Okay. We talked about Harper a
23 moment ago, but I don't think I actually
24 handed you a copy. Let me hand you a copy of
25 Exhibit 1005.

1 Do you recognize Exhibit 1005?

2 A. I recognize it.

3 Q. Okay. And this is the Harper
4 reference you reviewed in forming your
5 opinions in this case?

6 A. I believe so.

7 Q. Okay. Are the -- and you said
8 earlier you agreed that there were predictive
9 alerts in Harper, correct?

10 MR. SARASWAT: Objection, form.

11 A. Harper has predictive alerts.

12 BY MR. WILLIAMS:

13 Q. And do you recall if Harper's
14 predictive alerts are user settable?

15 I think this may be discussed in
16 paragraph -- around paragraph 118 of your
17 report -- or of your declaration, if that
18 helps.

19 MR. SARASWAT: Objection,
20 foundation.

21 A. Harper's -- Harper's patent does
22 not have nonuser settable alerts.

23 BY MR. WILLIAMS:

24 Q. And paragraph 117 of your
25 declaration, have you reviewed that one? Do

1 you see that paragraph?

2 A. I do.

3 Q. You cite there to Harper paragraph
4 202.

5 Do you see that?

6 A. I do.

7 Q. Okay. Let's see. Do you have
8 Harper paragraph 202?

9 A. Oh, sorry.

10 Okay.

11 Q. Okay. So that paragraph that you
12 rely on teaches that there are various
13 glucose thresholds that can be set by the
14 user, including thresh- -- a threshold for
15 projected low glucose level, correct?

16 MR. SARASWAT: Objection, form.

17 A. Yes, this paragraph discusses
18 the -- where the user may select glucose
19 threshold levels for projected low glucose
20 levels and high glucose.

21 BY MR. WILLIAMS:

22 Q. Yeah.

23 Is it -- so do you have an opinion
24 about whether it would have been within the
25 level of skill in the art at the time, in

1 2011, to make that threshold nonuser
2 settable?

3 MR. SARASWAT: Objection, scope
4 and form.

5 A. I don't understand exactly. Could
6 you elaborate maybe? I don't know.

7 BY MR. WILLIAMS:

8 Q. Okay. Would a person of ordinary
9 skill in the art in 2011 have been able to
10 make Harper's low glucose -- projected low
11 glucose threshold nonuser settable?

12 MR. SARASWAT: Objection, scope.

13 A. I -- I don't think a person
14 skilled in the art would have went there just
15 because of the nature of predictive alerts,
16 particularly -- particularly back then with
17 false-positive rates.

18 BY MR. WILLIAMS:

19 Q. So what is it about false-positive
20 rates that would have prevented a person of
21 ordinary skill in the art from going in that
22 direction?

23 MR. SARASWAT: Objection,
24 foundation and scope.

25 A. The -- as we had talked a little

1 bit about earlier, nuisance alerts, they -- a
2 large number of false-positives or a number
3 of false-positives -- false alerts causes --
4 causes alarm fatigue, and it could be a
5 safety issue where, you know, you're -- you
6 can stop using your alerts because you're --
7 they drive you crazy.

8 If you hard-coded something in
9 that the patient can switch off, that
10 would -- that would -- could kill a product
11 for a large percentage of people. And
12 that's, I think, what could well have
13 happened, particularly back then, if you have
14 something fixed that goes off falsely a lot.

15 You could compare it to your --
16 your household alarm. You might get rid of a
17 burglar alarm to prevent burglars from
18 entering your house if it went off falsely
19 every night and neighbors complain. That
20 would be the risk.

21 BY MR. WILLIAMS:

22 Q. Right.

23 I guess, my question then is, why
24 wouldn't the device manufacturer have been
25 able to set a threshold that was not user

1 changeable that minimized those false alerts?

2 MR. SARASWAT: Objection, scope,
3 and form.

4 A. Sorry, so the question is, why
5 would a manufacturer do it?

6 BY MR. WILLIAMS:

7 Q. No, different question.

8 If that was the concern, the
9 concern at the time was these false alerts,
10 why wouldn't the manufacturer have been in a
11 position to set a projected alert threshold
12 that minimized those false alerts?

13 MR. SARASWAT: Objection, scope.

14 A. I'm sorry, I still don't
15 understand.

16 If the manufacturer -- you mean
17 the manufacturer came up with a way to
18 minimize the alerts -- minimize
19 false-positive alerts, is that --

20 BY MR. WILLIAMS:

21 Q. No.

22 I'm asking if the manufacturer --
23 the only parameter that was being set in
24 Harper here that we're talking about right
25 now is the projected low threshold,

1 correct?

2 MR. SARASWAT: Objection, form.

3 A. Yeah, Harper -- Harper was -- was
4 a user -- a user selectable threshold.

5 BY MR. WILLIAMS:

6 Q. Right.

7 And so a user could select that
8 threshold high, or a user could select that
9 threshold low, within the range that was
10 available to the user in Harper, correct?

11 MR. SARASWAT: Objection, form.

12 A. Harper, they were able to -- they
13 were able to select the -- they were able to
14 select the threshold.

15 BY MR. WILLIAMS:

16 Q. Right.

17 So they had some range of
18 thresholds available to them from which they
19 could select, correct?

20 A. I believe so.

21 Q. Okay. And depending on what they
22 picked, they may create more or fewer false
23 alerts, correct?

24 MR. SARASWAT: Objection, scope.

25 A. You could -- you can -- you could

1 set thresholds to give less false-positives,
2 you know, by changing thresholds.

3 BY MR. WILLIAMS:

4 Q. I understand, and so that's my
5 question.

6 Why, then, couldn't the device
7 manufacturer have made that decision for the
8 user, picking a threshold that would create
9 fewer false-positives?

10 MR. SARASWAT: Objection, scope
11 and form, and foundation.

12 A. The alerts have always been
13 settable by the user, particularly the -- you
14 know, the predictive. Obviously the guide
15 has -- has the 55 alarm that's nonuser
16 settable, but it's not -- it's not a
17 predictive, it's a threshold alarm.

18 And so the -- the reason was to
19 allow the -- the reason was to allow the
20 patient or the user to be able to switch
21 their alarms off and have some freedom
22 with -- you know, with managing their
23 diabetes within whatever range they wanted.
24 Everybody is different.

25 Particularly with a predictive

1 alert where -- where some people might want
2 to know well in advance or people may not,
3 and that affects the false-positives and
4 gives them some control over it.

5 Did that answer the question? I'm
6 not sure.

7 BY MR. WILLIAMS:

8 Q. I'm not sure either, but we have
9 your answer.

10 What is it about predictive alarms
11 that made them necessary -- well, why is it
12 that you think a device manufacturer would
13 have been reluctant to make the predictive
14 alarm nonuser settable?

15 MR. SARASWAT: Objection, scope.

16 A. If you -- it can't be changed, and
17 if the -- it can't be changed. If the
18 manufacturer does it, it's nonuser settable.
19 They're stuck with it. And you could end up
20 getting alarms a lot, and that would -- that
21 would stop them from using the product.

22 BY MR. WILLIAMS:

23 Q. Okay. Let me ask you about a
24 different document, which has been marked as
25 Exhibit 1007.

1 A. Thank you.

2 Q. Are you familiar with this
3 document?

4 A. Yeah.

5 Q. And this is a patent application
6 published in July of 2009, correct?

7 A. Correct.

8 Q. And the first named inventor here
9 is Shariati.

10 Do you see that?

11 A. I do.

12 Q. Okay. And you reviewed this
13 document in preparing your opinions?

14 A. I did.

15 Q. Okay. Shariati teaches a
16 predictive hypoglycemia alert, correct?

17 MR. SARASWAT: Objection, form.

18 A. Yes, Shariati has a -- has a
19 predictive algorithm also.

20 BY MR. WILLIAMS:

21 Q. Okay. And I'm looking -- if you
22 want to open Shariati to paragraph 571.

23 A. I'm there.

24 Q. Okay. And in that paragraph --
25 you have 571, right?

1 A. Yep.

2 Q. Okay. So Shariati calls this
3 predictive alarm a predicted hypoglycemia
4 alarm, correct?

5 A. Yeah, hypo or hyper alarm.

6 Q. Okay. And this predictive alarm,
7 as I understand this explanation, includes a
8 settable time period indicating a horizon
9 over which the prediction is to occur.

10 Is that your understanding as
11 well?

12 MR. SARASWAT: Objection, form.

13 MR. WILLIAMS: Actually, let me
14 withdraw the question.

15 BY MR. WILLIAMS:

16 Q. What's your understanding of how
17 the predictive hypoglycemia alarm in Shariati
18 works as described here at paragraph 571?

19 A. So this -- this is one of those
20 prediction algorithms that looks like it
21 uses, you know, a filtering approach to get
22 the rate of -- get the rate of change, and
23 then it used that to extrapolate out a time
24 period, to extrapolate forward a time period.

25 And they have selectable criteria

1 of 5 minutes, 10 minutes, 15, 20 minutes, and
2 compared to -- predicted value against
3 thresholds, and they have a list of
4 thresholds here for hypo and hyperglycemia --

5 BY MR. WILLIAMS:

6 Q. Okay.

7 A. -- which can be programmed in the
8 computer system.

9 Q. Okay. Got it.

10 So is that -- do you understand
11 that to be two different ways that this may
12 work, then, one which uses a time period, a
13 selectable time period, and one that uses a
14 selectable threshold?

15 MR. SARASWAT: Objection, form.

16 A. If I understand the question
17 correctly, this is -- I mean, this would just
18 be one function with different -- you know,
19 you can choose your parameter for your
20 prediction threshold and choose your
21 parameter for your prediction horizon.

22 BY MR. WILLIAMS:

23 Q. Okay. So you could -- you could
24 select both. Both of those things could be
25 changed -- or selected, I should say; is that

1 correct?

2 A. You could --

3 MR. SARASWAT: Objection, form.

4 THE REPORTER: "You could" is your
5 answer?

6 THE WITNESS: No, I haven't
7 finished.

8 I was going to say, you could
9 change the prediction horizon to -- well, it
10 gives you the values here, 5, 10, 15, 20
11 minutes, which is how far ahead you're --
12 you're predicting. Which really means if
13 it's a 20-minute prediction horizon and you
14 set your threshold to -- and you can set your
15 threshold to different values.

16 If you set your threshold to 70 or
17 20 minutes, it's really saying you want to be
18 warned 20 minutes in advance before you hit
19 70 if -- if things are accurate.

20 BY MR. WILLIAMS:

21 Q. I see.

22 Now, these -- the time horizon and
23 the thresholds, Shariati teaches that those
24 can be programmed into the computer or user
25 selectable for both of those things, correct?

1 MR. SARASWAT: Objection, form.

2 A. Shariati teaches that it can be
3 user settable or programmed into the system
4 by a user.

5 BY MR. WILLIAMS:

6 Q. Where are you reading from?

7 A. They're two different quotes, but
8 different places. But he says that it can be
9 programmed in the computer system is one
10 quote and later quotes that as saying that
11 it's programmed -- programmable by a user.

12 Q. Where does he say that?

13 (Reporter clarification.)

14 BY MR. WILLIAMS:

15 Q. Sorry. Where does he say that?

16 A. Let me -- it's at paragraph 333.

17 Q. And what in paragraph 333
18 indicates to you that the user can program
19 this device?

20 A. There's a -- there's a -- it's the
21 line that says it's programmable by a user.

22 Q. Are you talking about the line
23 that says, "The digital value from the analog
24 to digital converter is programmable by a
25 user"?

1 Is that what you mean?

2 A. That's what I mean.

3 Q. Okay. What's being discussed
4 there?

5 MR. SARASWAT: Objection, form.

6 A. The user is programming the sample
7 rate, I believe.

8 BY MR. WILLIAMS:

9 Q. What is -- what is the sample rate
10 in the CGM device? What does that refer to?

11 A. It may not be used as much in CGM
12 technology, because it -- but it's the --
13 it's the rate at which you acquire samples
14 from the sensor.

15 Q. So paragraph 333 describes that as
16 the sample rate of the digital filter.

17 Do you see that?

18 A. The sample rate of the digital
19 filter, yeah.

20 Q. What is a digital filter, in this
21 context?

22 A. A digital filter is typically a
23 set of coefficients that are convolved in
24 some way with the sensor signal to typically
25 reduce noise, but can do other things.

1 Q. In your experience, is it typical
2 to permit the user of a CGM monitor to
3 program the coefficients of the digital
4 filter?

5 MR. SARASWAT: Objection, scope.

6 A. Definitely not. They wouldn't be
7 able to program coefficients of a filter, but
8 I don't think this refers to that. I don't
9 think this refers to the digital
10 coefficient -- the coefficients of the
11 digital filter. I think it refers to the --
12 the samples that are acquired over a period
13 of time, the rate -- the sample rate, the
14 rate at which sensor samples are acquired.
15 And if that varies, the digital filter has to
16 vary.

17 BY MR. WILLIAMS:

18 Q. Right.

19 So the sentence that you're
20 pointing to says, "In preferred embodiments,
21 the processor module is configured with a
22 programmable acquisition time; namely, the
23 predetermined time interval for requesting
24 the digital value from the A to D converter
25 is programmable by a user within the digital

1 circuitry."

2 Right, that's the sentence you're
3 relying on?

4 MR. SARASWAT: Objection,
5 foundation.

6 A. "Accordingly, the acquisition time
7 determines the sample rate" --

8 THE REPORTER: Sir, when you're
9 reading --

10 THE WITNESS: Yeah, gotcha.

11 "Accordingly, the acquisition time
12 determines the sample rate of a digital
13 filter. In preferred embodiments, the
14 processor module is configured with a
15 programmable acquisition time; namely, the
16 predetermined time interval for requesting
17 the digital value from the A to D converter
18 is" programmed by a user -- "is programmable
19 by a user."

20 BY MR. WILLIAMS:

21 Q. Right. Okay.

22 But that -- so the thing that's
23 programmable here is the acquisition time,
24 correct?

25 A. Correct.

1 Q. And that acquisition time is the
2 thing that determines the sample rate of the
3 digital filter, correct?

4 A. I think so. It's -- it's not
5 written real clearly, but that's what it
6 means.

7 Q. Yeah. Okay.

8 And so, in your experience, would
9 it be common to allow the user of a CGM to
10 program the sample rate of the digital
11 filter?

12 MR. SARASWAT: Objection, scope.

13 A. Sorry, could you tell me the
14 question again?

15 BY MR. WILLIAMS:

16 Q. Yeah, I can -- I can rephrase it.

17 In your experience, would it be
18 common to allow the user of a CGM to program
19 the sample rate of the digital filter?

20 MR. SARASWAT: Objection, scope.

21 A. I think it's a good idea. It has
22 a lot of benefits. It can -- the user can
23 decide on the resolution of the signal
24 they're seeing, for instance; could reduce
25 noise and increase battery life, things like

1 that. It's a -- it's -- I mean, it's done in
2 other devices.

3 BY MR. WILLIAMS:

4 Q. In which devices, I'm sorry?

5 A. Oh, any device where you control
6 the resolution of -- of an image or a signal
7 that's doing the same thing or something
8 similar.

9 Q. Have you ever seen a CGM device on
10 the market where a user -- an end user is
11 allowed to program the sample rate of the
12 digital filter?

13 MR. SARASWAT: Objection, scope.

14 A. I have not, not a commercial
15 device.

16 BY MR. WILLIAMS:

17 Q. Do you know if the FDA would ever
18 approve such a device?

19 MR. SARASWAT: Objection, scope,
20 foundation.

21 A. I -- I can't speak for FDA, I know
22 this. But I don't see why not. It's -- you
23 could certainly implement something like that
24 where a patient can get the benefits
25 without -- without making it technical, in a

1 way they can understand it, you know.

2 BY MR. WILLIAMS:

3 Q. Okay. Why would the user want
4 less resolution?

5 A. I mean, I -- I think several
6 reasons. Less resolution, you would be
7 acquiring the samples. There could be a
8 number of reasons.

9 You have less noise with less
10 resolution. If you're looking at a signal,
11 and you wanted to -- you don't want to see --
12 you don't want to see fine resolution, which
13 is really showing you a lot of noise, so it
14 would be to -- it would reduce noise.

15 If you're -- I mean, I think you
16 got two seconds to 511 seconds -- I think
17 there was two seconds to 500 and something,
18 that's quite a bit. So really, in
19 electronics, you know, the device could even
20 be going to sleep between sample periods if
21 it's long so it could really preserve battery
22 life or something or...

23 Yeah, I think it creates -- it
24 creates user options and preferences.
25 Everybody is different.

1 BY MR. WILLIAMS:

2 Q. And you think the average
3 continuous glucose monitor user would
4 understand the tradeoffs involved in setting
5 the digital filter acquisition time?

6 MR. SARASWAT: Objection,
7 foundation and scope.

8 A. As I was saying, I think it could
9 be, you know, presented in nontechnical
10 terms. You know, if you -- if you have a
11 lower sample rate, it could be -- it could be
12 during a period where your glucose levels
13 aren't changing much, so you don't care to
14 have it very often.

15 High sample rates, two seconds are
16 very high, and you would -- you'd be getting
17 a lot of noise, and you have to -- you have
18 to think what actionable events happen in a
19 period of two seconds.

20 So, yeah, it's kind of -- you
21 know, it's like digital filters are complex
22 things, but -- but users understand it when
23 you talk about a graphic equalizer, turn up
24 to bass, things like that. I think it could
25 be -- I think there's benefits for a user.

1 BY MR. WILLIAMS:

2 Q. I want to turn your attention now
3 back to paragraph 571 of Shariati.

4 (Off-the-record discussion.)

5 MR. WILLIAMS: Do you want a
6 break?

7 MR. SARASWAT: Yeah, I was
8 actually going to say it looks like we've
9 been on for almost an hour and 15 since last
10 time.

11 MR. WILLIAMS: Okay. Let's take a
12 break.

13 (Recess taken at 4:29 p.m. to 4:39 p.m.)

14 BY MR. WILLIAMS:

15 Q. So just in Shariati, if you'd turn
16 back to 571.

17 A. Okay.

18 Q. Okay. So the sentence -- there's
19 two places this occurs in 571 where Shariati
20 says "which can be programmed into the
21 computer or user selectable."

22 You see those two instances in
23 571?

24 A. "The filtered ROC value on a
25 time to" -- oh, sorry.

1 Yeah, "ROC value on a time" --
2 sorry. I should speak to myself. I'm just
3 trying to...

4 I got it.

5 Q. Okay. You see those two places
6 where he says that?

7 A. I do.

8 Q. All right. What do you think --
9 what's your understanding of what the word
10 "or" means there?

11 A. It means either.

12 Q. Okay. Let's go --

13 A. Or -- yeah.

14 Q. Okay. Great.

15 Let's look at Say, which has been
16 previously marked as Exhibit 1008.

17 Are you familiar with
18 Exhibit 1008?

19 A. I am.

20 Q. And this is the Say reference that
21 you considered in your declaration?

22 A. Is this it?

23 Q. Yeah, that was a question. I'm
24 asking you.

25 Is this the Say reference you

1 considered?

2 A. This is it.

3 Q. You have Exhibit 1008, right?

4 A. I believe so, yeah. I'm just
5 looking at the patent number. Let me see.

6 Yep, this is it. Yep.

7 Q. Okay. Great.

8 Now if you'd turn to Column 45 of
9 Say.

10 Around line 27, there's a sentence
11 that begins "The analyte monitor..."

12 Do you see that?

13 A. I do.

14 Q. Okay. So it reads, "The analyte
15 monitor device may be configured so that the
16 threshold levels for these or any other
17 conditions may be programmable by the patient
18 and/or a medical professional."

19 Do you see that?

20 A. I do.

21 Q. Okay. Do you have an
22 understanding of whether the word "may" there
23 means that these thresholds may not be
24 programmable by a patient or a medical
25 professional?

1 MR. SARASWAT: Objection, form.

2 A. I mean, I take it to mean they --
3 they can program it.

4 Yeah, I mean, I don't know. But
5 the "may" word, I mean, it certainly doesn't
6 allude to that there's an option where -- or
7 a lack of an option for them to be able to
8 program it.

9 BY MR. WILLIAMS:

10 Q. Would a person of ordinary skill
11 in the art have been able to make those
12 thresholds nonprogrammable by the patient
13 and/or a medical professional?

14 MR. SARASWAT: Objection, scope.

15 A. I take to it mean that you can
16 program it, a higher rate -- I don't see -- I
17 take it to mean that the patient or a medical
18 professional can program it. I don't see
19 a -- an opposite case where they could not.

20 BY MR. WILLIAMS:

21 Q. Yeah, my question was a little
22 different.

23 A. Sorry.

24 Q. I mean, I asked that question, and
25 you answered it, so we got that. Now I'm

1 asking a different question.

2 Could a person of ordinary skill
3 in the art have made these thresholds such
4 that they were not programmable by a patient
5 or a medical professional?

6 MR. SARASWAT: Objection, scope.

7 A. I go back to the case where I
8 don't know why they -- why they would.

9 BY MR. WILLIAMS:

10 Q. Okay. Going down to line 52 of
11 Column 45.

12 Let me know when you get there.

13 A. I'm there.

14 Q. That paragraph begins, "The alarm
15 system 104 may also or alternatively, be
16 activated when the rate of change or
17 acceleration of the rate of change in analyte
18 level increase or decrease reaches or exceeds
19 a threshold rate or acceleration."

20 Do you see that?

21 A. Starting at -- sorry, is that
22 starting at 47 to --

23 Q. No, sorry. This is around line
24 52 --

25 A. Oh, sorry.

1 Q. -- or 53.

2 A. The one that starts with "The
3 alarm system 104"?

4 Q. Yes.

5 A. Okay. I'm there.

6 Q. Do you see that? Okay.

7 And it goes on to say, "For
8 example, in the case of a subcutaneous
9 glucose monitor, the alarm system might be
10 activated if the rate of change in glucose
11 concentration exceeds a threshold value which
12 might indicate that a hyperglycemic or
13 hypoglycemic condition is likely to occur."

14 Do you see that?

15 A. I see it.

16 Q. Okay. Would -- is this talking
17 about a predictive alert?

18 A. I think it's talking about an
19 alert. I think -- I don't think you get
20 hypoglycemia from acceleration.

21 You could get there from, you
22 know, potential hypoglycemia from a rate of
23 change if you knew the threshold, but then
24 you're -- you got to turn that into a hypo --
25 you'd have to change it to make it a

1 predictor.

2 Q. So is that change you're talking
3 about something a person of ordinary skill in
4 the art would have known how to do?

5 MR. SARASWAT: Objection, scope.

6 A. If you know -- if you know the
7 threshold or the rate of change, that's how
8 they're -- they're warning of a hypoglycemia
9 or hypoglycemic -- you got to put the two
10 together, but it's not rocket science.

11 BY MR. WILLIAMS:

12 Q. Okay. The rate of change in
13 analyte level, would that, in your view,
14 satisfy a parameter indicative of glucose as
15 used in the '215 patent in Claim 1?

16 MR. SARASWAT: Objection, form,
17 and scope.

18 A. I do see them a bit differently.

19 I mean, glucose is milligrams a
20 deciliter, and a rate of change is time --
21 time dependent. I -- but I don't personally
22 tie them together. I don't see the rate of
23 change falling into that category.

24 BY MR. WILLIAMS:

25 Q. What is an example of something

1 that would satisfy the parameter indicative
2 of glucose value in Claim 1 of the '215
3 patent?

4 A. Well, a prediction of glucose.

5 Q. Is that it, only prediction?

6 MR. SARASWAT: Objection, scope.

7 A. I mean -- I mean, there's got to
8 be other things. I mean, I'm just talking
9 different sensors or something or -- I mean,
10 for me rate of change is a different -- a
11 different sort of metric.

12 BY MR. WILLIAMS:

13 Q. Just so I'm clear, rate of change
14 here, it's rate of change of the glucose, of
15 the analyte value, correct?

16 A. Right.

17 Q. And that's what Say is talking
18 about here, right?

19 And you're saying that a rate of
20 change of glucose is not, in your view, a
21 parameter indicative of glucose value; is
22 that right?

23 MR. SARASWAT: Objection,
24 compound, foundation.

25 A. I mean, I think indicative of

1 glucose value is you're -- you know, you're
2 trying to get to something in milligrams per
3 deciliter, and rate of change is on its own.
4 I don't feel it -- you know, for example, if
5 you know your -- if you know your rate of
6 change of glucose, it doesn't mean you have
7 any idea what your glucose might be.

8 BY MR. WILLIAMS:

9 Q. How could a CGM calculate the rate
10 of change of glucose without knowing what
11 glucose value is?

12 MR. SARASWAT: Objection, scope.

13 BY MR. WILLIAMS:

14 Q. Do you think it could?

15 A. I don't think I could.

16 Q. All right.

17 MR. WILLIAMS: How much time do I
18 have left, gentlemen?

19 MR. SARASWAT: So it looks like --

20 MR. GIUNTA: 40 minutes.

21 MR. WILLIAMS: Okay.

22 MR. GIUNTA: Yeah, 40 -- yeah, 45
23 minutes, somewhere in there.

24 MR. WILLIAMS: Thank you.

25 MR. SARASWAT: I have us starting

1 at 4:39 this round.

2 MR. WILLIAMS: Okay. Got it.

3 BY MR. WILLIAMS:

4 Q. That reminds me of something.

5 Let's go back to Say for a second, which is
6 probably this. No, that's not it. Oh, yeah,
7 you've got it.

8 I'm sorry. It wasn't Say that I
9 wanted to go back to at all, it was Shariati.
10 That's why I'm confused. Let me ask you
11 about Figure 4C.

12 Do you see Figure 4C?

13 A. I do.

14 Q. Okay. Looks like Figure 4C is
15 discussed starting around paragraph 372 of
16 Shariati. I just want to make sure. I'm
17 understanding the figure correctly.

18 It looks like this figure is
19 showing the current glucose level with a
20 cross-hatched line 456; is that right?

21 A. I believe so.

22 Q. And that arrow 458 is showing the
23 direction that the glucose value is trending
24 at that time?

25 MR. SARASWAT: Objection, scope.

1 A. That's correct.

2 BY MR. WILLIAMS:

3 Q. And then Figure 4D shows a value
4 80 and an arrow and then some dotted arrows.

5 Do you see that?

6 A. I do.

7 MR. SARASWAT: Objection,
8 foundation and scope.

9 BY MR. WILLIAMS:

10 Q. In paragraph 376, Shariati
11 describes that value with reference 460 as
12 corresponding to analyte value, correct? So
13 that would be -- the number 80 there would be
14 the current glucose value?

15 MR. SARASWAT: Objection,
16 foundation and scope.

17 BY MR. WILLIAMS:

18 Q. Is that correct?

19 A. So 460 is the numerical
20 representation of the most recent -- a
21 numerical representation of the most recent
22 measured analyte value.

23 BY MR. WILLIAMS:

24 Q. In this case, the analyte would
25 likely be glucose, correct?

1 MR. SARASWAT: Objection, scope
2 and foundation.

3 A. Yeah, that would be a glucose
4 value and --

5 (Reporter clarification.)

6 A. The system could be -- would be
7 calculated to give a glucose value.

8 BY MR. WILLIAMS:

9 Q. Okay. And the arrow that's shown
10 there, 462, you see that arrow?

11 A. I do.

12 Q. It describes that arrow as
13 corresponding to the rate of change of the
14 analyte concentration, correct?

15 MR. SARASWAT: Objection, scope,
16 and foundation.

17 A. I'm sorry, what was the question
18 again?

19 So there's an arrow pointing up --

20 BY MR. WILLIAMS:

21 Q. In Figure 4D, the arrow pointing
22 up is described in paragraph 376 and is
23 corresponding to the rate of change of the
24 analyte concentration, correct?

25 MR. SARASWAT: Objection, form and

1 scope, foundation.

2 A. Sorry. This is representing a --
3 symbolizing a rate of change, I guess.

4 BY MR. WILLIAMS:

5 Q. Okay. And the -- the paragraph
6 further describes the bolded arrow, 462,
7 which is pointing up, as representing, quote,
8 "relatively quickly increasing rate of
9 change," correct?

10 MR. SARASWAT: Objection, scope.

11 A. I'm sorry, what's that paragraph
12 number again?

13 BY MR. WILLIAMS:

14 Q. 4 -- sorry. 376.

15 A. Okay. So the bold arrow
16 represents a relatively quickly increasing
17 rate of change.

18 Q. Okay. And it shows some dotted
19 line arrows in that figure as well, correct?

20 A. Correct.

21 MR. SARASWAT: Objection, scope.

22 BY MR. WILLIAMS:

23 Q. And those dotted line arrows are
24 described as showing other positive and
25 negative rates of change, correct?

1 MR. SARASWAT: Objection, scope.

2 A. Yeah, the up arrows represent
3 positive rate of change, and the downward
4 arrows a negative rate of change.

5 BY MR. WILLIAMS:

6 Q. An arrow pointing to the right,
7 would that indicate no change, in your view?

8 MR. SARASWAT: Objection, scope.

9 A. I believe so. That would -- I
10 take that to mean no rate of change or low
11 range of change, very low -- I would take
12 the -- the horizontal arrow as with -- which
13 is 90 degrees to the vertical, to mean a -- a
14 low rate of change.

15 Q. Shariati describes a predictive
16 hypoglycemia alarm at paragraph 571, correct?
17 We talked about that earlier.

18 A. Correct.

19 Q. Okay. Is that -- is that a -- is
20 that the same as an alarm based on a rate of
21 change of an analyte?

22 MR. SARASWAT: Objection,
23 foundation and scope.

24 A. A -- an alert associated with a
25 rate of change would be different from a -- a

1 predictive glucose alert.

2 BY MR. WILLIAMS:

3 Q. Okay. In paragraph 16 of your
4 declaration you mention -- the last bullet on
5 that paragraph talks about "Objective factors
6 indicative of nonobviousness, sometimes
7 referred to as 'secondary considerations.'"

8 Do you see that?

9 A. I do.

10 Q. Did you discuss any of those in
11 your declaration?

12 A. I don't recall anything regarding
13 nonobviousness.

14 Q. I'm sorry. Regarding objective
15 factors of nonobviousness. Is that what you
16 mean?

17 A. I -- yeah, I can't think offhand.

18 Q. Okay.

19 MR. WILLIAMS: I have no further
20 questions.

21 MR. SARASWAT: Let's go off the
22 record.

23 (Recess taken at 5:16 p.m. to 5:25 p.m.)

24 /

25 /

1 EXAMINATION

2 BY MR. SARASWAT:

3 Q. Dr. Keenan, could you please get
4 Exhibit 2006 and put that in front of you?

5 A. Sorry, 2006 was --

6 Q. That was the Kamath article. It's
7 entitled "Methods of Evaluating the Utility
8 of Continuous Glucose Monitor Alerts."

9 So, Dr. Keenan, do you have
10 Exhibit 2006 in front of you?

11 A. I do.

12 Q. Okay. Could you please turn to
13 the last page of the -- well, I guess it's
14 not the last page.

15 Could you please turn to page 65
16 of the article that has the word
17 "Conclusions" on it?

18 A. I got it.

19 Q. Okay. Could you please look at
20 the left-hand column on this page. And maybe
21 about a halfway down -- yeah, maybe about a
22 halfway down that column, do you see that
23 there's a sentence that begins with the words
24 "In a study intended"?

25 A. I see it.

1 Q. Okay. And that sentence says, "In
2 a study intended to evaluate the
3 effectiveness of the 'down alert' at
4 predicting overnight hypoglycemia, although
5 the sensitivity to detect hypoglycemia was
6 improved from 8% with a threshold alert to
7 77% with the down alert,
8 65% of down alerts were false (BG greater
9 than 70 milligrams per deciliter within plus
10 or minus 30 minutes from the alert) compared
11 to 16% of the threshold alert."

12 Do you see that?

13 A. I do.

14 Q. Okay. And do you recall being
15 asked some questions earlier today by
16 Mr. Williams about this sentence?

17 A. I do.

18 Q. And the sentence says that 65
19 percent of down alerts were false, correct?

20 A. Correct.

21 Q. And the down alerts referred to in
22 this sentence are predictive alarms, correct?

23 MR. WILLIAMS: Objection to form,
24 leading.

25 A. Correct, I believe so.

1 BY MR. SARASWAT:

2 Q. So this sentence is saying that
3 65 percent of predictive alarms were false,
4 correct?

5 MR. WILLIAMS: Objection,
6 leading.

7 A. Correct.

8 BY MR. SARASWAT:

9 Q. Does higher sensitivity
10 necessarily result in an improved system --

11 MR. WILLIAMS: Objection to
12 form --

13 BY MR. SARASWAT:

14 Q. -- if -- sorry.

15 MR. WILLIAMS: Sorry, go ahead.

16 BY MR. SARASWAT:

17 Q. Yeah.

18 Does higher sensitivity
19 necessarily result in an improved system if
20 it increases the number of false alarms?

21 MR. WILLIAMS: Objection to
22 form.

23 A. It does not. Increasing the
24 sensitivity will -- increases the number of
25 true positives, but will likely increase the

1 number of false-positives. Which -- which --
2 there's -- you get to a point where too many
3 false-positives will break the system.

4 BY MR. SARASWAT:

5 Q. Do you recall testifying earlier
6 today that predictive alarms have their place
7 despite their high false-positive rates?

8 A. I do.

9 Q. So is it your opinion that the
10 high false alarm rate of predictive alarms
11 was so bad that a POSA would not have used
12 them at all?

13 MR. WILLIAMS: Objection to
14 form.

15 A. In -- in what circumstance?
16 Related here with this error rate?

17 BY MR. SARASWAT:

18 Q. In the -- in the -- in the
19 predictive alarms that were known prior to
20 2012, is it your opinion that the high
21 false-positive rate of those alarms was so
22 bad that a POSA would not have used
23 predictive alarms at all?

24 MR. WILLIAMS: Objection to
25 form.

1 A. The sensors were -- a POSA
2 wouldn't -- wouldn't use it with the high
3 false-positive rate. A POSA wouldn't
4 implement a system that has a false-positive
5 rate.

6 BY MR. SARASWAT:

7 Q. So you agree that there were
8 predictive alarms with user settable
9 thresholds known in the art prior to the
10 patent, correct?

11 A. Correct. I don't recall exactly
12 when products were launched, but yes.

13 Q. Could you please turn to paragraph
14 55 of your declaration.

15 And so it says, "As can be seen
16 from my discussion of the patent in
17 Section V.A to V.B above, the inventors of
18 the '215 patent did not follow the
19 conventional thinking (which I describe in
20 the paragraphs above in this section) and
21 instead developed a system in which
22 predictive alerts use nonuser settable
23 thresholds," correct?

24 A. Correct.

25 MR. WILLIAMS: Objection, leading.

1 BY MR. SARASWAT:

2 Q. And do you see that "nonuser
3 settable" is emphasized?

4 A. I do.

5 MR. WILLIAMS: Objection, leading.

6 BY MR. SARASWAT:

7 Q. So do you stand by -- do you still
8 stand by the opinion in paragraph 55?

9 A. Absolutely.

10 Q. Okay. So the -- so is it correct
11 the conventional thinking you refer to in
12 paragraph 55, which the inventors did not
13 follow, was to have user settable thresholds
14 for predictive alerts?

15 MR. WILLIAMS: Objection,
16 leading.

17 A. Sorry. Could you repeat that,
18 please?

19 BY MR. SARASWAT:

20 Q. Is it correct that the
21 conventional thinking you refer to in
22 paragraph 55 was that predictive alerts would
23 have user settable thresholds?

24 MR. WILLIAMS: Same objection.

25 A. Correct. Because -- because they

1 were problematic.

2 BY MR. SARASWAT:

3 Q. Okay. So do you see the word --
4 okay.

5 So you see at the end of that
6 paragraph it says -- after the comma -- or
7 can you read the part of that sentence after
8 the comma?

9 MR. WILLIAMS: Objection to form.

10 MR. SARASWAT: All right. I'm
11 going to withdraw the question.

12 BY MR. SARASWAT:

13 Q. Can you please look at paragraph
14 55 again.

15 A. Okay.

16 Q. And can you please read paragraph
17 55 out loud.

18 A. "As can be seen from my discussion
19 of the patent in Sections V.A. and V.B above,
20 the inventors of the '215 patent did not
21 follow the conventional thinking (which I
22 describe in the paragraphs above in this
23 section) and instead developed a system in
24 which predictive alerts" are nonuser settable
25 thresholds -- use -- "alerts use nonuser

1 settable thresholds."

2 BY MR. SARASWAT:

3 Q. So is it correct that the
4 conventional thinking you're referring to in
5 paragraph 55 was for predictive alerts to
6 have user settable thresholds?

7 MR. WILLIAMS: Objection,
8 leading.

9 A. Correct, that was -- that's the
10 conventional thinking.

11 BY MR. SARASWAT:

12 Q. And why was the conventional
13 thinking to have user settable thresholds for
14 predictive alerts?

15 A. For one, you could -- you could
16 turn alerts off if it became bothersome.

17 Q. And could you please look at
18 Figure 3 in Exhibit 2006?

19 A. Actually, no. Could you please
20 look at Figure 5 in Exhibit 2006?

21 A. Can I make a point about the data
22 at all? It's just that I noticed it's -- oh,
23 sorry, not -- sorry, apologize.

24 Q. Do you recall being asked some
25 questions earlier today about Figure 5 in

1 Exhibit 2006?

2 A. I do.

3 Q. And can you also look at Table 4
4 in Exhibit 2006?

5 A. Okay.

6 Q. And do you recall being asked
7 about Table 4 in Exhibit 2006 earlier today?

8 A. I remember talking about the
9 graph. I can't really remember the table.

10 Q. Well, let's turn back to Figure 5.
11 Do you recall being asked about
12 Figure 5 earlier today?

13 A. I do.

14 Q. Okay. And do you recall being
15 asked questions about the performance data
16 shown in Figure 5 earlier today?

17 A. I do.

18 Q. Okay. Now, could you please turn
19 back to the page -- it's page 65 of the
20 article, the page that has the word
21 "Conclusions."

22 A. Okay.

23 Q. And could you please look at the
24 first full paragraph in the left-hand column?

25 A. It starts with "A high bias"?

1 Oh, sorry, the first full
2 paragraph. Okay. It starts with "This
3 investigation"?

4 Q. Correct.

5 Could you please read aloud the
6 first three sentences of the first full
7 paragraph in the left-hand column on page
8 65?

9 A. "This investigation focused on the
10 evaluation of CGM alerts as they occur in
11 real-time and the perspective capability of
12 alerts to help patients avoid undesirable
13 excursions."

14 Q. And then could you please read the
15 next two sentences also?

16 A. "The alerts evaluated in this
17 investigation are threshold alerts that sound
18 when the glucose ratings cross a patient's
19 selected level."

20 Q. And please will you read the next
21 sentence.

22 A. "These alerts are distinct from
23 alerts designed implicitly to predict glucose
24 excursions called projected alerts."

25 Q. So if we look back at Figure 5,

1 are the alerts whose performance are
2 described -- withdrawn.

3 Does Figure 5 describe the
4 performance of real-time alerts?

5 A. I got to read in the text how it
6 describes it.

7 Q. All right. I'll withdraw the
8 question, and I'll ask a different question.

9 Let's turn back to page 65, and
10 let's look at that first full paragraph in
11 the left-hand column again.

12 A. Okay.

13 Q. And the first sentence says, "This
14 investigation focused on the" valuation --
15 sorry. I'll start over.

16 The first full sentence says,
17 "This investigation focused on the evaluation
18 of CGM alerts as they occur in real-time and
19 the predictive capability of alerts to help
20 patients avoid undesirable excursions."

21 Do you see that?

22 A. I do.

23 Q. And the next sentence says, "The
24 alerts evaluated in this investigation are
25 threshold alerts that sound when glucose

1 readings cross a patient's selected level."

2 Do you see that?

3 A. I do.

4 Q. And the next sentence says, "These
5 alerts are distinct from alerts designed
6 explicitly to predict glucose excursions
7 called projected alerts."

8 Do you see that?

9 A. I do.

10 Q. Now, if we look at Figure 5, is it
11 your under-- is it your understanding that
12 the alerts described in -- that the alerts
13 whose performance is described in Figure 5
14 are real-time alerts?

15 Well, here, I'll ask you a
16 different question.

17 Is it your understanding that the
18 performance data shown in Figure 5 is from
19 the same investigation referred to as "this
20 investigation" in the sentences that we just
21 read from page 65?

22 A. I would assume so.

23 Q. Okay.

24 A. This investigation, this data.

25 Q. So is it your understanding

1 that -- and is it your understanding that the
2 alerts ref- -- that the alerts that are the
3 subject of this investigation referred to in
4 the sentences we read on page 65 are
5 real-time alerts?

6 A. It looks like this data is
7 reflecting real-time alerts.

8 Q. Okay. So is it your understanding
9 that the performance data reflected in
10 Figure 5 is performance data for real-time
11 alerts?

12 A. It is.

13 Q. Could you please turn to
14 Exhibit 1001, which is -- oh, yeah, sorry.
15 Yeah, yeah.

16 Dr. Keenan, I apologize, but I
17 think earlier you had referenced a comment
18 that you wanted to make about the data in
19 Figure 5.

20 Do you recall that, just a few
21 minutes ago when I was questioning you?

22 A. Oh, no, it was more -- the comment
23 that I was going to make was based on the --
24 in this paragraph talking about the 65
25 percent of down alerts from the -- it was

1 just a -- the comment was going to be that it
2 was -- it was an overnight study, and during
3 the day that number would be much higher.

4 Q. Okay. Could you please turn to
5 Exhibit 1001, which is the '215 patent?

6 Okay. Could you please turn to
7 Column 1 in the '215 patent.

8 A. Okay.

9 Q. And could you please look at the
10 "Background" section, which starts on line
11 30?

12 A. Okay.

13 Q. And the "Background" section says,
14 "The present systems and methods relate to
15 processing analyte sensitive data from a
16 continuous analyte sensor. More particularly
17 the present systems and methods relate to
18 providing accurate predictive alarms to a
19 user."

20 Do you see that?

21 A. I do.

22 Q. Do you recall being asked -- and
23 so do you see the words "accurate predictive
24 alarms" towards the end of that section?

25 A. I do.

1 Q. Do you recall being asked earlier
2 today about that reference to accurate
3 predictive alarms?

4 A. I do.

5 Q. Do you recall anything described
6 in the '215 patent -- withdrawn.

7 Do you recall any technique
8 described in the '215 patent to improve the
9 accuracy of predictive alarms?

10 A. I do.

11 Q. What is that?

12 A. For real-time predictive alerts?
13 To improve accuracy of -- sorry.

14 Q. Yeah.

15 What -- what techniques do you
16 recall that are described in the '215 patent
17 that improve the accuracy of predictive
18 alarms?

19 A. Let me see.

20 I mean, I recall it having a --
21 having the fixed threshold for the -- for a
22 predictive alert allows you to improve
23 accuracy by tuning an algorithm to one
24 threshold.

25 Q. Could you please turn to Column 22

1 of the '215 patent -- sorry. I'll start
2 over, because I had the right number.

3 Could you please turn to Column 22
4 of the '215 patent?

5 A. Okay.

6 Q. And could you please look at line
7 40 in Column 22?

8 A. Yes.

9 Q. And earlier, in response to one of
10 my questions, you referred to having the
11 fixed threshold for a predictive alert allows
12 you to improve accuracy by tuning an
13 algorithm to one threshold.

14 Do you recall saying that?

15 A. I do.

16 Q. Now, if we look at line 40 in
17 Column 22, do you see that it says, "Use of
18 prediction algorithm parameters (e.g.,
19 reliance on modeled versus measured data,
20 time sensitive waiting of past data,
21 prediction horizon PH and prediction
22 threshold TVP) tuned in advance may increase
23 our optimized warning time for patients
24 before a severe event occurs and may minimize
25 the number of nuisance false alarms heard by

1 the user."

2 A. Yeah, I see it.

3 Q. Yeah.

4 So is that what you were referring
5 to when, earlier in response to one of my
6 questions, you referred to having the fixed
7 threshold for a predictive alert allows you
8 to improve accuracy by tuning an alarm to one
9 threshold?

10 MR. WILLIAMS: Objection,
11 leading.

12 A. That's correct.

13 If you're -- having multiple
14 thresholds is multiple targets. If you
15 have a -- you have your data sets, and you're
16 just shooting the parameters and the
17 algorithm to one threshold, you can improve
18 accuracy or performance.

19 BY MR. SARASWAT:

20 Q. So -- so can you please just read
21 Column 22, line 40 to 45 to yourself and let
22 me know when you're done.

23 A. Okay.

24 Okay.

25 Q. So what is your understanding of

1 what that passage that you just read to
2 yourself is talking about?

3 MR. WILLIAMS: Objection to
4 form.

5 A. Well, what I see this saying is
6 that if -- you're basically tuning the
7 algorithm to one threshold, and that allows
8 you to better tune -- better tune the
9 parameters for that threshold; therefore, at
10 that threshold, you'll likely get better
11 performance than other thresholds.

12 BY MR. SARASWAT:

13 Q. Could you please take a look at
14 Exhibit 2015?

15 A. What is 2015?

16 Q. 2015 is the one that says
17 "Medtronic Guardian REAL-time" on the front.

18 A. Okay.

19 Q. And could you please turn to the
20 third page of the document. It's the one
21 that has "Copyright 2006" on top.

22 A. Okay.

23 Q. And do you see on the first line
24 on that page it says, "Copyright 2006,
25 Medtronic MiniMed Incorporated, all rights

1 reserved"?

2 A. Yes.

3 Q. Okay. And do you recall being
4 asked some questions earlier today about
5 Exhibit 2015?

6 A. I do.

7 Q. And do you recall being asked some
8 questions earlier today about the time at
9 which the product described in Exhibit 2015
10 may have been released?

11 A. Yeah, I recall being asked when it
12 was launched.

13 Q. Okay. And --

14 A. Or something -- something along
15 those lines.

16 Q. And do you recall testifying that
17 you thought that the product described in
18 Exhibit 2015 was released later than 2006?

19 A. Yes. And I know that copyright
20 2006, but I thought -- I thought it was
21 launched much later.

22 Q. And am I -- what was the basis for
23 that belief that you expressed earlier this
24 morning -- withdrawn.

25 Do you recall testifying that the

1 reason you thought the product described in
2 Exhibit 2015 was released sometime after 2006
3 was that the product contained a pump of some
4 kind?

5 MR. WILLIAMS: Objection to form.

6 A. I'm not sure I understand the
7 question.

8 BY MR. SARASWAT:

9 Q. Okay. So I'm going to -- so you
10 were asked the question by Mr. Williams in
11 reference to Exhibit 2015, "What is that
12 device?"

13 And your answer, according to the
14 transcript, was: Guardian REAL-time and
15 actually looks like a pump.

16 Do you recall that exchange?

17 A. I do.

18 Q. Okay. So is -- is it the case
19 that the reason you thought the product
20 described in Exhibit 2015 was released after
21 2006, that you believe this product may have
22 had a pump?

23 MR. WILLIAMS: Objection to form
24 and leading.

25 A. The -- if you look at the Guardian

1 RT monitor, it looks different. The Guardian
2 REAL-time is actually the shape of the pump.
3 The pump looks like --
4 (Reporter clarification.)

5 A. The insulin pump looks the same as
6 the Guardian REAL-time monitor. They both
7 look the same in terms of having, you know,
8 the exact same shape. It's -- it's used in
9 the same packaging.

10 BY MR. SARASWAT:

11 Q. So are you able to tell from
12 looking at the picture on the cover page of
13 Exhibit 2015 whether or not the product
14 described has a pump?

15 MR. WILLIAMS: Objection to
16 form.

17 A. I -- no, I don't believe that this
18 has a pump.

19 BY MR. SARASWAT:

20 Q. Okay. So if the pro- --
21 withdrawn.

22 MR. SARASWAT: Let's take a break
23 for a few minutes.

24 (Recess taken at 6:02 p.m. 6:11 p.m.)

25 MR. SARASWAT: Back on the

1 record.

2 BY MR. SARASWAT:

3 Q. Okay. So, Dr. Keenan, before the
4 break I asked you if you're able to tell from
5 looking at the picture on the cover of 2015
6 whether or not the part described has a pump,
7 and your response was, No, I don't believe it
8 has a pump.

9 Do you recall that?

10 A. I do.

11 Q. Okay. So earlier today when
12 Mr. Williams was asking you about
13 Exhibit 2015, I thought you had said that you
14 thought that the product described in
15 Exhibit 15 -- in Exhibit 2015 was released
16 later than 2006, and that the reason you
17 thought that was because the product has a
18 pump.

19 Did I misunderstand you?

20 A. Maybe. I mean, I -- I was just
21 going back trying to remember, you know, when
22 I joined Medtronic, how long was it after
23 Medtronic that it got released, so it felt
24 later than 2006. That's all.

25 The -- I mean, it looks like a

1 pump was -- the algorithms -- they used the
2 same packaging as the pump, I believe. The
3 packaging is the same as the -- the MiniMed
4 pump.

5 Q. Okay. So your belief that the
6 product may have been released after 2006 --
7 withdrawn.

8 So am I correct that your belief
9 that the product may have been released
10 sometime after 2006 was based on the
11 possibility that the device described may
12 have a pump?

13 MR. WILLIAMS: Objection to
14 form.

15 A. I just -- I'm trying to recall my
16 time at Medtronic. It was nearly -- nearly
17 20 years ago, you know, when I first joined
18 and started working on the algorithms.

19 You develop these algorithms, and
20 they -- they go into the products. All the
21 products have CGM, CGM alone or CGM with a
22 pump.

23 Well, there's old standalone
24 pump --
25 /

1 BY MR. SARASWAT:

2 Q. Okay.

3 A. -- that doesn't have it.

4 And so I was just trying to -- I
5 don't -- honestly, I don't -- I don't know
6 when these products got launched. I was
7 just -- so I'm not even exactly sure which
8 algorithms were done at which time; you know,
9 which upgraded algorithms I developed, you
10 know, an improved calibration algorithm,
11 which is in the products now. I don't know
12 exactly when it went in and what version it
13 went in and things like that.

14 Q. All right. Could you please just
15 turn back to the third page of Exhibit 2015?

16 A. Yep.

17 Q. Do you see the copyright 2006 date
18 at the top?

19 A. I do.

20 Q. Do you have any reason to believe
21 that that date is inaccurate?

22 MR. WILLIAMS: Objection, form.

23 A. I -- I don't know. I mean, I
24 assume it's right, just because -- I don't
25 know how -- I don't know where the mistake

1 would be. I imagine these things -- you take
2 it for granted that's what it is.

3 MR. SARASWAT: All right. No
4 further questions.

5 MR. WILLIAMS: I have one.

6 FURTHER EXAMINATION

7 BY MR. WILLIAMS:

8 Q. When you were talking about
9 Exhibit 2006, you said too many false alerts
10 would break the system.

11 What did you mean?

12 A. Just that if -- if you have a high
13 false alert rate, it would -- it wouldn't be
14 good enough to be a product.

15 Q. Do you still have 2006 -- it's
16 this one right here.

17 On page 65, which is kind of the
18 last text page on the document --

19 A. Yep.

20 Q. -- there's a reference to a
21 McGarraugh and colleagues report.

22 Do you see that?

23 A. I do.

24 Q. Okay. And that was a report on
25 the Abbott Navigator device, correct?

1 MR. SARASWAT: Objection, scope.

2 A. Correct, that's the Navigator.

3 BY MR. WILLIAMS:

4 Q. Okay. And they describe there the
5 addition of projected alerts was intended to
6 increase warning time, correct?

7 MR. SARASWAT: Objection,
8 foundation.

9 And scope, objection as to scope
10 also.

11 A. It looks like they were using a
12 threshold alert with a higher -- a higher --
13 a higher level to -- to predict -- to warn of
14 potential hypoglycemic event early.

15 BY MR. WILLIAMS:

16 Q. Where do you see a discussion of
17 the threshold that you're referring to?

18 A. So more recently McGarraugh and
19 colleagues reported on the performance of the
20 Navigator projected alert -- oh, I apologize,
21 I said projected alert -- with the threshold
22 alert setting of 85 milligrams a deciliter.

23 So it looks like they set the
24 threshold at 85.

25 Q. Right.

1 Okay. And when they did that,
2 47.7 of the true alerts occurred after the
3 low glucose excursion, correct?

4 MR. SARASWAT: Objection, scope
5 and foundation.

6 A. That's what it says after -- with
7 the setting of 85 milligrams a deciliter,
8 47.7 percent of TAs occurred after a glucose
9 excursion --

10 BY MR. WILLIAMS:

11 Q. Okay.

12 A. -- of less than 70.

13 Q. Okay. So the next sentence says,
14 "The addition of projected alerts was
15 intended to increase warning time. But to
16 avoid the occurrence of FAs, the projected
17 alerts were only activated when glucose was
18 falling rapidly."

19 Did you see that?

20 MR. SARASWAT: Objection, scope
21 and foundation.

22 A. I see that.

23 BY MR. WILLIAMS:

24 Q. Okay. And then you say, "As a
25 result, 27.7 percent of true projected alerts

1 occurred after the low glucose excursion had
2 begun."

3 Correct?

4 MR. SARASWAT: Objection, scope.

5 A. Correct, that's what it says.

6 BY MR. WILLIAMS:

7 Q. Okay. So a couple things.

8 I guess FAs, that's false alert,
9 right, or false alarm?

10 MR. SARASWAT: Objection, scope.

11 A. I believe so.

12 BY MR. WILLIAMS:

13 Q. Yeah. Okay.

14 So here the authors were aware of
15 the usefulness of avoiding the occurrence of
16 false alarms, right?

17 MR. SARASWAT: Objection,
18 foundation and scope.

19 A. I disagree that it would avoid the
20 occurrence of false alerts. But -- but not
21 doing the -- not doing a calculation with
22 rapid -- with glucose falling rapidly would
23 reduce the false alerts, but it would also
24 reduce true positives.

25 /

1 BY MR. WILLIAMS:

2 Q. I'm sorry, you said -- okay.

3 Did you say not doing the
4 calculation or doing the calculation?

5 A. If you -- basically what I'm
6 saying is, is if glucose is falling rapidly,
7 if you don't do a calculation as in you don't
8 report a true-positive or a false-positive,
9 you don't do anything, that would -- you're
10 not going to get a false-positive if you
11 don't do anything; you're not going to get a
12 true-positive either.

13 BY MR. WILLIAMS:

14 Q. Right.

15 In this case, the McGarraugh
16 authors chose to activate the projected
17 alerts only when glucose was falling rapidly
18 as a way to avoid false alerts, correct?

19 MR. SARASWAT: Objection, scope,
20 foundation and hearsay.

21 A. You also made the -- they
22 wouldn't -- by not actually doing anything,
23 it's going to reduce false alerts and also
24 true alerts.

25 /

1 BY MR. WILLIAMS:

2 Q. I see.

3 A. So they're only using it during
4 certain conditions.

5 Q. What do you mean by "not actually
6 doing anything"? I don't understand that.

7 MR. SARASWAT: Objection, scope.

8 A. So "The addition of projected
9 alerts was intended to increase the warning
10 time. But to avoid the occurrence of false
11 alerts, the projected alerts were only
12 activated when glucose was falling rapidly."

13 So the algorithm wasn't activated
14 all the time.

15 BY MR. WILLIAMS:

16 Q. I see. Okay. I see.

17 So do you agree that by the time
18 of this Kamath article, a person of ordinary
19 skill in the art would have a way to decrease
20 the occurrence of false alerts by only
21 activating them when glucose was falling
22 rapidly?

23 MR. SARASWAT: Objection, scope,
24 foundation, hearsay.

25 A. It's -- it really is -- it's much

1 more complicated than that.

2 When -- actually, when glucose is
3 falling rapidly, you can get many false
4 alerts also. Artifacts cause all kinds of
5 things. It could be falling rapidly, but not
6 actually, you know, pass the threshold. And
7 this should all really be accounted for in --
8 you know, in a predictive algorithm.

9 So it's -- I think it's
10 interesting what they did, but I don't know
11 that -- I certainly don't think it's obvious,
12 and I don't know that it would have worked --
13 potentially worked well.

14 MR. WILLIAMS: Okay. No further
15 questions.

16 Okay. We're off the record.

17 THE REPORTER: So, Mr. Williams,
18 you're ordering the original, correct?

19 MR. WILLIAMS: The original in
20 three days, if we can get it.

21 THE REPORTER: And a rough
22 tonight?

23 MR. WILLIAMS: Yeah, that would be
24 great.

25 THE REPORTER: And, Mr. Saraswat,

1 are you getting a copy?

2 MR. SARASWAT: Yes. We'd like the
3 rough tonight. I guess, how does it work on
4 the actual final? If they're already
5 ordering the rush, do we just get it at the
6 same time or do we order it separately?

7 THE REPORTER: You do have to pay
8 for an expedite.

9 MR. SARASWAT: Okay. If we don't
10 pay for the expedite, what's the regular
11 delivery period?

12 THE REPORTER: It's 10 business
13 days.

14 MR. SARASWAT: 10 business days,
15 okay. Yeah, 10 business days is fine.

16 What is the cost difference
17 between the expedite and the regular?

18 THE REPORTER: It would be 50
19 percent and so forth.

20 MR. GIUNTA: You can make this
21 decision.

22 MR. SARASWAT: Five days.

23 THE REPORTER: Anant, you had a
24 two real-time, right?

25 MR. SARASWAT: On our side, yes.

1 (Deposition concluded at 6:28 p.m.)

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1 COMMONWEALTH OF MASSACHUSETTS

2 SUFFOLK, SS.

3
4 I, Sandra A. Deschaine, Registered
5 Professional Reporter and Notary Public
6 within and for the Commonwealth of
7 Massachusetts at large, do hereby certify
8 that the deposition of Desmond Barry Keenan,
9 Ph.D., in the matter of Abbott Diabetes Care
10 Inc., vs. Dexcom, Inc., at Wolf, Greenfield,
11 Sacks, 600 Atlantic Avenue, Boston,
12 Massachusetts, on Wednesday, March 29, 2023,
13 was taken and transcribed by me; that the
14 witness provided satisfactory evidence of
15 identification as prescribed by Executive
16 Order 455 (03-13) issued by the Governor of
17 the Commonwealth of Massachusetts; that the
18 witness is reading and signing; that the
19 transcript produced by me is a true record of
20 the proceedings to the best of my ability;
21 that I am neither counsel for, related to,
22 nor employed by any of the parties to the
23 action in which this deposition was taken,
24 and further that I am not a relative or
25 employee of any attorney or counsel employed
by the parties thereto, nor financially or
otherwise interested in the outcome of the
action on this 2nd day of April 2023.

17
18
19 _____
20 Sandra A. Deschaine
21 Registered Professional Reporter
22

23 My Commission Expires:
24 July 5, 2024
25

DEPOSITION SIGNATURE PAGE

Job No. SY006871

Case Caption: Abbott Diabetes Care, Inc.,
vs. Dexcom, Inc.

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I
have read the entire transcript of my
Deposition taken in the captioned matter or
the same has been read to me, and the same is
true and accurate, save and except for
changes and/or corrections, if any, as
indicated by me on the DEPOSITION ERRATA
SHEET hereof, with the understanding that I
offer these changes as if still under oath.
Signed on the ____ day of _____, 2023.

DESMOND BARRY KEENAN, PH.D.

1 DEPOSITION ERRATA SHEET

2 Job No. SY006871

3 DESMOND BARRY KEENAN - MARCH 29, 2023

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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.

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

**ERRATA SHEET FOR THE MARCH 29, 2023 DEPOSITION OF
DR. BARRY KEENAN**

I, Dr. Barry Keenan, do hereby make the following corrections to my March

29, 2023 deposition transcript:

Page	Line	Change/Correction	Reason
8	3	“refuses” to “reflects”	Transcription error
15	9	“let to” to “led to”	Transcription error
21	9	“biomechanical” to “biomedical”	Transcription error or misspoke
22	18	“protective” to “predictive”	Transcription error
24	17	“correct the system spec” to “write the system spec”	Transcription error
50	23	“projective” to “projected” (both times)	Transcription error
51	4	“projective” to “projected”	Transcription error
55	16	“off it” to “on it”	Transcription error
61	7	“projective” to “projected”	Transcription error
61	13	“projective” to “projected”	Transcription error
67	20	“projective” to “projected”	Transcription error
81	13	“fast” to “best”	Transcription error
81	18	“hit” to “hate”	Transcription error
95	22	“large generator” to “alarm generated”	Transcription error
96	6	“in” to “and”	Transcription error
109	1	“known” to “non”	Transcription error
109	9	“known” to “non”	Transcription error
113	24	“neuro networks” to “neural networks”	Transcription error
114	8	“neuro networks” to “neural networks”	Transcription error
121	15	“common filter” to “Kalman filter”	Transcription error
124	15	“common filter” to “Kalman filter”	Transcription error
124	24	“common filter” to “Kalman filter”	Transcription error
130	18	“of parts” to “in part”	Transcription error
139	16	“column and filters” to “Kalman filters”	Transcription error
148	6	“5 milligrams” to “55 milligrams”	Transcription error or misspoke
153	9	“can switch off” to “can’t switch off”	Transcription error
194	18	“ratings” to “readings”	Transcription error
201	16	“shooting” to “tuning”	Transcription error

I declare under penalty of perjury that, except for any correction noted above, the transcript is an accurate record of the statements made by me.

Dated: April 18, 2023



Dr. Barry Keenan