

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.	)	
Petitioner,	)	
	)	Case No.:
vs.	)	IPR 2023-01251
	)	
ABBOTT DIABETES CARE INC.,	)	
Patent owner.	)	
_____	)	

DEPOSITION OF BRIAN D. GROSS

Portland, Oregon

Thursday, May 2, 2024; 8:14 a.m.

TAKEN IN BEHALF OF THE PATENT OWNER

REPORTED BY:

Victoria A. Guerrero, CSR, RDR, RMR, CRR

Job No. 20217

Pages 1 through 167

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ABBOTT Exhibit 2227, Page 1 of 205
Dexcom, Inc. v. Abbott Diabetes Care Inc.
IPR2024-00521

ERRATA SHEET

CASE NAME: Dexcom, Inc. v. Abbott Diabetes Care Inc., IPR2023-01251

DATE OF DEPOSITION: May 2, 2024

DEPONENT NAME: Brian D. Gross

<u>PAGE#</u>	<u>LINE #</u>	<u>CORRECTION FROM</u>	<u>CORRECTION TO</u>	<u>REASON</u>
7	16	Infectious	for Infectious	Transcription error
11	19	curb	curve	Transcription error
19	2	telenium	tellurium	Misspelling
19	2	oxide	dioxide	Transcription error
21	2	Agilant	Agilent	Misspelling
21	7	Agilant	Agilent	Misspelling
21	8	Agilant	Agilent	Misspelling
21	14	Phillips	Philips	Misspelling
21	16	Phillips	Philips	Misspelling
22	13	the monobase	non-invasive	Transcription error
23	11	Phillips	Philips	Misspelling
24	1	Phillips	Philips	Misspelling
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24	18	Phillips	Philips	Misspelling
24	13	being	becoming	Transcription error
24	25	business	businesses	Transcription error
26	11	Phillips	Philips	Misspelling
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28	21	Phillips	Philips	Misspelling
28	21	Agilant	Agilent	Misspelling
29	1	Agilant	Agilent	Misspelling
29	2	Phillips	Philips	Misspelling

<u>PAGE#</u>	<u>LINE #</u>	<u>CORRECTION FROM</u>	<u>CORRECTION TO</u>	<u>REASON</u>
32	8	Agilant	Agilent	Misspelling
32	17	Agilant	Agilent	Misspelling
32	9	Phillips	Philips	Misspelling
32	18	Phillips	Philips	Misspelling
33	24	make	take	Transcription error
35	20	Camillas	Camillus	Misspelling
37	14	carbohydrate activity	carbohydrate and activity	Transcription error
48	1	post perennial	postprandial	Transcription error
57	10	central	essential	Transcription error
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146	14	serves as electro	surface electrical	Transcription error
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148	10	Phillips	Philips	Misspelling
153	13	Phillips	Philips	Misspelling
159	12	is	isn't	Transcription error

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Name

Date

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3

4 DEXCOM, INC.)
5 Petitioner,) Case No.:
6 vs.) IPR 2023-01251
7 ABBOTT DIABETES CARE INC.,)
8 Patent owner.)
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17 BE IT REMEMBERED that, pursuant to notice, the
18 deposition of BRIAN D. GROSS was taken before
19 Victoria A. Guerrero, Oregon Certified Shorthand
20 Reporter, Registered Diplomate Reporter, Registered
21 Merit Reporter, and Certified Realtime Reporter, on
22 Thursday, May 2, 2024, commencing at the hour of
23 8:14 a.m., in the conference room of the law firm of
24 Klarquist Sparkman LLP, in the City of Portland,
25 County of Multnomah, State of Oregon.

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EXAMINATION:
By Mr. Carrozza

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		* * *		

1 Thursday, May 2, 2024; 8:14 a.m.

2 Portland, Oregon

3 ooOoo

4 Whereupon, BRIAN D. GROSS, having first
5 been sworn by the Oregon Certified
6 Shorthand Reporter, testified under oath as
7 follows:

8
9 EXAMINATION

10
11 BY MR. CARROZZA:

12 Q Good morning, Mr. Gross. Let's start off
13 spelling your first and last name for the record?

14 A Certainly. Brian, B-r-i-a-n, D, as in
15 David, G-r-o-s-s.

16 Q I see you brought some materials in with
17 you today.

18 A Yes.

19 Q Do you mind if I take a look at those real
20 quick?

21 A Please.

22 Q Thank you. So this is not every exhibit,
23 but it looks like a lot of the exhibits. Or is this
24 every exhibit that you've cited in your declaration?

25 A It's most. I think some of the larger

1 exhibits that were multihundred pages have been
2 omitted.

3 Q And is there anything in this binder that
4 you're aware of that is not something cited in your
5 declaration?

6 A No.

7 Q I'm not going to go through all of those
8 right now. Thank you. Can you --

9 What's your current residential address?

10 A I live at No. 45 Settlers Ridge Road in
11 North Andover, Massachusetts.

12 Q Are you currently employed?

13 A I am self-employed.

14 Q What's the name of your company?

15 A I am the founder and CEO of Genomics
16 Infectious Disease.

17 Q You're represented by counsel today,
18 correct?

19 A I'm represented by counsel, correct.

20 Q And that's Mr. Mason?

21 A Mr. Mason.

22 Q Have you ever been deposed before?

23 A I was a participant in a deposition related
24 to a product liability issue with my previous
25 employer.

1 Q Outside of that deposition, have you ever
2 been deposed?

3 A No, sir.

4 Q So your attorney, Mr. Mason, may have
5 explained to you how depositions work, you may have
6 some knowledge from your previous experience, but
7 let's go over a few ground rules to make sure we
8 start off on the same page. Okay.

9 First, you understand that you're under
10 oath?

11 A I do.

12 Q And this is the same oath that you would
13 take if you were to testify in court?

14 A Understood.

15 Q I'm going to ask you questions throughout
16 the day. Mr. Mason may object from time to time,
17 and he has his right do that. But do you understand
18 that unless he instructs you not to answer a
19 question, that you have an obligation to answer the
20 questions?

21 A I do.

22 Q If you don't understand a part of the
23 question I ask, I ask you to ask me for
24 clarification, please. Thank you.

25 We'll take frequent breaks, about every

1 hour, but if you need one, just speak up.

2 Victoria, the court reporter, is going to
3 try and take down every word we say. So let's do
4 our best to try to avoid talking over each other.
5 Sound fair?

6 A Very good.

7 Q And then Mr. Gross, are you on any
8 medications that would inhibit your ability to
9 recall information?

10 A No, I'm not.

11 Q And is there any reason that you cannot
12 provide truthful and accurate testimony today?

13 A No, there is not.

14 Q Great. Let's get started.

15 I've printed these. Let's put them to use.
16 You're free to use your binder if you think there's
17 some reason that you feel more comfortable, but
18 let's start off with your CV, which is Exhibit 1009.

19 (Exhibit 1009, CV of Brian Gross, was
20 referenced.)

21 BY MR. CARROZZA:

22 Q Do you recognize Exhibit 1009 as your CV?

23 A I do and it is.

24 Q Is this a current copy of your CV -- or was
25 it current at the time it was submitted?

1 A It is current to the time it was submitted.

2 Q As far as you know, is everything in the CV
3 accurate?

4 A Yes.

5 Q Let's start off on page 4. We'll focus
6 first on your education. Just go over that. So you
7 have a Bachelor of Science degree in electrical
8 engineering; is that right?

9 A That's correct.

10 Q That's from the Worcester Polytechnical
11 Institute?

12 A Worcester.

13 Q How do you say that?

14 A Worcester, like in Worcestershire Sauce.

15 Q Thank you. Do you have a separate
16 bachelor's degree in biomedical engineering?

17 A No. The BS is in electrical engineering
18 with a biomedical focus, graduated with honors.

19 Q Okay.

20 A My master's is in biomedical engineering.

21 Q So undergraduate, electrical engineering
22 with focus in biomedical engineering and then a
23 master's in biomedical engineering; is that right?

24 A That's correct.

25 Q And your undergraduate degree, you received

1 that in 1990?

2 A That's correct.

3 Q And you received your master's degree in
4 1991?

5 A That is correct.

6 Q Now, from 1982 to 1986, you also attended
7 the Syracuse University, right?

8 A That is correct.

9 Q And that was to study industrial design and
10 engineering?

11 A Correct.

12 Q Did you receive a degree?

13 A Not from Syracuse.

14 Q Why not?

15 A Industrial design is a five-year BID
16 program. Three years into it I found that the type
17 of challenges that industrial designers were solving
18 were not technically focused. The problems were how
19 blue should this be or how soft should that curb be.

20 And since I had become a paramedic and a
21 respiratory therapist by that time, I was really
22 focused on clinical problems and problems in the
23 biomedical space, which drew me into the engineering
24 realm.

25 Syracuse Engineering has a bioengineering

1 focus, not a bioinstrumentation focus, and that's
2 primarily the reason why I transferred to Worcester
3 Polytechnical Institute, which had a specific focus
4 in bioinstrumentation.

5 Q So how far into the program at Syracuse did
6 you advance?

7 A Three years, I believe, is when I
8 transferred from the five-year program to WPI.
9 Yeah. So my attendance was from '83 to '88 and from
10 '88 to '90 for the BS and then an additional year
11 for the following master's.

12 Q And there's also this entry here. 1986 AAS
13 respiratory care. Can you tell me about that?

14 A Certainly. Syracuse is a fairly expensive
15 university. And at the time I was funding my way
16 working as a paramedic for the university, which
17 provided some income to offset my tuition.

18 I acquired interest in healthcare,
19 respiratory care program, which resulted in my
20 attending and becoming certified and licensed as a
21 respiratory care practitioner or RRT. That gave me
22 additional clinical insights into the types of
23 problems that biomedical engineers have to solve,
24 given that it's between the patient and the
25 engineering or the technology.

1 So I was working probably eight hours less
2 than a full shift of two weeks as a respiratory
3 therapist attending university full-time. And
4 continuing to work as a paramedic for the
5 university, as well as volunteering in the
6 organizations around the community, as you can see
7 from community service.

8 Q All right. Thank you for that. Let's talk
9 about your work experience, which let's start on
10 page 3 and work our way backwards.

11 A Okay.

12 Q So from 1983 to 1988, you mentioned you
13 were a paramedic/skills evaluator. Was this for
14 different ambulance services?

15 A Correct. The way the paramedic program
16 worked in upstate New York at that time, since I was
17 in one of the first groups of paramedics to be
18 certified in upstate, they had county jurisdiction.
19 So as a skills evaluator, I was responsible for the
20 recertification of other paramedics and the training
21 of other paramedics.

22 And you can see a variety of organizations
23 that I worked for directly as a care provider as a
24 paramedic, as well as -- all these organizations are
25 within the county where I also served as a skills

1 evaluator.

2 Q Then from 1985, and it says to present,
3 that you are a respiratory care practitioner; is
4 that right?

5 A So yes, although I'm currently not actively
6 participating in direct care anymore, I am still
7 licensed in the commonwealth of Massachusetts as a
8 licensed respiratory care practitioner.

9 Q Is that something you have to renew from
10 time to time?

11 A It is. It is. Just like nursing and other
12 allied health professions.

13 Q And do you have to take ongoing continuing
14 education courses?

15 A I do.

16 Q And so for that particular -- well, let me
17 ask -- strike that. Let me start over.

18 When's the last time that you were active
19 as a respiratory care practitioner?

20 A So I utilized my respiratory care license
21 during research activities through my employer at
22 Phillips Healthcare. Many of the research
23 activities resulted in CEU available or CEU
24 optional -- CEU-bearing activities. So attending
25 conferences, presenting papers, being an

1 investigator on specific research activities; those
2 qualify as CEUs once recognized by the Commonwealth.

3 Q And so outside -- so that was for research,
4 though, right, that you just mentioned?

5 A Presentation of clinical papers and
6 presentation of -- participation in clinical
7 training conferences.

8 For example, I'm also a member of Society
9 for Critical Care Medicine at the time, and CEUs
10 were granted for participating in the critical care
11 educational programs for SCCM and also overseas at
12 European Society for Critical Care, which I also
13 attended.

14 Q Okay. Let me ask a more direct question
15 because I don't think I'm asking you very well.

16 In that position as a respiratory care
17 practitioner, have you taken care of patients, is my
18 question?

19 A Oh, thank you for the clarification.

20 Q It's my fault.

21 A Yes. I was employed at St. Joseph's
22 Hospital in Syracuse, New York, where I served as a
23 critical care respiratory care practitioner for
24 adult ICU, for neonatal ICU, for traumatology, for
25 the floors.

1 I also served as a home care respiratory
2 care practitioner in Massachusetts where I was
3 responsible for providing care to patients in the
4 home setting, also was working for a period of time
5 at University of Massachusetts, also in the critical
6 care environment, floor care, and chronic care
7 environment.

8 And finally, at Memorial Hospital in
9 Worcester, Massachusetts, prior to their merger into
10 one healthcare organization, where I also functioned
11 as an in-hospital respiratory care practitioner.

12 Q Okay. Thank you for that. And can we put
13 time frames on each of those different positions
14 that you mentioned? Ballpark, you don't have to
15 give me exact dates.

16 A Yes. So the Massachusetts activities would
17 have been from '88 to '90, '91. The New York
18 activities obviously would have been between my
19 licensing or my credentialing in the mid-80s until
20 my departure in '88.

21 Q Very good. Thank you. So from 1989 to
22 1991, you also have listed on your CV that you were
23 a research fellow; is that correct?

24 A Correct. Worcester Polytechnic Institute
25 provided me funding during this period where I was

1 directed in sponsored research. My activities there
2 included developing an artificial lung that was
3 designed to operate within the -- in the gut. And
4 the clinical evaluation of that under Yorkshire
5 swine model, which actually became my thesis.

6 Q What was the model that you just mentioned?

7 A Yorkshire swine. It's a domesticated pig.

8 Q Then from -- let's see. I think this goes
9 on to page 2 of your CV, Exhibit 1009. From 1991 to
10 1993 you were a scientist for the company VivaScan
11 skin; is that right?

12 A That's correct.

13 Q You worked on near infrared acousto-optic
14 tunable filters; is that right?

15 A Yeah. The application was to develop
16 measurement technologies for non-invasive glucose
17 monitoring. At the time there were a lot of people
18 working on electrochemical technologies. Some were
19 working on polarimetric measurements, for example in
20 the eye.

21 And our focus was on developing
22 differential spectral analysis that would be
23 suitable for noninvasive, completely noninvasive
24 technologies.

25 Q Did that ever materialize into a commercial

1 product?

2 A The technology was funded by a blood
3 glucose monitoring or blood glucose measurement
4 company that terminated funding, I guess, after
5 1993. So I don't know if the technology has
6 actually evolved into a product. I know the patents
7 that were filed are still active.

8 Q What was the company that funded that?

9 A The company that funded it was called
10 VivaScan -- I'm sorry, LifeScan, which is a Johnson
11 & Johnson Company.

12 Q So what was your role?

13 A I was one of the three members of the
14 technical team. It was a very small start-up. My
15 role ranged from designing and building discrete
16 component electrical instrumentation. I was also
17 responsible for managing whatever animal and human
18 subject studies we were doing. I was part of the
19 science team.

20 So we were reviewing the interactions
21 between the software and the hardware that we were
22 running and working with a PhD physicist to reduce
23 to practice some fairly new technologies in
24 acousto-optic tunable filters, which is basically a
25 digital solid state filter that you can modulate

1 light amplitude and frequency by putting a standing
2 sound wave across a tellurium (phonetic) oxide
3 crystal.

4 Q I'm sorry if you've already explained this,
5 but maybe I missed it. So this technology that
6 we're talking about here from VivaScan, this was
7 trying to analyze glucose levels in a patient by
8 using, is it infrared?

9 A Near infrared.

10 Q Near infrared. Okay.

11 In what substance or tissue or fluid of a
12 person is the glucose being analyzed, if that
13 question makes sense to you?

14 A So if you look at the patents that were
15 filed, we're making differential light measurements
16 through any part of the body that we could modulate
17 the tissue content. So most of the animal studies
18 were based on the nape of a neck in rat models.

19 So the way the measurement worked is you
20 would squeeze, make an optical measurement, release
21 the squeeze to bring fresh interstitial fluid into
22 the sample, and make a measurement. And the
23 measurement was related to the glucose
24 concentration.

25 So transferring to a human, you can

1 envision the ear, you can envision the pinch between
2 the thumb and the forefinger. Any skin flap would
3 be suitable for this type of measurement.

4 Q Okay. I understand now. Thank you.

5 From 1993 to 2001, you were a field
6 trial/clinical validation manager; is that right?

7 A That's correct.

8 Q That was initially for HP Medical Systems?

9 A Yeah. Hewlett Packard Medical Systems in
10 Waltham, Massachusetts, was the headquarters for
11 that division. HP was in need of someone to help
12 them with their clinical studies and managing some
13 of their design challenges that they were finding
14 were less than acceptable in market.

15 So by implementing a quality process
16 improvement and by bringing projects through this
17 process, I was able to help them reduce their defect
18 quality or defect counts post release, as well as
19 provide them better insights into the design
20 tradeoffs that needed to occur.

21 And in that role, I was servicing multiple
22 cross-functional teams spanning across the
23 portfolios. So this is from patient monitoring to
24 home care monitoring to the other assets that
25 Phillips -- excuse me, that Hewlett Packard was

1 manufacturing on market with at that time.

2 Q Did HP Medical Systems become Agilent
3 Technologies?

4 A Yeah. HP decided they didn't want their
5 medical and test businesses because the computers
6 and printers were going to be their future. And as
7 a result, they split the company into Agilent and
8 Hewlett Packard. And Agilent essentially became the
9 medical products and the testing measurement group.
10 So the gas chromatography systems, the wave
11 modulators, things that weren't computers and
12 printers, essentially.

13 Q Then did Phillips acquire Agilent in 2001?

14 A That's correct. Around 2001 Phillips
15 closed the acquisition for integration into the
16 Phillips Healthcare. At the time it was Phillips
17 North America that the business was run under.

18 Q So from 2001 through 2006, you have listed
19 on your CV that you were the senior manager of
20 clinical research; is that right?

21 A That's correct.

22 Q And in that role, did you perform clinical
23 research or oversee clinical research?

24 A Both. I was responsible for the design and
25 execution of clinical studies. I was also

1 responsible for overseeing the teams that were doing
2 clinical validations for products under the quality
3 management system.

4 Q And what were the clinical studies -- what
5 was the subject matter of the clinical studies that
6 you were involved with?

7 A They ranged depending on the project. Many
8 medical devices required clinical testing prior to
9 clearance. So doing data collection with a finished
10 product is required in order to get that data before
11 the FDA.

12 So for example, at least one of the studies
13 that I was involved with was looking at the monobase
14 of blood pressure measurement in adults and in
15 neonates compared to an indwelling catheter.

16 And doing that data collection pursuant to
17 the standards that are required and the data
18 reductions required to now bring that data to the
19 regulatory team for inclusion and submissions.

20 Q And from 2014 through -- I'm sorry. I
21 skipped one. Back up.

22 From 2006 through 2014 you were the
23 principal scientist/clinical systems architect; is
24 that right?

25 A Yeah. I was promoted because of my impact

1 in the organization and because of my impact for
2 peer and customer outside of the organization. So I
3 was developing the opportunity and the skills to
4 help drive the implementation teams on their
5 trade-off decisions as part of my responsibility.

6 And as a clinical systems architect, I was
7 also responsible for managing the key opinion
8 leaders and making sure that their feedback and
9 insights into the technology and business roadmaps
10 were voiced appropriately.

11 And again, my primary focus, as Phillips
12 became a combination of acquired businesses, that
13 these things looked and felt like they came from the
14 same company, they interoperated correctly, they
15 spoke the same protocols, they all had a common
16 battery strategy or common radio strategy when
17 applicable.

18 So that was really the key focus at that
19 time.

20 Q Okay. Were you also the CTO?

21 A No. I worked for the CTO.

22 Q You worked for the CTO. Okay.

23 From 2014 to 2022 you were a fellow
24 scientist/clinical systems architect, right?

25 A That's correct. The impact on the business

1 and other businesses within Phillips was recognized,
2 I was promoted to fellow, responsible for driving
3 innovation across the cluster, doing a lot of
4 alignment in architecture, ensuring that quality
5 management systems and safe agile practices are
6 being followed appropriately. Safe agile being an
7 iterative method of product development.

8 Tutoring and mentoring less experienced
9 engineers and developers through the learnings at
10 least I had accumulated in almost a decade of
11 working in the field.

12 Q And did you retire from Phillips in 2022?

13 A I did. After being a fellow, I was
14 responsible for several innovations that were
15 focused in the business, not the research
16 organization. The last -- one of the last
17 innovations I was responsible for was a molecular
18 epidemiology system that Phillips brought to market
19 as a new business. But then at the foothills of
20 COVID, decided to double down on boxes and imaging
21 systems and whatnot.

22 So they decided to essentially dry dock
23 that business. As part of my retirement, I was able
24 to obtain a license to what I had been working on,
25 and hence the transition into Genomics Infectious

1 Disease, which is the business that I stood up.

2 Q Very good. So all the dates that we've
3 talked about here, these are all accurate to the
4 best of your recollection, right?

5 A Yes, to the best of my recollection.

6 Q And so just to be sure on one particular
7 date, from 2001 through 2006 you were the senior
8 manager of clinical research, right?

9 Let me -- before you even answer, let me
10 strike that. I'll tell you what I'm asking.

11 Do you have a LinkedIn profile?

12 A Uh-huh.

13 Q And so did you prepare the content of your
14 LinkedIn profile?

15 A I curate that when I can.

16 Q Your LinkedIn profile says that you were
17 the senior manager of clinical research from 1994 to
18 2001. And that's not what it says on your CV, and
19 I'm just trying to figure out which one is wrong.

20 A I'm sorry, which?

21 Q Let me share it with you. Make this an
22 exhibit. This will be Exhibit 2011.

23 (Exhibit 2011, LinkedIn Summary of Brian
24 Gross, was marked.)

25 ///

1 BY MR. CARROZZA:

2 Q So Victoria just handed you what's been
3 marked Exhibit 2011. This is a printout of your
4 LinkedIn resume.

5 A Uh-huh.

6 Q And take a minute to look it over and see
7 if you recognize it as your LinkedIn resume.

8 A This looks accurate to at least one
9 iteration of it.

10 Q So the first question I have is on page 2.
11 It says Phillips, that you worked for Phillips for
12 30 years, five months. That's including the time
13 actually from the acquisitions from HP to Agilant
14 then Phillips, right?

15 A Yeah, LinkedIn doesn't recognize that.

16 Q I figured. Thank you.

17 So then the question I have here is it
18 shows on page 3 or it says on page 3 that you're the
19 senior manager of clinical research from 1994 to
20 2001. But your CV says that you had that position
21 from 2001 to 2006. And so I'm trying to understand
22 which one's wrong, which one's right?

23 A Yeah. So the promotion to principal
24 scientist occurred in 2006. So I may have combined
25 those two roles just to make my resume a little more

1 compact.

2 Q On LinkedIn?

3 A On LinkedIn, correct.

4 Q So you would say that your CV that's
5 submitted as Exhibit 1009 in this IPR is more
6 granular and accurate?

7 A I would say that.

8 Q All right. Thank you for all that. Let's
9 start off with a couple other technological
10 questions.

11 First, do you know what a continuous
12 glucose monitoring system is?

13 A I'm sorry?

14 Q Continuous glucose monitor, do you know
15 what that is?

16 A I know of a few continuous glucose
17 monitoring systems.

18 Q If I refer to that as a CGM, will you
19 understand what I mean?

20 A If that's what you're referring to. So a
21 CGM containing a glucose oxidase or a similar sensor
22 below the cutaneous tissue?

23 Q We can go with that, but CGM is just sort
24 of a generic acronym for a continuous glucose
25 monitor. And I just want to make sure if I use that

1 acronym, that you'll understand what I'm referring
2 to.

3 A I will understand that the genus of glucose
4 monitoring systems is what you're referring to.

5 Q And if we talk about something specific
6 like electrochemical, I'll specify.

7 A Okay.

8 Q You understand what a blood glucose monitor
9 is or blood glucose meter, sometimes they're called?

10 A A test strip meter?

11 Q Yes.

12 A I do.

13 Q If I referred to that as a BGM throughout
14 the day, will you understand what I mean?

15 A Forgive me if I ask you to clarify, but
16 yes, I think we can move forward with that.

17 Q Fair point. And then do you know what an
18 insulin pump is?

19 A I do.

20 Q Now, of the companies you worked for, HP
21 Medical Systems, Agilant Technologies, and Phillips,
22 they didn't offer any CGM products, right?

23 A No. We were evaluating if that was a
24 relevant component to our portfolio. I was involved
25 in some of those technical assessments.

1 Q And none of HP Medical Systems, Agilant
2 Technologies, or Phillips offered insulin pumps,
3 right?

4 A Same answer. That we were evaluating if
5 that fits into the portfolio. We did provide
6 interface to hospital pumps, which are capable of
7 insulin delivery.

8 Q And so during your time with these
9 companies from 1993 to 2022, your work didn't
10 involve CGMs on a daily basis, right?

11 A From 1993 'til --

12 Q 2022 when you retired.

13 A Again, from time to time I was part of an
14 evaluation and due diligence team looking at these
15 technologies for inclusion into product portfolio.

16 Q And so these weren't products that your
17 company offered. This was looking into technology
18 that other companies offered?

19 A Correct.

20 Q And what was your work in evaluating these
21 other companies' products?

22 A As part of the cross-functional team
23 evaluating the quality, the manufacturability, the
24 design, sustainability; there's a fairly substantial
25 rubric that we used as part of our due diligence.

1 Q When you say quality, what do you mean by
2 quality?

3 A Quality in terms of adherence to quality
4 management systems. This is the FDA umbrella by
5 which the organization produces these products. As
6 well as the quality of the work and the
7 specification and the manufacturing records that the
8 organization produces.

9 Q And what are the products that you
10 evaluated?

11 A As I said, there were a variety of
12 technologies that we were evaluating. I'm not at
13 liberty to disclose which ones.

14 Q Why is that?

15 A That would be considered proprietary and
16 confidential under the previous agreements with my
17 employer.

18 Q Without naming specific products, were they
19 continuous glucose monitors?

20 A A few of the devices had capabilities to
21 deliver continuous glucose measurements, yes.

22 Q What do you mean by they had the capability
23 to deliver?

24 A So again, without disclosing the details of
25 the technologies, the intention was a continuous or

1 quasicontinuous measurement of glucose, of blood
2 glucose in man. That was the intended measurement
3 that these devices were producing.

4 Q Were they based on electrochemical sensors?

5 A Again, I can't go into the details. I'm
6 sorry.

7 Q I think that's a detail you can disclose
8 because I don't know what products or companies
9 you're even referring to at this point.

10 A There was a variety --

11 Q Unless you want to consult with your
12 attorney.

13 A No. There were a variety of technologies
14 that these companies were claiming had the
15 capabilities of delivering continuous glucose in man
16 and in the critical care setting. Some of them were
17 electrochemical, others were not.

18 Q And putting aside the products that you've
19 evaluated from other companies, the companies that
20 you worked for did not offer continuous glucose
21 monitors, right?

22 A So the companies that I worked for, in
23 particular VivaScan, was looking to develop
24 continuous glucose capabilities or noninvasive
25 glucose monitoring capabilities. In that work the

1 technologies that I was working with and responsible
2 for included in vitro glucose monitoring, which is
3 based on similar technologies to what I think some
4 of the electrochemical CGMs are based on.

5 Q All right. So let's make sure that my
6 question is clear.

7 Of the companies you worked for from 1993
8 to 2022, which include HP Medical Systems, Agilent
9 Technologies, and Phillips, none of those companies
10 offered continuous glucose monitoring products,
11 correct?

12 A Correct. That's a market they chose not to
13 participate in.

14 Q And same question with reference to the
15 companies, none of those companies offered insulin
16 pumps as well, right?

17 A As I said, the Hewlett Packard, Agilent and
18 Phillips technologies provided interfaces to insulin
19 pumps in the healthcare setting.

20 Q But they didn't offer insulin pumps
21 themselves, correct?

22 A Correct. In fact, the interfaces were to a
23 variety of insulin pumps, so there were specific
24 interfaces developed for many different insulin
25 pumps that were available on market at the time.

1 Q What do you mean by interface?

2 A So in the healthcare setting, if you want
3 to provide useful information beyond just a
4 standalone box, getting that information integrated
5 into the monitoring system is usually done through a
6 variety of communication protocols from the
7 standalone device into the networked monitoring
8 system.

9 So now the monitor, the patient monitor has
10 the ability to provide the user more useful and
11 contextually rich data by which they can treat the
12 patient.

13 So looking at a continuous ECG waveform and
14 blood pressure trends superimposed with insulin pump
15 rates or dextrose administration rates was a very
16 valuable context setting information set for the
17 clinical user.

18 So a variety of devices, including
19 ventilators and standalone pumps and, you know,
20 literally any device that had electronic interface,
21 we took great effort to make sure that that data
22 could be aggregated and contextualized in the
23 presence of the patient monitor so the care team
24 could make most useful information available to
25 their care decisions.

1 Q Let me make sure I understand what you're
2 saying here.

3 The context of a particular biomedical
4 signal is what you're saying is helpful? That
5 wasn't phrased well. I just want to make sure I
6 understand what you're saying, so let me rephrase
7 that question. Start over.

8 If you have just a single biomedical signal
9 like an EEG waveform, is what you're saying in your
10 previous answer that the context about other factors
11 that correlate with that EEG waveform is what's
12 helpful?

13 Strike that question. Let me just ask.
14 What did you mean by context driven? You used the
15 word "context." I'm trying to understand that.

16 A Sure. So a critically ill patient may have
17 vaso active medications, medicines that cause the
18 blood pressure to either go up or down, depending on
19 what the clinical problem is.

20 When you ventilate that patient, in other
21 words, you have a breathing tube in and you're
22 driving air in and out so that the patient can
23 oxygenate, the positive pressure in their chest
24 causes perturbations or changes to the continuous
25 blood pressure.

1 So contextualizing the impact of what the
2 ventilator is doing with the blood pressure and the
3 medications you're giving is what the care team
4 needs to have, that full view of contextualized care
5 data, in order to determine should I turn the
6 ventilator down or turn the med up or do something
7 else.

8 Q I understand now. Thank you. I know
9 you're a paramedic, but you're not a medical doctor,
10 right?

11 A Correct.

12 Q And so you don't have a medical degree?

13 A Correct. My handwriting was too neat.

14 Q Have you ever treated anyone with diabetes?
15 Well, that's not phrased well. Let me strike it.

16 Have you ever treated a patient with
17 diabetes for a diabetic episode?

18 A Numerous events and numerous occasions.

19 Q Give me some examples.

20 A In my time in Camillas, New York, I worked
21 for West Area Volunteer Ambulance, WAVES. There
22 were numerous diabetics in the coverage area that I
23 was summoned to repeatedly, ranging from diabetic
24 coma to insulin shock, where as a paramedic I was
25 called to immediate medical care to stabilize the

1 patient, bring them to the hospital.

2 Q And what would you do if -- what treatment
3 would you provide for a patient that was in diabetic
4 shock or coma?

5 A Depends on the -- you know, the condition
6 and the nature. There were medications that I could
7 administer. I could draw blood and do a blood
8 glucose strip measurement. I could administer
9 glucose or D50, for example, you know, to remedy the
10 issue.

11 In the absence of a definitive cause for an
12 altered consciousness, for example, there were
13 protocols in place that I could operate under.

14 Q Okay. Let's talk specifically about CGMs.
15 Since you're not a doctor, you've never prescribed a
16 CGM to a patient, right?

17 A That's correct.

18 Q You've never helped a diabetic patient
19 select a CGM that's right for them?

20 A Other than a colleague or a friend that had
21 CGM technologies, that's correct.

22 Q Do you, yourself, have diabetes, if you are
23 willing to answer that question?

24 A No, I do not.

25 Q In your role as a paramedic, have you ever

1 administered insulin to anybody?

2 A No, that was not an administration that was
3 sanctioned of the protocols at the time I was
4 practicing.

5 Q Do you know what the term "basal insulin"
6 refers to?

7 A In which context, please?

8 Q In the context of calculating the amount of
9 insulin to administer to a diabetic patient.

10 A I've heard the term.

11 Q Do you know what it means, though?

12 A So I understand it is an insulin
13 administration protocol pursuant to what a
14 particular person's carbohydrate activity is in that
15 contextualized equilibrium.

16 Q Have you ever heard the term "bolus
17 insulin"?

18 A I have.

19 Q Do you know what that term means?

20 A I do.

21 Q What's bolus insulin mean?

22 A So bolus insulin would be a larger than --
23 well, not a larger. It would be an amount of
24 insulin to be administered in a single dose as
25 opposed to a lower dose that would be titrated over

1 time.

2 Q Have you ever calculated a bolus insulin
3 dose for anyone?

4 A I have not.

5 Q Have you ever calculated a basal insulin
6 dose for anyone?

7 A I have not.

8 Q Have you ever used a CGM personally?

9 A I have.

10 Q Which CGMs have you used, in what context?

11 A In a project that I recently completed with
12 Department of Defense, we were looking at glucose
13 level changes and were using a DexCom CGM. I do not
14 recall which model.

15 Q What time frame was that?

16 A This is DOD work that was completed -- let
17 me try to think when that project ended. Earlier
18 this decade, 2000 [sic], 2022.

19 Q So what was your experience or what did you
20 do with the CGM?

21 A I'm not sure what you mean.

22 Q My question was have you ever used one?
23 And you answered yes. So my question is, what did
24 you do with it?

25 A So the CGM was used as a collection of

1 biosensors for data collection under specific
2 conditions that DARPA and DITRA were interested in
3 for detecting specific threats to the military
4 workforce.

5 Q Thank you for that. I don't think I'm
6 asking the question clearly enough.

7 When you say that you used a CGM, did you
8 apply it to yourself?

9 A No. I was not a subject in the study.

10 Q And have you ever applied a CGM to
11 yourself?

12 A No, I have not.

13 Q Have you ever tested a CGM in any other
14 context besides this DARPA work?

15 A Other than the evaluation of technologies
16 that we discussed previously, no.

17 Q Have you ever torn down a CGM?

18 A I have not.

19 Q Have you ever reverse engineered a CGM?

20 A What do you mean by "reverse engineered"?

21 Q Try to figure out how different aspects of
22 it work.

23 A So I haven't had the need. A lot of the
24 operational principles, practices, and technologies
25 are fairly well defined and published.

1 Q Have you ever reviewed source code for any
2 software that runs on a CGM?

3 A I have not.

4 Q Have you ever reviewed data that's stored
5 on a CGM? And let me clarify this. Glucose data
6 stored on a CGM.

7 A I have.

8 Q In what context?

9 A Again, referring back to the Department of
10 Defense contract, extracting and analyzing the data
11 coming out of the CGM system, I was part of the
12 analysis that the team and I were doing.

13 Q Did you ever use an insulin pump?

14 A Again, other than interfacing to in the
15 context of critical care, no.

16 Q Have you ever tested an insulin pump?

17 A With regards to the hospital setting, yes.
18 That's part of the validation verification of the
19 interfacing.

20 Q When you are testing it, are you testing it
21 on patients or testing it in more of a laboratory
22 setting?

23 A The bench testing is in the laboratory
24 setting. The clinical validation would be in the
25 live clinical setting.

1 Q Have you ever torn down an insulin pump?

2 A Other than as a manufacturer required for
3 cleaning or for reloading, no.

4 Q Have you ever reverse engineered an insulin
5 pump?

6 A No.

7 Q Have you ever reviewed source code for
8 software that runs on an insulin pump?

9 A With regards to the interfacing, yes.

10 Q But that software would not -- would the
11 software run on the insulin pump itself?

12 A So the insulin pump or the generic pump
13 would have a communication protocol running inside
14 of it; that in order to do the interface to
15 downstream systems, you would need to understand how
16 it's going to communicate, what data it's going to
17 communicate, and how do you map that into the
18 ontology, or the concepts that the downstream system
19 understands.

20 So that would require that you would have
21 to understand how the insulin pump communicates via
22 instant communication interface or how the infusion
23 pump communicates through its interface.

24 Q I understand. Thank you.

25 And did that entail looking at source code

1 or did that entail analyzing software that ran on
2 the pump?

3 A Typically that would entail reviewing the
4 manufacturer's specifications, designing tests
5 around that to ensure that the interface would be
6 safe and effective on both sides of the
7 communication. And then doing an implementation
8 and, again, bench testing and clinical validation
9 after that.

10 Q Have you ever used BGM on yourself to take
11 a glucose measurement?

12 A The BGM, you're referring to a strip?

13 Q Yes.

14 A I have.

15 Q In what context?

16 A So I recall taking blood glucose strip
17 measurements during my work with VivaScan. We were
18 doing some human studies. And I was not a subject,
19 although I was encouraged by the subjects who have
20 to take strip measurements dozens of times a day in
21 some cases to experience that, and I took advantage.

22 I knew what it meant to be pricking your
23 finger daily repeatedly to get blood out in order to
24 find at least a spot value of where you stand.

25 Q So in your opinion, is a blood glucose

1 meter or strip meter or a CGM typically more
2 accurate?

3 A That's a difficult question to answer given
4 that each of those devices have their own stated
5 reliability and accuracy as part of their labeling.

6 Q Are you saying, then, in some context a CGM
7 is more accurate of a person's glucose levels than a
8 blood glucose meter is?

9 A No. What I'm saying is that the strips
10 have a -- typically have a labeled statistical
11 variance that one should expect. That the true
12 glucose compared to a clinical laboratory
13 measurement would fall in between for any given
14 value that you get off of the meter. CGMs have the
15 same behavior compared to either a blood glucose
16 strip test or a clinical laboratory result.

17 Q And if you were to compare the two, would
18 you agree that blood glucose meters are more
19 accurate of a person's glucose levels than a CGM is?

20 MR. MASON: Objection. Form. Scope.

21 BY MR. CARROZZA:

22 Q Hold on before you answer. What was your
23 form objection?

24 MR. MASON: Form objection is what do you
25 mean by "more accurate"?

1 BY MR. CARROZZA:

2 Q Do you understand what I mean by the words
3 "more accurate" of a person's glucose levels?

4 A So at any given point in time, the value
5 that is available to the user has a statistical
6 probability of being related to the standard measure
7 by which that device is designed against or built
8 against.

9 So you have the uncertainty of the golden
10 measure, which in this case -- many cases of CGMs
11 would be the strip. And then you have the
12 uncertainty of the CGM data, the uncertainty of the
13 CGM value that can be impacted by, you know, a
14 variety of different things. You know, rate of
15 change, temperature, age of the sensor, things of
16 that nature, and others, that can impact the
17 accuracy, I think as you describe it, within the
18 system.

19 Q So if a person wanted to know what their
20 glucose levels were at this point in time, would you
21 suggest to them to use either a CGM or a BGM?

22 A So given I don't have to make that decision
23 for a patient, they should get that information from
24 their endocrinologist or physician. I'm not sure I
25 have an opinion.

1 Q So sitting here today, you would not agree
2 that a blood glucose strip meter is more accurate of
3 a person's glucose levels than a continuous glucose
4 monitoring system; is that your testimony?

5 MR. MASON: Objection. Scope.

6 MR. CARROZZA: You can answer.

7 MR. MASON: Form.

8 THE WITNESS: Repeat your question,
9 please.

10 MR. CARROZZA: Can you read it back,
11 please.

12 MADAM COURT REPORTER: "QUESTION: So
13 sitting here today, you would not agree that a
14 blood glucose strip meter is more accurate of a
15 person's glucose levels than a continuous
16 glucose monitoring system; is that your
17 testimony?"

18 THE WITNESS: So given that the continuous
19 glucose systems are typically calibrated or run
20 calibration algorithms against the strip, if
21 the strip is, again, within the date range
22 that's required and if the blood is acquired
23 appropriately, it does appear that that is a
24 suitable calibration point.

25 Therefore, it would be considered a

1 higher level of standard compared to a CGM
2 output, especially if the CGM output is
3 questionable.

4 I believe the user is suggested or
5 advised to get a strip measurement to confirm
6 or to update, in many cases, calibration.

7 BY MR. CARROZZA:

8 Q There's a lag time that's inherent in CGM
9 readings, right?

10 A A lag time between?

11 Q Between what a person's actual glucose
12 levels are and what the CGM will display as far as
13 their glucose levels.

14 A For a discrete point in time, that's
15 correct.

16 Q And that's because the amount of glucose
17 that's in a person's interstitial fluid is going to
18 lag behind the glucose in their blood, correct?

19 A That's at least one reason for the lag or
20 the delay in the glucose value that you get a CGM
21 compared to blood glucose from a core blood sample.

22 Q And another source of lag would also be the
23 processing that goes on in a continuous glucose
24 monitor?

25 A That would be in another example of delay.

1 Q Are there other reasons for a lag of
2 glucose readings being shown on a CGM versus what
3 they actually are that you can think of?

4 A In some cases the sensor transceiver cannot
5 communicate with the display, at which point that
6 data would be delayed to the user. That would be
7 another example.

8 Q And let's put aside any -- any issues with
9 the functioning of a system. Let's assume the
10 system is functioning as the way it's intended.

11 What I'm asking is are there any other
12 reasons why the glucose level shown on a CGM is
13 going to lag behind what the person's actual glucose
14 levels are at a given point in time?

15 A Yes. As we discussed, there's latency in
16 the physiology. There's latency in the
17 electrochemical conversion to a signal. There's
18 latency in the processing and filtering. There's
19 latency in the transmission. There are many
20 reasons. Those are at least some of them.

21 Q Okay. Thank you. In the U.S. do you know
22 what units glucose concentration is measured in?

23 A Typically it's in milligrams per deciliter.

24 Q Do you know what a target range is for an
25 average adult human for glucose?

1 A Depends on whether fasting, post perennial.

2 Q Do you have, like, just a rough sense of
3 what typically a person's glucose levels are when
4 they're not hyper- or hypoglycemic?

5 A So under normal physiology, I believe the
6 normal glucose is between 80 and 120 milligrams per
7 deciliters.

8 Q Have you ever instructed anyone on how to
9 use a CGM?

10 A Referring back to the Department of Defense
11 contract work, I was involved in the organization of
12 the instrumentation instructions whereupon I was
13 relying on the manufacturer's installation or
14 assembly and insertion literature. So that was
15 handed over to the clinical team as the artifacts to
16 drive their clinical practice for the research
17 project.

18 Q What about a patient with diabetes? Have
19 you ever instructed a patient on how to use a CGM?

20 A That is not within my practice domain.

21 Q Have you ever helped a diabetic patient
22 determine what appropriate thresholds they should
23 have for a target glucose range?

24 A Again, that's beyond the practice domain of
25 my licensure.

1 Q Understood. You're familiar with the term
2 "hyperglycemia," right?

3 A Clinical definition, yes.

4 Q That's when a person's glucose levels are
5 higher than a certain threshold?

6 A That's a reasonable definition.

7 Q Are there ways that you're aware of to
8 treat hyperglycemia?

9 A There are.

10 Q What are some of the ways that you would
11 treat hyperglycemia?

12 A If the patient is insulin dependent,
13 modifying the insulin rate or a bolusing, for
14 example.

15 Q You're familiar with the term
16 "hypoglycemia"?

17 A In the clinical context, yes.

18 Q That refers to when a patient's glucose
19 levels are below some certain threshold?

20 A That's a reasonable definition.

21 Q What are some causes of hypoglycemia that
22 you're aware of?

23 A So from my practice experience in the case
24 of a diabetic, too much insulin compared to
25 carbohydrate intake or activity levels can result in

1 hypoglycemia.

2 Q Are there ways that you're aware of to
3 treat hypoglycemia?

4 A Yes.

5 Q What are some of those ways?

6 A Administering fast-acting carbohydrates,
7 such as 50 percent dextrose solution, certain
8 medications that release glucose out of the liver,
9 like glucagon, were within the practice protocols at
10 the time I was operating.

11 Q Have you ever heard the terms "adjunctive"
12 and "non-adjunctive" use of CGMs?

13 A I'm not familiar with that term.

14 Q Have you ever heard the term "MARD,"
15 M-A-R-D, with respect to CGMs?

16 A Is that an acronym that you can share?

17 Q It's an acronym for the mean absolute
18 relevant difference; are you familiar with that
19 term?

20 A I don't recall reading it.

21 Q So if I were to ask you what the MARD value
22 was for the Medtronic Paradigm in 2007, would you
23 understand what my question is asking?

24 A Based on your definition, I would assume
25 that if that is a performance specification, it

1 would be in the manufacturer's labeling.

2 Q All right. We've been going for an hour.
3 Want to take just a short break?

4 MR. MASON: Sure.

5 THE WITNESS: Certainly.

6 MR. CARROZZA: Go off the record.

7 (Off record from 9:15 a.m. to 9:29 a.m.)

8 BY MR. CARROZZA:

9 Q So during the break, Mr. Gross, did you
10 review any materials that would be relevant to your
11 testimony here today?

12 A No. I did, when we -- just before we got
13 back on the record, I did look through a few of the
14 references. Because your question about MARD may
15 have come across in reviewing some of the
16 performance characteristics, but nothing jumped out.

17 Q Okay. So with respect to that term "MARD,"
18 do you know what the MARD was in any of the studies
19 of the Paradigm insulin pump?

20 A Is there a reference that we can review
21 that you think -- or that might have disclosed that?

22 Q There are. There's many of them. I guess
23 my question is more or less, it doesn't sound like a
24 term that you've paid a lot of attention to for this
25 IPR specifically, right?

1 MR. MASON: Objection. Form.

2 THE WITNESS: So in my disclosure or in my
3 declaration, I don't believe I used the term
4 "MARD."

5 BY MR. CARROZZA:

6 Q And before the break I had mentioned two
7 terms. One was adjunctive and the other one was
8 non-adjunctive use.

9 Do you remember me asking that question?

10 A I do.

11 Q I'll just explain to you what they mean so
12 that we can move forward because I'll have some
13 questions about it.

14 Adjunctive use is when a CGM product
15 requires the patient to use finger sticks to confirm
16 their glucose levels before they make any treatment
17 decisions or insulin dosing decisions.

18 Non-adjunctive use is when a CGM is
19 approved because it's reliable and accurate enough
20 that a person could use just the CGM readings
21 themselves to make treatment decisions.

22 Do you understand that now?

23 A As you've described it, yes.

24 Q So maybe the terms adjunctive and
25 non-adjunctive use weren't clear to you before that.

1 Were you familiar with the concept that the FDA
2 required certain -- the labeling on CGMs that would
3 require a patient to confirm the readings with
4 finger sticks, were you familiar that concept?

5 A So as part of the declaration, I had not
6 reviewed exhaustively all the CGMs on market.

7 Q Okay.

8 A Specifically with regards to FDA clearance.

9 Q So the Medtronic Paradigm insulin pump,
10 which is the subject of one of your exhibits, right?

11 A That's correct.

12 Q The FDA approved the Medtronic insulin pump
13 for adjunctive use only, meaning that patients were
14 required to take finger stick measurements to make
15 treatment decisions, right? Do you recall that, I
16 should ask?

17 A Like so -- I'm going to review what the
18 Medtronic MiniMed document that I reviewed had to
19 say.

20 (Exhibit 1011, Affidavit of Nathaniel E.
21 Frank, Exhibits A and B, was referenced.)

22 BY MR. CARROZZA:

23 Q We can short circuit that and I'll just
24 point you to a specific place.

25 A So on page 38 of Exhibit 1011, I see that

1 the sensor and transmitter user safety information
2 describes, if alerts -- it alerts if glucose levels
3 fall above or below preset values. Values are not
4 intended to be used directly for making therapy
5 adjustments, but rather to provide an indication of
6 when a finger stick may be required.

7 Q And in that same exhibit, 1011, if you turn
8 to page 10, there's a frequently asked question
9 about two-thirds of the way down with a heading that
10 says "Calibration"; do you see that?

11 A On page 10 there's a heading of
12 "Calibration," I see that.

13 Q And the question says, Does the MiniMed
14 Paradigm REAL-Time system replace finger stick
15 measurements?

16 Do you see that question?

17 A I do.

18 Q And then the answer says, No, you still
19 need to use your blood glucose meter to confirm a
20 continuous glucose monitoring (CGM) reading before
21 treating and to calibrate the CGM system. The FDA
22 has approved realtime CGM with conservative
23 labeling. So finger stick measurements are still
24 required before therapy adjustments are made.

25 Did I read that right?

1 A That's what I see in this document.

2 Q I'm representing to you that's what
3 adjunctive use means. That you still have to use
4 finger stick measurements before you make treatment
5 decisions. Do you understand the term now?

6 A I do.

7 Q Okay. Thank you.

8 A I do relative to the MiniMed documentation.

9 Q And are you aware that as of 2009, every
10 commercially available CGM was approved only for
11 adjunctive use?

12 A I don't recall seeing any information
13 either regarding that or disputing that, and I don't
14 recall using adjunctive technologies or
15 non-adjunctive technologies in my declaration.

16 Q So then would you have known that the first
17 CGM to be approved for non-adjunctive use was in
18 2016?

19 MR. MASON: Object to the form.

20 THE WITNESS: Again, I do not have
21 adjunctive or non-adjunctive referenced in my
22 declaration. I don't believe I have that in my
23 declaration.

24 BY MR. CARROZZA:

25 Q Have you ever heard the term "ICGM" before?

1 A ICGM, can you describe what the acronym
2 stands for?

3 Q I can tell you what the term means. I
4 don't remember if the "I" is integrated or something
5 else. But if you're not familiar with it, then we
6 don't have to go further with it.

7 A Okay. There are many things that I can
8 imagine ICGM would represent.

9 Q Have you ever heard the term "automated
10 insulin delivery" or AID?

11 A I suppose I can imagine what that would
12 represent in terms of the context of an insulin pump
13 making a decision within the boundaries it's
14 programmed for, based on the input of a blood
15 glucose value.

16 Q Very good. That is what it means. As of
17 2009 there were no CGMs that you're aware of that
18 were approved for automated insulin delivery
19 systems, right?

20 MR. MASON: Objection. Form.

21 THE WITNESS: So given the definition of
22 automatic insulin delivery and given the
23 MiniMed Paradigm functionality, it appears that
24 there may be at least some features of ICGM --
25 I'm sorry -- automated insulin delivery that

1 were being supported by that.

2 I'm unaware of if it is a regulatory
3 term or if it's an engineering term or function
4 that's being described here. It is not a term
5 I used in my declaration as far as I know.

6 BY MR. CARROZZA:

7 Q Okay. Fair enough. So one of the goals of
8 CGMs is to provide users with accurate glucose data,
9 right?

10 A That would be a key, central performance,
11 yes.

12 Q I mean, if the data is inaccurate, it
13 wouldn't be useful to provide to a patient, right?

14 A In fact, it should not be provided to a
15 patient if it's not accurate.

16 Q Suppose CGM data is off by 20 milligrams
17 per deciliter from what a user's actual blood
18 glucose levels are at a certain point in time.

19 Would you consider that accurate or
20 inaccurate?

21 MR. MASON: Objection. Form. Scope.

22 THE WITNESS: Again, in my declaration I
23 don't believe I described or used accuracy in
24 the construction of how the technologies are
25 applied here. So if you're asking me is

1 20 milligrams per deciliter a big error --

2 BY MR. CARROZZA:

3 Q That is my question.

4 A -- in some contexts, it could be.

5 Q So do you have opinions on how accuracy
6 plays a role in CGMs?

7 A So accuracy from a patient's perspective is
8 an element that they will grow to trust to the use
9 of the system. If they find that they're feeling
10 hypoglycemic and the CGM is telling them they're not
11 and they verify with the blood glucose strip, which
12 would be the gold standard that they are, then that
13 accuracy would be perceived, I believe, by the user
14 as unacceptable, or at least in this case needs to
15 be explained, is it a sharp change in blood glucose,
16 is it a burst of activity, or things of that nature.

17 So from the user's perspective, I can
18 envision and I think accuracy would be viewed as a
19 very important parameter.

20 Q What about from a clinical perspective, do
21 you have opinions on how accuracy plays a role in
22 CGM?

23 A So I'll reflect back to the same analogy
24 that if a patient doesn't have trust in the system,
25 then I think their supervising clinicians might also

1 have concerns over the reliability of the data they
2 generate.

3 Q And a moment ago my question was whether or
4 not you would consider a CGM to be accurate if it
5 was off by 20 milligrams per deciliter; do you
6 remember that question?

7 A I do.

8 Q Let's take that a little further to another
9 extreme. What if the CGM data were off by
10 50 milligrams per deciliter from what a person's
11 actual glucose levels are, you would agree that that
12 is not accurate, right?

13 MR. MASON: Objection. Form. Scope.

14 THE WITNESS: So again, there are
15 conditions where anything greater than 20 could
16 be impactful in the care decision, especially
17 in cases of hypoglycemia.

18 BY MR. CARROZZA:

19 Q So if a patient were using a CGM and it
20 showed them readings of 100 milligrams per
21 deciliter, when in fact the real glucose levels are
22 50 milligrams per deciliter, that patient is
23 actually hypoglycemic at that point, right?

24 MR. MASON: Objection. Form.

25 THE WITNESS: Could be.

1 BY MR. CARROZZA:

2 Q And the CGM is showing them in a pretty
3 acceptable range of a hundred milligrams per
4 deciliter, right?

5 A In your scenario the patient or the wearer
6 would probably be feeling effects of hypoglycemia if
7 their true blood value was that low.

8 Q So they'd want to do a finger stick
9 measurement to confirm?

10 A A finger stick or if they can attribute
11 their feeling of hypoglycemia to high activity or
12 low carbohydrate intake, or whatever the case may
13 be, they may take a little sugar and see how they
14 feel.

15 Q If a person's glucose levels are trending
16 downward, but a CGM is showing them trending upward,
17 that would be a pretty big red flag that the CGM is
18 not very accurate, correct?

19 MR. MASON: Objection. Form.

20 THE WITNESS: So your hypothetical,
21 without the context of what is the measurement
22 that you're comparing it to, what is the user's
23 activity level, carbohydrate intake, and are
24 there other reasons for this divergent glucose
25 information. There can be many reasons for

1 things of that nature to happen. I'm not clear
2 on what you're driving at in terms of...

3 BY MR. CARROZZA:

4 Q So my questions are not so much from a
5 diabetic's perspective. My question is more about
6 the accuracy of technology. Okay?

7 A Uh-huh.

8 Q And what I'm asking here is if a CGM is
9 indicating a person's glucose level is trending in
10 one direction when, in fact, they're trending in the
11 opposite direction from a pure technological
12 standpoint, you would agree with me, though, that
13 CGM is not very accurate?

14 MR. MASON: Objection. Form.

15 THE WITNESS: The value that the CGM is
16 reporting may be, indeed, accurate to the
17 subcutaneous location that it's monitoring. So
18 if the blood glucose cord level is dropping, or
19 vice versa, if the blood glucose cord level is
20 rising but the cutaneous value is dropping,
21 there may be physiologic reasons for that.

22 So there's at least a plausible
23 explanation where the CGM data, although it may
24 not be directly core blood trending, that may
25 be happening. And in fact, it's likely those

1 conditions would need to be trapped and
2 detected within the system, especially in the
3 presence of core blood or finger stick data, as
4 perhaps a reason for recalibration.

5 BY MR. CARROZZA:

6 Q So I know you have your declaration
7 printed. Let's use this version so that my
8 paralegal doesn't feel like she wasted her time.
9 Let's all use this one.

10 (Exhibit 1008, Declaration of Brian D.
11 Gross, was referenced.)

12 BY MR. CARROZZA:

13 Q The court reporter's handing you
14 Exhibit 1008. This is the declaration of Brian D.
15 Gross submitted in IPR 2023-01251.

16 And Mr. Gross, do you recognize the exhibit
17 that the court reporter is handing you as your
18 declaration?

19 A It appears to be the declaration. Yes.

20 Q And is that your signature on the last
21 page?

22 A Page 150 signed July 24, 2023, yes.

23 Q And you signed this under the penalty of
24 perjury, right?

25 A Correct.

1 Q Do you remember where you were when you
2 signed this?

3 A I was probably at home.

4 Q You drafted this declaration, right?

5 A I actively participated in the drafting of
6 this declaration.

7 Q So you didn't draft the entire declaration
8 yourself?

9 A So this was an iterative process working
10 with counsel. But I actively participated in the
11 drafting of this document. These are my opinions.

12 Q Those are your opinions, but you didn't
13 write every word, correct?

14 A That's correct.

15 Q Did you write a first draft?

16 A There were multiple drafts used.

17 Q But did you write the first draft?

18 MR. MASON: Objection. Form. And I'm
19 going to caution the witness not to discuss any
20 privileged communications with counsel or the
21 status of any drafts. And obviously, you know
22 that any drafts are protected.

23 MR. CARROZZA: Understood.

24 MR. MASON: As other communications with
25 counsel.

1 MR. CARROZZA: Okay. Withdrawn.

2 BY MR. CARROZZA:

3 Q When were you retained by Klarquist or
4 DexCom to work on this IPR?

5 A If memory serves, probably in Q1 of the
6 previous year.

7 Q Would that be first quarter of 2023?

8 A That sounds about right.

9 Q In paragraph 2 on page 8 of your
10 declaration it says that you're being compensated at
11 your usual and customary rate; what is that rate?

12 A Being compensated at a customary rate for
13 the delivery of my services. Are you interested in
14 retaining me?

15 Q No. My question is what is that rate?
16 What is the dollar amount of that rate?

17 A That I view as confidential. But it's
18 consistent with my experience and with my salary
19 level prior to retirement.

20 Q What's confidential about your rate?

21 A I view that as private information.

22 Q And so you're refusing to answer that
23 question?

24 MR. MASON: I think maybe can we agree to
25 designate this portion of the transcript as

1 confidential?

2 I think the witness maybe -- I'm not
3 putting words in his mouth, but may have
4 reasons why his rate is confidential for
5 purposes of working in the industry, and does
6 not want to share that publically.

7 MR. CARROZZA: Yeah. We can do that,
8 sure. We can designate this part of the -- can
9 we go off the record for just a second?

10 (Off record from 9:51 a.m. to 9:53 a.m.)

11 MR. CARROZZA: Back on the record.

12 All right, Counsel. Thank you for
13 taking the time to speak with me about what we
14 can do for disclosing Mr. Gross' compensation.
15 We would agree to redact that part of the
16 transcript if you're fine with that as well.

17 MR. MASON: Yes. With the understanding
18 that his rate will be redacted from the
19 transcript prior to filing at the PTAB, then we
20 are okay with that.

21 And then obviously, as discussed, if
22 you need to reference it in the briefing for
23 some reason, then we can work to come to terms
24 under a protective order, maybe the default
25 protective order, and then designate that

portion of the transcript under the protective order.

BY MR. CARROZZA:

Q Okay. Great. With that stipulation between attorneys, are you comfortable now disclosing what your rate is?

A Yeah. My rate is [REDACTED]. And [REDACTED] for travel.

Q Have you ever been an expert witness before?

A Not in a proceeding.

Q In any other context?

A I've been an expert opinion in serving my businesses as they're making decisions. But not in a proceeding of a legal nature.

Q I understand. And for your work on this IPR, who have you submitted your invoices to? Klarquist?

A Klarquist, yes.

Q And do you recall approximately how much money you've billed so far to date? Again, we're willing to redact this part.

MR. MASON: Okay. If the witness can answer.

THE WITNESS: Yeah. I mean, I don't have

access to my invoices or payments. Probably on the order of [REDACTED].

BY MR. CARROZZA:

Q I'm going to mention a few people and I just want to know if you know any of them or have any interactions with them.

Do you know who Dr. Morton Jensen is?

A Jensen. Off the top of my head, without reviewing my contacts or the materials.

Q Doesn't ring a bell?

A Doesn't ring a bell.

Q Were you aware that DexCom had filed another IPR petition against the '056 patent?

A I was unaware.

Q Do you know who Dr. John Villasenor is?

A Again, without the context of my contacts or being able to review the cited materials, doesn't ring a bell.

Q Fair enough.

Do you know who Dr. Majid Sarrafzadeh is?

A Again, without reviewing my contacts and without reviewing the cited materials, doesn't sound familiar.

Q Do you know who Dr. John Mastrototaro is?

A John Mastrototaro is an inventor on a few

1 of the cited materials that I reference in my
2 declaration.

3 Q Have you ever met Dr. Mastrototaro?

4 A Not personally, no.

5 Q Have you ever spoken with him?

6 A No, I have not.

7 Q Besides any of the documents that are
8 submitted as exhibits in this IPR, have you reviewed
9 any work product from Dr. Mastrototaro?

10 A I have not. Just materials that are
11 referenced in this exhibit were the materials that
12 were relied on for the declaration.

13 Q And outside of that, you haven't reviewed
14 any other work from Dr. Mastrototaro to your
15 recollection, right?

16 A Not that I can recall.

17 Q Have you ever reviewed any deposition
18 testimony of Dr. Mastrototaro?

19 A I have not.

20 Q Do you recall ever listening to any
21 deposition testimony of Dr. Mastrototaro?

22 A I do not.

23 Q In connection with this IPR, did you
24 perform any prior art searches on your own?

25 A No. The materials that I was asked to

1 perform an opinion against are presented here and
2 provided by counsel.

3 Q So the prior art that you provided opinions
4 on, those are not references that you personally
5 located, correct?

6 A I'm not going to comment on prior drafts,
7 but in the declaration that we're discussing today,
8 the materials here have been provided by counsel.

9 Q So you reviewed the prior art that counsel
10 provided you and then you opine on whether that
11 prior art rendered the claims of the '056
12 unpatentable; do I have that right?

13 MR. MASON: I'm just going to caution the
14 witness to not disclose any privileged
15 communications with counsel. With that
16 caution, you can answer.

17 THE WITNESS: So in my introduction to the
18 engagement, I was specifically asked to provide
19 my opinions regarding whether claims 1 through
20 12, 4 through 28, and 30 of the '056 patent
21 would have been obvious to persons having
22 ordinary skill in the art, POSITAs, as of April
23 2009.

24 And after reviewing the prior art
25 discussed herein, it's my opinion in each of

1 the claims 1 through 12, 14 through 28, and 30
2 of the '056 patent would have been obvious to a
3 POSITA.

4 BY MR. CARROZZA:

5 Q So turning to page 9 of your declaration,
6 Exhibit 1008, your opinions that the claims of the
7 '056 patent would have been unpatentable are based
8 on six prior art references listed on in
9 paragraph 9, correct?

10 A Those are some of the references that I
11 base my opinion on. The rest of the references are
12 provided in the table of contents exhibit, or I'm
13 sorry, in the table of citations that starts on the
14 bottom of page 11 and continues through the top of
15 page 14 of my declaration.

16 (Exhibit 1012, Patel 2009 Patent
17 Application Publication, was referenced.)
18 (Exhibit 1015, Patel 2008 Patent
19 Application Publication, was referenced.)
20 (Exhibit 1017, US Patent 6,641,533 Causey,
21 was referenced.)
22 (Exhibit 1019, Mastrototaro US Patent
23 Application Publication, was referenced.)
24 (Exhibit 1023, Shahmirian US Patent
25 Application Publication, was referenced.)

1 BY MR. CARROZZA:

2 Q Do you have Exhibit 1012 in your binder?

3 A Patel-2009?

4 Q Before you answer, I was just going to run
5 through a bunch of exhibits to make sure you have
6 them. If not, I was just going to give them to you.
7 So let's just run through them.

8 A Yeah. 1012, I do have.

9 Q Do you have all of Exhibit 1011?

10 A 1011, I do have in its entirety.

11 Q Do you have Exhibit 1015?

12 A 1015, I have in its entirety.

13 Q Do you have Exhibit 1017?

14 A 1017 Causey, I have in its entirety.

15 Q And 1019?

16 A Mastrototaro-2006, 1019, I have in its
17 entirety.

18 Q And Exhibit 1023?

19 A Shahmirian, June '24, 2024, 1023, I have in
20 its entirety.

21 Q And there's no markings on any of the
22 exhibits in your binder, correct?

23 A No.

24 Q And there's nothing, no pages inserted or
25 anything additional as far as you're aware of?

1 A No. The only additional material is the
2 summary of the challenged claims separated out.

3 Q So I think it makes sense to use your
4 binder instead of passing a lot of paper around.

5 A Save a tree.

6 MR. MASON: If you're pulling copies, I'll
7 take a copy.

8 MADAM COURT REPORTER: Obviously, I need
9 them for the transcript.

10 MR. CARROZZA: You do.

11 MR. MASON: If you've got yours
12 electronically and just want to refer to them,
13 then --

14 MR. CARROZZA: Yeah, I think it may be
15 easier.

16 BY MR. CARROZZA:

17 Q So the claims that you analyze in your
18 declaration, those are the claims that you were told
19 to analyze, right?

20 A Those are the claims that I was asked to
21 evaluate, correct.

22 Q Do you know why you weren't asked to
23 evaluate claims 13 or 29?

24 MR. MASON: I issue the same caution as I
25 issued before.

1 THE WITNESS: At the time, no.

2 BY MR. CARROZZA:

3 Q I know you have a lot of education, but
4 you're not an attorney, right?

5 A Correct.

6 Q And so counsel explained certain legal
7 principles to you to understand for purposes of your
8 declaration; is that right?

9 A Correct.

10 Q It begins at paragraph 12 of your
11 declaration?

12 A Yes, paragraph 12, section 5, of my
13 declaration summarizes accurately my understanding
14 of patent law and requirements for my evaluation and
15 opinion.

16 Q And so you understand that for a patent
17 claim to be anticipated, that would mean that a
18 single prior art reference discloses all of the
19 elements of the claim whether implicitly or
20 explicitly; do you understand that concept?

21 And this is in paragraph 15 of your
22 declaration, if that helps.

23 A Yeah. So going back to 13, the scope of
24 the claim patent, that the patent claim term should
25 generally be given the ordinary meaning. The term

1 should have, to a person ordinarily skilled in the
2 art, in questions after reading the patent, as the
3 earliest claim priority date.

4 I understand a person ordinarily
5 skilled-in-the-art is deemed to read the claim term
6 not in the context of a particular claim --

7 Q And I don't mean to cut you off, but we do
8 have limited time. So my question is not about
9 whether you can read your declaration. My question
10 is about paragraph 15 and the concept of
11 anticipation specifically.

12 Paragraph 15 says, I understand that a
13 prior art reference anticipates an asserted claim
14 and thus renders the claim unpatentable if all
15 elements of the claim are disclosed in that prior
16 art reference, either explicitly or inherently
17 (i.e., necessarily present or implied).

18 Do you see paragraph 15?

19 A I do.

20 Q Did I read that correctly?

21 A You did.

22 Q Do you have an understanding now that
23 anticipation requires a single prior art reference
24 to render claims unpatentable?

25 A So I see in paragraph 15 that if all

1 elements of a claim are disclosed in a prior art,
2 not necessarily a single prior art. I think you --

3 Q Are you familiar with the term
4 "obviousness"?

5 A I am.

6 Q In patent law?

7 A I'm familiar with obviousness as it applies
8 to the understanding that a claim is unpatentable.
9 If it requires that the claim would have been
10 obvious in the perspective of a POSITA at the time
11 of the alleged invention.

12 Q And do you understand the distinction
13 between the anticipation and the obviousness in
14 patent law?

15 And again, I understand you're not a patent
16 attorney. I understand that. But I want to make
17 sure. Do you understand the distinction between
18 anticipation and obviousness in patent law?

19 MR. MASON: Objection. Form.

20 THE WITNESS: Yeah, I believe I understand
21 the difference.

22 BY MR. CARROZZA:

23 Q And so do you understand that at least one
24 difference is for anticipation a single prior art
25 reference must disclose all of the claim elements?

1 Whereas for obviousness -- no. Strike that. Let's
2 move past this line of questions.

3 Paragraph 19 of your declaration references
4 a term called "secondary considerations." Do you
5 see that?

6 A I understand that secondary considerations
7 include, among other things, commercial success of
8 the patent invention, skepticism of those having
9 ordinary skill in the art at the time of invention,
10 unexpected results of the invention, any long-felt
11 but unsolved need in the art that was satisfied by
12 the alleged invention, the failure of others to make
13 the alleged invention, praise of the alleged
14 invention by those having ordinary skill in the art,
15 and copying of the alleged invention by others in
16 the field.

17 Q And Mr. Gross, I understand that you would
18 want to use your declaration as a crutch to answer
19 some of these questions, and I just want to make
20 sure -- I'm really not asking for a recitation of
21 what's in here. I'm asking whether you understand
22 certain things. I just want to make sure we're
23 using our time efficiently here, so I'm going to
24 rephrase my question.

25 I'm going to rephrase my question and focus

1 more on your first sentence that says, I further
2 understand that certain factors may support or rebut
3 the obviousness of a claim; do you see that
4 sentence?

5 A I do.

6 Q And so is it your understanding that
7 secondary considerations can rebut the obviousness
8 of a claim?

9 A So as I stated in paragraph 19, certain
10 considerations, secondary considerations, may
11 support or rebut the obviousness claim.

12 Q And did you inquire with anyone about
13 whether any secondary considerations were relevant
14 here?

15 MR. MASON: Just issue a precaution.

16 THE WITNESS: I'm sorry. Could you repeat
17 your question, please?

18 MR. CARROZZA: Could you read that back,
19 Victoria?

20 MADAM COURT REPORTER: "QUESTION: And did
21 you inquire with anyone about whether any
22 secondary considerations were relevant here?"

23 THE WITNESS: I have not been advised that
24 secondary considerations were present in this
25 material.

1 BY MR. CARROZZA:

2 Q Secondary considerations would be evidence
3 that Abbott would put forward to rebut obviousness;
4 do you understand that?

5 MR. MASON: Objection. Form.

6 THE WITNESS: So you're asking me if I
7 recognize that Abbott would be presenting a
8 secondary consideration.

9 BY MR. CARROZZA:

10 Q Right. I want to make sure you understand
11 some of the concepts that we're talking about here
12 and so that's what my question is asking. So let me
13 ask it this way.

14 It's DexCom's position in this IPR that the
15 '056 patent is obvious in view of the prior art,
16 correct?

17 A That's my understanding.

18 Q And you understand it's Abbott's position
19 that it's not obvious in view of the prior art,
20 right?

21 A That's my understanding.

22 Q So you would understand that it would be
23 Abbott's burden to establish secondary
24 considerations to rebut DexCom's assertion of
25 obviousness; do you understand that concept?

1 MR. MASON: Objection. Form.

2 THE WITNESS: I'm not an attorney.

3 BY MR. CARROZZA:

4 Q Okay. Are you aware that Abbott and DexCom
5 are involved in several patent infringement lawsuits
6 throughout the world?

7 A I am aware of that.

8 Q Did you know that one of those lawsuits
9 involve DexCom's G6 product?

10 A I'm not aware of what specific materials
11 are part of that litigation.

12 Q Did you know that Abbott has asserted two
13 patents related to the '056 patent against DexCom in
14 certain litigation?

15 A Again, I'm not aware of the details of the
16 litigation.

17 Q But did you know that?

18 A Did I know that Abbott was asserting --

19 Q Two patents related to the '056 patent
20 against DexCom?

21 A I don't believe I was aware of that.

22 Q And so you, obviously, haven't reviewed
23 those two other patents, correct?

24 A I was asked to evaluate the '056 material,
25 which is what I did.

1 Q Were you aware that DexCom has asserted one
2 of your patents as prior art against one of Abbott's
3 patents?

4 A Again, I'm not aware of the litigation
5 details.

6 Q But were you aware of that fact?

7 A No, sir.

8 Q And so in preparing your declaration and
9 your opinions in this IPR, it sounds like you didn't
10 ask whether Abbott has asserted secondary
11 considerations to rebut obviousness for those two
12 other patents related to the '056 patent, right?

13 MR. MASON: Again, I'll just caution the
14 witness not to disclose any communications with
15 counsel. You can answer the question.

16 THE WITNESS: So insofar as secondary
17 considerations, I am not aware and they did not
18 come into -- I'm not aware of secondary
19 considerations and the material presented in my
20 declaration is representative of that.

21 BY MR. CARROZZA:

22 Q Okay. Switch gears a little bit. And I
23 just want to see if you have a relationship with
24 some of these parties.

25 So besides this IPR, have you ever been

1 affiliated with DexCom in any way?

2 A The only relationship that I have had with
3 DexCom is pursuant to the DOD work where we were
4 using DexCom technology as part of the signal
5 portfolio that was being used for obtaining data.

6 Q And was DexCom a part of that project?

7 A They were a subcontractor under the
8 Phillips contract to deliver CGM technologies for
9 data collection.

10 Q Did you interact with anyone from DexCom in
11 your work on that project?

12 A I don't recall the names of the parties,
13 but I was working with their clinical delivery team,
14 given that we needed to develop stock for these
15 materials, some have shelf lives. And we need to
16 ensure that the research sites were getting the
17 materials that they were required to have as part of
18 this contracted research.

19 Q Have you ever worked for DexCom?

20 A No.

21 Q Besides this IPR, have you ever consulted
22 for DexCom?

23 A No.

24 Q And besides this IPR, have you ever been
25 compensated by DexCom for any other reason?

1 A No.

2 Q Did you speak with anyone from DexCom in
3 preparing your declaration?

4 A No.

5 Q Did you speak with DexCom -- excuse me.
6 Did you speak with anyone from DexCom in
7 connection with preparing for today's deposition?

8 A No.

9 Q Have you ever worked for Medtronic?

10 A No.

11 Q Have you ever consulted for Medtronic?

12 A No.

13 Q Have you ever been compensated by Medtronic
14 for any reason?

15 A I have not.

16 Q Have you ever spoken with Medtronic for any
17 reason in relation to this IPR?

18 A I have not.

19 Q What about in relation to any of the
20 lawsuits pending between Abbott and DexCom, have you
21 ever spoken to someone from Medtronic in that
22 context?

23 A No, sir.

24 Q Have you ever spoken with an attorney
25 representing Medtronic?

1 A I don't know.

2 Q I mean, obviously, you're not aware of it?

3 A I'm not aware. I don't know who I spoke
4 with at breakfast.

5 Q Understood. Fair point.

6 Did you speak with anyone from Medtronic in
7 preparing your declaration?

8 A No.

9 Q Did you speak with anyone from Medtronic in
10 connection with preparing for today?

11 A No.

12 Q Have you ever worked for Abbott?

13 A No.

14 Q Have you ever consulted for Abbott?

15 A Not directly, although Abbott was a
16 producer of point-of-care testing that we did
17 integrate into the monitoring domain. So it's not a
18 consulting relationship, but it was more of a
19 co-development relationship. At the time it was
20 unrelated to CGM technology. It was really about
21 point-of-care testing.

22 Q And have you ever been compensated by
23 Abbott for any reason?

24 A No.

25 Q Have you ever been owed compensation but

1 not paid by Abbott for any reason?

2 A No, Counselor.

3 Q Thank you. All right. Turning to
4 paragraph 31 in your declaration, Exhibit 1008. Are
5 you there?

6 A Page 20, paragraph 31 of Exhibit 1008.

7 Yes, I am there.

8 Q And here you provide bullet point summary
9 of four concepts involved in the claims of the '056
10 patent, right?

11 A Correct.

12 Q And that first concept relates to two and
13 three electrode sensors that generate analyte
14 signals; is that right?

15 A Referencing back to Harper as referenced,
16 yes.

17 Q And then another, the second bullet point
18 is calibration to determine a sensitivity ratio that
19 is used to convert sensory data at analyte levels;
20 is that right?

21 A Again, referencing back to the Harper '056
22 material, correct.

23 Q And the third concept is signal processing.
24 For example, filtering, clipping, digitizing,
25 conditioning; that's the third concept, right?

1 A Correct.

2 Q And then the fourth concept is RF
3 transmissions. And you specify a couple different
4 frequency ranges and technologies; is that right?

5 A As provided in Harper '056, correct.

6 Q And so you singled out these four specific
7 concepts because they're aspects of the challenged
8 claims that you say were each well-known fundamental
9 concepts of glucose monitoring by April 2009; is
10 that right?

11 A With reference to the material below,
12 correct.

13 Q And so in paragraphs 32 through 36 of your
14 declaration, you have opinions on glucose sensors
15 and electrodes, right?

16 A Correct. I do want to call to your
17 attention a typographical error on page 23.

18 Q And what is that error?

19 A Figure 4, with reference to Exhibit 1026,
20 the section that's referenced should be 0338 not
21 0038 as presented in the declaration.

22 Q Hmm. So the citation should be
23 Exhibit 1026, paragraph 0338?

24 A That's correct.

25 Q Okay. And now, it's your opinion that

1 analyte sensors with two or three electrode
2 configurations were well known by POSITAs by 2009,
3 right?

4 A Yes. It is my opinion. In fact, these
5 electrodes were in in vitro technologies well before
6 that.

7 Q Now, in CGM systems the term "glucose
8 sensor" refers to, like, a little thin filament or
9 wire that gets inserted subcutaneous, right?

10 MR. MASON: Objection. Form.

11 THE WITNESS: So the typical glucose
12 sensor containing three electrodes, glucose
13 oxidase working electrode, counter electrode,
14 reference electrode, consisting of
15 silver/silver chloride.

16 BY MR. CARROZZA:

17 Q And so in a typical CGM, the glucose
18 sensor, that connects to electronics, right? I'm
19 just trying to get nomenclature down.

20 A Okay.

21 Q That's what I'm driving at here. So the
22 term "sensor" in the context of a CGM is referring
23 to the small filament or wire that goes into your
24 skin?

25 A So most or some of the CGM systems separate

1 the sensor from the processing capability. Some
2 it's integrated. But if we want to use the term
3 "sensor" or "sensor unit" as the non-electronics of
4 the silver/silver chloride and the electrode
5 component that needs processing and power to
6 activate it, I think we can move forward with that
7 definition.

8 Q And that's the definition -- or that's the
9 way the '056 patent uses the term "sensor," right?

10 MR. MASON: Objection. Form.

11 THE WITNESS: '056 describes a sensory
12 unit which connects to a transmitter unit in
13 figure 1 of '056. And in the specification it
14 goes into some detail about that.

15 BY MR. CARROZZA:

16 Q Do you have Exhibit 1011 handy?

17 A I do.

18 Q Turn to page 23 of Exhibit 1011.

19 A So page 23 of Exhibit 1011. I'm there.

20 Q Do you see the top table or box where it
21 says glucose sensor?

22 A Feature of the glucose sensor with the
23 specification of inserted virtually painlessly under
24 the skin, usually in the stomach area, sends
25 electronic signal measuring the amount of glucose in

1 your interstitial fluid, replace the glucose sensor
2 every three days.

3 Q Do you see that?

4 A Okay.

5 Q So that's using the term "sensor" in the
6 context of the small filament or wire that goes
7 under your skin, right?

8 A There is a component that sends an
9 electronic signal, correct.

10 So there are other references to this
11 electronic -- or this sensor in the declaration.
12 Mastrototaro is another example. The reference from
13 Style is another example.

14 Q Understood. Let's take a look at page 40
15 of your declaration. And actually, before we go
16 straight to page 40, let's back up and go to
17 page 38.

18 A Okay.

19 Q In beginning of paragraph 66 it says, It is
20 also my opinion that the '886 Provisional supports
21 claim 1 of Patel-2009 as detailed in the chart
22 below; do you see that?

23 A I do.

24 Q And so the chart that follows, this is a
25 chart that contains disclosure from Patel-2009's

1 Provisional that in your opinion supports claim 1 of
2 Patel-2009, right?

3 A Correct. I identified the differences in
4 the paragraph above noting that they're
5 substantially similar.

6 Q Okay. And now let's go to page 40
7 specifically. And in that bottom row, on the
8 right-hand side of the bottom row you say, It is my
9 opinion that this paragraph 10 supports the follow
10 elements of claim 1 of Patel-2009: A housing
11 detachably coupled to a sensor located on a body of
12 a user; do you see that?

13 A Yes, Counselor. I apologize. That's a
14 second typo. That reference to this paragraph 0010
15 should read these paragraphs referencing 0050, 0051,
16 0054, as are indicated on the left side of that
17 cell.

18 Q You predicted my question. I was trying to
19 figure that out. It didn't seem to jive. I assumed
20 that was the case, but I wanted to clarify with you.

21 A So clarified.

22 Q So everything in those paragraphs that you
23 mentioned, 50, 51, 54, and then the figures that are
24 shown, that is all related to the one limitation,
25 the housing detachably coupled to a sensor located

1 on a body of a user, right?

2 A Yeah. If we look in 50, it's specifically
3 called out, A telemetered characteristic sensor
4 transceiver is coupled to a sensor set, referencing
5 10, by a cable through a connector that is
6 electrically coupled to the connector block of the
7 connector portion of the sensor set.

8 And further, in the same reference, the
9 telemetered characteristic sensor includes a housing
10 that supports a printed circuit board, batteries,
11 antenna, and the cable in the connector.

12 And then further, the printed circuit board
13 of the telemetered characteristic sensor includes a
14 sensor interface, processing electronics, timers, et
15 cetera. With reference that alternative
16 embodiments, the sensor interface may be configured
17 in the form of a jack to accept different cables to
18 work with different sensors.

19 And then finally in that reference
20 reflecting on figure 13, we have an example of a
21 transceiver block that is a receiving unit of the
22 sensor itself.

23 Q Thank you for that. You mentioned the word
24 "housing" in there. I want to talk about that for a
25 second. Do you have Patel-2009 handy, which is

1 Exhibit 1012?

2 A I do.

3 MR. MASON: Counsel, just for Victoria's
4 sake, we've been going an hour, just so you're
5 aware.

6 MR. CARROZZA: Thank you. Couple
7 questions here and we'll wrap.

8 MR. MASON: Just letting you know.

9 BY MR. CARROZZA:

10 Q All right. I just want to talk about the
11 word "housing" for a minute. So if you look at
12 Patel-2009, paragraph 58, it says -- if you look at
13 the top of the right-hand column, I'm going to start
14 mid-sentence.

15 It says, The housing 106 is formed from an
16 upper case 114 and a lower case 116. They're sealed
17 with an ultrasonic weld to form a waterproof or
18 resistant seal to permit cleaning by immersion or
19 swabbing with water, cleaners, alcohol, or the like;
20 do you see that?

21 A I do.

22 Q And so is it your opinion that a housing
23 formed from an upper case and a lower case -- no.
24 Strike that question.

25 Is it your opinion that an upper case and a

1 lower case being formed or sealed together in this
2 manner would be a housing?

3 A So in this particular reference, they're
4 describing the housing of the electronics component
5 of the CGM. The integrated housing would have to
6 include the sensor such that the signals can
7 actually get to the electronics.

8 Q And what if we were to go all the way down
9 at the bottom of that paragraph 58. It says, The
10 housing may simply be formed from a potted epoxy or
11 other material, especially if the battery life
12 relative to the device cost is long enough or if the
13 device is rechargeable.

14 Would it be your opinion that a CGM
15 component formed from potted epoxy is, in fact, a
16 housing?

17 MR. MASON: Objection. Form.

18 THE WITNESS: So again, in order for the
19 CGM to be functional, you need to include the
20 sensor. Otherwise, you're just talking about
21 the transceiver.

22 BY MR. CARROZZA:

23 Q I'm sorry. My question's not asking about
24 the sensor. I'm asking from Patel-2009, that
25 description there of what a housing can be, I'm

1 asking if it's your opinion that that would also be
2 a housing.

3 MR. MASON: Objection. Form.

4 THE WITNESS: So when Patel is describing
5 the transceiver component, I think it's clear
6 that he's talking about the housing of the
7 electronics, but not the complete CGM.

8 BY MR. CARROZZA:

9 Q Understood. And again, my question is a
10 little more basic than maybe it's coming off to you.
11 I'm asking if a CGM component formed from potted
12 epoxy, whether you would consider that a housing?

13 MR. MASON: Objection. Form.

14 THE WITNESS: It certainly can be an
15 example of part of the housing, given that he
16 describes or they describe the transceiver
17 component as one of the components of the CGM.
18 But I think it's safe to assume and it's
19 important to recognize that there are multiple
20 housings within the construction. For example,
21 in paragraph 60 Patel tells us that in
22 preferred embodiments the sensor interface may
23 be permanently connected to the sensor set.

24 So in here there's clearly an
25 indication that the sensor is part of the

1 electronics and housing.

2 BY MR. CARROZZA:

3 Q So suppose an encapsulate material is
4 poured over electronics and is allowed to settle or
5 solidify. Is that housing in your opinion?

6 MR. MASON: Objection. Form. Scope.

7 THE WITNESS: What is meant by -- so what
8 does the function of the housing do?

9 BY MR. CARROZZA:

10 Q Well, I think my question's a little
11 different. So let's maybe explain it differently.
12 Suppose I have a circuit board of electronics on it.
13 Okay?

14 A Uh-huh.

15 Q And I were to pour an encapsulate material
16 over it so that it solidifies around it. Is that a
17 housing in your opinion?

18 MR. MASON: Objection. Form. Scope.

19 THE WITNESS: It could be. It depends on,
20 you know, in what context you're describing
21 housing. It could be part of the housing that
22 covers the electronics or protects the
23 electronics.

24 MR. CARROZZA: Okay. This is a good time
25 to break.

1 (Off record from 10:36 a.m. to 10:55 a.m.)

2 BY MR. CARROZZA:

3 Q Back on the record.

4 Paragraph 94 of your declaration. This is
5 on page 63. Are you there?

6 A Paragraph 94 talk about Patel providing a
7 transceiver that performs data calibrations, sensor
8 glucose value calculation to convert raw sensor
9 signals into calibrated process glucose, referring
10 back to claim 1 D.

11 Q So in this paragraph 94, you're discussing,
12 at least in that part, Patel-2009, right?

13 A In that paragraph, yes, that's correct.

14 Q And then the second sentence says, The
15 transceiver calibrates the sensor's readings with
16 calibration data received from a remote device, for
17 example, readings from a blood glucose meter; did I
18 read that right?

19 A Referencing paragraph 42 of Patel-2009,
20 again, this is reference 1012, paragraph 42, which
21 is referenced in paragraph 94 of my declaration,
22 Patel teaches the telemetered characteristic sensor
23 transceiver generally includes the capability to
24 transmit and receive data.

25 For example, in a preferred embodiment, the

1 sensor transmitter will receive a calibration value,
2 e.g., from a blood glucose meter, et cetera, convert
3 raw sensor signals into calibrated processed glucose
4 values using algorithms stored in the sensor
5 transceiver and then transmit the calibrated glucose
6 values to a third-party device which has a display
7 to show the calibrated glucose values, e.g.,
8 characteristic monitor.

9 So that's one of the three references that
10 feed into the claim which says that the -- receive
11 the sensor data from the glucose sensor and store
12 the sensor data in the memory of the data processing
13 and transmitter unit, process the sensor data using
14 calibration data to provide processed sensor data,
15 wherein the calibration data comprises data
16 associated with a sensitivity of the glucose sensor,
17 and wherein the process sensor data is stored in the
18 memory of the data processing and transmitter unit.

19 So here Patel is essentially telling us you
20 get the data from a third device, a blood glucose
21 strip reader, and you use that in the transceiver
22 unit to perform data calibration and glucose value
23 calculation to convert that raw sensor into a
24 calibrated or processed glucose value.

25 Q So claim 1 of the '056 patent uses the term

1 "calibration data," right?

2 A In which subsection of the claim? In 1D,
3 the term "calibration data" does appear.

4 Q Right. And I want to make sure I'm clear
5 on this. You're equating the term "calibration
6 data" with readings from a blood glucose meter,
7 right?

8 MR. MASON: Objection. Form.

9 THE WITNESS: No. Data from a blood
10 glucose strip is used to generate the
11 calibration data. By itself is not the
12 calibration.

13 BY MR. CARROZZA:

14 Q Your second sentence doesn't say that,
15 though, does it?

16 MR. MASON: Objection. Form.

17 THE WITNESS: Which paragraph and which
18 sentence?

19 BY MR. CARROZZA:

20 Q Paragraph 94, second sentence, it says, The
21 transceiver calibrates the sensor's readings with,
22 quote, calibration data received from a remote
23 device, for example, readings from a blood glucose
24 meter; do you see that sentence?

25 A I do.

1 Q And so in that sentence you are equating
2 calibration data with readings from a blood glucose
3 sensor, correct -- excuse me, from a blood glucose
4 meter?

5 MR. MASON: Objection. Form.

6 THE WITNESS: So the references in Patel
7 that I list there include 64 and 81. 64
8 describes a stabilization process. A reading
9 may be transmitted from the sensor set to the
10 telemetered characteristic sensor transceiver
11 to the characteristic monitor, and then the
12 user will input a calibrated glucose reading
13 into the characteristic monitor.

14 BY MR. CARROZZA:

15 Q All right. So you're equating --

16 A I'm sorry. In 81 Patel goes on to say, In
17 accordance with another embodiment, the present
18 invention, the telemetered characteristic sensor
19 transceiver may irregularly or aperiodically
20 exchange data with other network nodes in an
21 asynchronous manner. For example, a blood glucose
22 meter may aperiodically transmit blood glucose
23 values to the transceiver, wherein the meter blood
24 glucose values are preferably stored and used by the
25 transceiver to calibrate calculated sensor glucose

1 values.

2 Patel goes on in paragraph 90 to talk about
3 in one aspect of the invention, realtime calibration
4 and glucose calculation algorithms are coded in the
5 transceiver. Mapping that back to claim 1D, the
6 elements are, I think, recognized by a POSITA of
7 what's being done here.

8 BY MR. CARROZZA:

9 Q And so let me just be very clear with my
10 question. Is it your position that readings from a
11 blood glucose meter are, quote, calibration data
12 within the scope of claim 1? That's my question.

13 A They are part of --

14 MR. MASON: Objection. Form.

15 THE WITNESS: -- part of the calibration
16 data.

17 BY MR. CARROZZA:

18 Q So the readings themselves are not
19 calibration data, is that what you're saying?

20 A So the readings are needed in order to --

21 MR. MASON: Same objections.

22 THE WITNESS: The readings are needed in
23 order to generate a sensitivity coefficient,
24 which is essentially the calibration.

25 ///

1 BY MR. CARROZZA:

2 Q And now Patel-2009 is talking about
3 performing this calibration in the transmitter unit
4 of its system, right?

5 A The transceiver unit, correct.

6 Q Transceiver. So in the Patel-2009 system,
7 calibrated glucose values are being transmitted from
8 the transceiver to the receiver, correct?

9 MR. MASON: Objection. Form.

10 THE WITNESS: So Patel-2009 describes the
11 transceiver communicating to a plethora of
12 devices that are capable of displaying data and
13 were consuming that data. One of them is a
14 monitor or a display that can generate a trend
15 of that data.

16 BY MR. CARROZZA:

17 Q And so let me lay a foundation and explain
18 what I'm getting at because it might not be so
19 clear.

20 So in a system like what's described in
21 Patel-2009, there is a sensor from which raw
22 glucose values are being determined, right?

23 A Yes.

24 Q And in a system like Patel-2009, you could
25 have the raw sensor data transmitted to a receiver

1 and then have the receiver perform the calibration
2 process, right, that's one way of doing it?

3 MR. MASON: Objection. Form.

4 THE WITNESS: That's not what Patel is
5 teaching, though.

6 BY MR. CARROZZA:

7 Q Right. And that's my point. Patel is
8 saying instead of doing that, you're calibrating the
9 values in the transmitter unit and then transmitting
10 calibrated values to the receiver, right?

11 A That's what Patel is teaching. And in
12 fact, I think a POSITA would recognize that as a
13 preferred way to ensure that any downstream client
14 of the glucose data understands what the glucose
15 data is, rather than a raw current, for example.

16 Q And are you familiar with the Paradigm
17 insulin pump as a product?

18 MR. MASON: Objection. Form.

19 THE WITNESS: So I'm familiar with the
20 Paradigm system as referenced in Exhibit 1011.

21 BY MR. CARROZZA:

22 Q And do you know if the Paradigm system
23 is -- if the transmitter in the Paradigm system is
24 transmitting calibrated glucose values or raw
25 glucose values?

1 MR. MASON: Objection to form.

2 THE WITNESS: So referencing
3 Exhibit 1011 -- so I'm going to refer you back
4 to paragraph 74 of my declaration, the Paradigm
5 REAL-Time system discloses a continuous glucose
6 monitoring system comprised of Paradigm insulin
7 pump, minilink transmitter, and glucose sensor
8 components. In these references, the glucose
9 sensor measures the amount of glucose in the
10 interstitial fluid --

11 (Reporter requests clarification.)

12 THE WITNESS: The Paradigm REAL-Time
13 discloses a continuous glucose monitoring
14 system comprised of Paradigm insulin pump,
15 minilink transmitter, and glucose sensor
16 components. The glucose sensor measures the
17 amount of glucose in interstitial fluid as an
18 electronic signal. The minilink transmitter
19 receives and processes signals from the glucose
20 sensor and sends glucose values to the insulin
21 pump through radio frequency.

22 So that, to answer your question,
23 that suggests that the transmitter is doing the
24 conversion from raw signal to glucose value.

25 ///

1 BY MR. CARROZZA:

2 Q That's how you interpret that?

3 A Yeah. Referencing the Exhibit 1011, the
4 cited references clearly indicate that the
5 transceiver is the source for the calibrated glucose
6 data.

7 Q So your opinions about the combination of
8 Patel-2009 and the Paradigm -- so I just want to be
9 clear.

10 Your opinions about the combination of
11 Patel-2009 and the Paradigm is based on your
12 understanding that both calibrate sensory data in
13 the transmitter units; is that right?

14 MR. MASON: Objection. Form.

15 THE WITNESS: So my combination relies on
16 Patel-2009 to essentially have the glucose
17 sensor, the sensor transceiver, where stored
18 glucose values live, and two-way communication
19 links to a variety of display monitor assets.

20 The Paradigm capability is
21 essentially to identify when there's missing
22 glucose data and detect conditions by which
23 that situation is occurring.

24 So Patel-2009 retains the glucose
25 values on the transceiver. There's also a

1 clear indication that that's also what Paradigm
2 is doing. But the reconstruction is based on
3 Patel-2009.

4 BY MR. CARROZZA:

5 Q Let's assume that in the Paradigm system
6 the transmitter actually transmitted raw glucose
7 values and that the calibration occurred in the
8 receiver. Okay? Let's just assume that to be the
9 case. Follow me?

10 A In the Paradigm system?

11 Q In the Paradigm system.

12 A Okay. So you're asking me to suppose --

13 Q Suppose that's the case.

14 A Suppose that. Okay.

15 Q If data is missing in the Paradigm system
16 from a failed wireless connection, the data that's
17 missing is raw glucose values, right?

18 MR. MASON: Objection. Form.

19 THE WITNESS: I'm not sure I understand
20 the implementation details that you're
21 proposing.

22 BY MR. CARROZZA:

23 Q If the --

24 A Let me be clear. Because in order to have
25 a glucose value, you would need to have a

1 calibration coefficient to turn raw signals into
2 that. So you've either got calibrated and suitable
3 or valid glucose value that you can share with the
4 user or you don't.

5 So I'm not clear in your hypothetical what
6 the purpose of sending a glucose value to the
7 display when you may not know it's valid.

8 Q Let's be clear. When you use the term
9 "glucose value," what are you referring to?

10 A I'm referring to a conversion of the raw
11 amperometric measurement into a calibrated glucose
12 value based on the available glucose calibration
13 coefficients necessary to do that conversion. So
14 nanoamps compared to milligrams per deciliter per
15 nanoamp.

16 Q Right.

17 A That's the calibration coefficients.

18 Q So for purposes of our deposition here
19 today, let's maybe establish a couple of terms so
20 we're talking about the same things. Because I get
21 a sense that sometimes we're maybe talking past each
22 other.

23 Can we agree that raw sensor data is the
24 digitized or the data representation of the glucose
25 values from the sensor before those values have been

1 calibrated?

2 If I use the term "raw sensory data" to
3 mean that, would you understand what I mean?

4 A What units does that signal possess?

5 Q Does that matter?

6 A It does.

7 Q Why?

8 A Nanoamps is what the sensor signal is
9 presented in.

10 Q Sure. But those nanoamps are going to be
11 sampled and digitized, right, in a practical system
12 that uses it?

13 MR. MASON: Objection. Form.

14 THE WITNESS: So back to your original
15 hypothesis or to your original question.

16 BY MR. CARROZZA:

17 Q All I'm trying to do first is establish a
18 vocabulary that we can make sure that we're saying
19 the same thing. And so I want to distinguish
20 between raw sensory data and calibrated sensory
21 data.

22 Do you understand the distinction between
23 those two?

24 A So I have an understanding that raw sensor
25 data is potentially invalid, typically in the units

1 of nanoamps, or it's a current, and then requires
2 filtering and other processes, at least filtering
3 and other processes, to become a glucose value.

4 Q Okay. Are you familiar with the
5 analog-to-digital conversion in electronics
6 generally?

7 A I am familiar with that, yes.

8 Q And the output of an analog-to-digital
9 converter is going to be digital counts, correct?

10 MR. MASON: Objection. Form.

11 THE WITNESS: It could be a digital count.

12 In the context of the glucose conversion, it
13 would be a digital sample of the current that
14 was measured from the electrode system.

15 BY MR. CARROZZA:

16 Q Okay. So we're on the same page. It would
17 be a digital representation of the current --

18 A We would agree with that.

19 Q Let's call that raw sensory data. Okay?

20 A Agreed. But that's not -- do we agree
21 that's not yet glucose data?

22 Q Yes, we do agree.

23 A Okay.

24 Q And so it would require some calibration in
25 order to turn that raw glucose data into a value

1 that's actually displayed to the user.

2 Do we agree on that point?

3 A I agree --

4 MR. MASON: Objection. Form.

5 THE WITNESS: -- but you confuse me by
6 saying "sensor glucose data." That term is --
7 doesn't make sense because a sensor, as we
8 agreed, is a measure of current.

9 BY MR. CARROZZA:

10 Q I'm not too sure I used that term, but if I
11 did, I will withdraw it. I stand corrected. All
12 right. In any event, we're on the same page now.

13 So raw sensor data -- or raw glucose data,
14 whatever -- when I use the term "raw," I'm referring
15 to before it's been calibrated; do we understand
16 that?

17 A I understand raw sensor data to be the
18 current measured from the sensor.

19 Q All right. And so in the Paradigm system,
20 do you have an understanding as to whether the
21 transmitter transmitted raw sensor data or
22 calibrated data to the insulin pump?

23 MR. MASON: Objection. Form.

24 THE WITNESS: So the Paradigm system
25 describes that there's calibrated glucose data

1 from the transceiver to the pump. And the pump
2 was displaying valid available glucose data.

3 BY MR. CARROZZA:

4 Q Okay. And so it's your understanding that
5 when the Paradigm insulin pump did not receive data
6 because of a failed wireless connection, that the
7 data it didn't receive was calibrated glucose data;
8 that's your understanding?

9 MR. MASON: Objection. Form.

10 THE WITNESS: So referencing the
11 Exhibit 1011, page 8, halfway into the FAQs,
12 the question is how much data does the minilink
13 realtime transmitter store?

14 And the answer from that FAQ is when
15 the minilink realtime transmitter is separated
16 from the insulin pump for more than 6 feet,
17 approximately 2 meters, the transmission is
18 considered out of range. And the transmitter
19 holds 40 minutes of memory. So even if your
20 system is out of range, continuous glucose
21 monitoring data can be repopulated in the pump.

22 The pump is displaying calibrated
23 glucose data. So a POSITA would recognize that
24 given the conditions necessary to do the
25 calibration live in the transceiver, then

1 sending the pump something other than glucose
2 information doesn't make too much sense.

3 It would be obvious to do the
4 calculation and the storage of finished glucose
5 or best glucose calculation in the transceiver,
6 and then only send the useful glucose data to
7 the pump, given there's no reason for the user
8 to see bogus or erroneous glucose values
9 because they need to know what their glucose is
10 to determine how to modify the pump.

11 BY MR. CARROZZA:

12 Q Let's turn to paragraph 95 of your
13 declaration.

14 A On page 63?

15 Q Yes.

16 A Okay.

17 Q That first sentence, it says, The processor
18 in Patel-2009 necessarily stores sensor data in
19 memory at least during filtering calibration and
20 calculation because POSITAs would understand that
21 the transceiver's processor stores sensor data in
22 memory (for example, processor cache, buffer, RAM)
23 while filtering sensor signals, calibrating sensor
24 readings, and calculating glucose values from
25 calibrated sensor readings; did I read that right?

1 A That is correct.

2 Q Now, Patel-2009 doesn't disclose that it
3 stores sensor data in memory. It's your opinion
4 that it does, right?

5 MR. MASON: Objection. Form.

6 THE WITNESS: So I think Patel-2009
7 explicitly calls for that, whereas in
8 paragraph 42 of Patel, reference 1012, the
9 telemetered characteristic sensor transceiver
10 generally capable to transmit and receive data.
11 For example, in a preferred embodiment, the
12 sensor transmitter will receive calibration
13 data from a blood glucose meter, paraphrasing,
14 convert raw sensor signals into calibrated
15 process glucose values using algorithms stored
16 in the transceiver -- in the sensor
17 transceiver. Then transmit the calibrated
18 glucose values to a third-party device which
19 has a display to show calibrated glucose
20 values.

21 I think it's very clear that the
22 teaching is you do the calculation there.

23 BY MR. CARROZZA:

24 Q That wasn't my question. My question is,
25 Patel-2009 does not disclose storing the raw sensor

1 signals in the transceiver, right?

2 MR. MASON: Objection. Form.

3 THE WITNESS: So in order to do the
4 filtering and clipping and other activities,
5 you absolutely need to store those digital
6 values in memory on the transceiver.

7 BY MR. CARROZZA:

8 Q Temporarily, right?

9 A Perhaps. You could -- you could do a more
10 permanent disclosure of the current signals, which
11 is likely what would be necessary if you want to
12 retro-- retrocalibrate data. For example, if the
13 calibration is old.

14 Q But that's not disclosed in Patel-2009 is
15 my point, right?

16 MR. MASON: Objection. Form.

17 THE WITNESS: That's not what claim 1D
18 calls for. Claim 1D calls for sensor data in
19 the glucose sensor to store sensor data in the
20 memory of the processing and transmitter unit,
21 process the sensor data using calibration data
22 to provide processed sensor data. That's
23 exactly what Patel-2009 is calling for.

24 Whereas, the calibration data
25 comprises associated sensitivity of the glucose

1 sensor. Patel is clearly calling for a blood
2 glucose test result to generate that
3 calculation. And a POSITA, I think, would have
4 found that obvious to do it in the -- in the
5 transceiver and would necessarily need to store
6 those raw currents to do it.

7 BY MR. CARROZZA:

8 Q Okay. And I know you're answering a
9 question that you want to answer and not my
10 question, so I'm going to ask it one more time.

11 You cannot point to me anywhere in
12 Patel-2009 that says raw sensor signals are stored
13 in the transceiver, right?

14 MR. MASON: Objection. Form.

15 THE WITNESS: I'm sorry, Counselor. I
16 thought, certainly, 42 describes that very
17 clearly.

18 BY MR. CARROZZA:

19 Q Beyond paragraph 42, can you point to me
20 any other disclosure in Patel-2009 that would
21 disclose storing raw sensor signals in the
22 transceiver?

23 A So in addition to that reference,
24 Patel-2009 also includes a reference at
25 paragraph 84, where in a sense -- in accordance with

1 another embodiment of the present invention, the
2 telemetered characteristic sensor transceiver is
3 capable of performing data calibration and sensor
4 glucose value calculation unlike preexisting glucose
5 sensor transmitter.

6 Because the transceiver is capable of
7 two-way communication and substantial power --
8 processing power, the transceiver can receive and
9 store calibration data from a remote network device,
10 such as a metered blood glucose value, and use this
11 data to calibrate the sensor's readings.

12 Again, that's -- you need to have the raw
13 glucose current stored in memory in order to do that
14 calculation.

15 Q And once that calculation is performed,
16 there's no disclosure of storing the raw sensor
17 data, right?

18 MR. MASON: Objection. Form. You may
19 answer.

20 THE WITNESS: The POSITA, if there were
21 reasons to have that sensor data -- the raw
22 sensor data around, would hold onto it.

23 BY MR. CARROZZA:

24 Q Okay.

25 A I think that's -- you know, if you've got

1 room for it and there are other algorithms, one can
2 envision that you would need to look at the
3 long-term trends to determine the overall health of
4 the system, as an example, that having that
5 available in memory would be useful.

6 Q I understand that you're saying that, but
7 what I'm asking is that there's no disclosure of
8 that in Patel-2009?

9 MR. MASON: Same objection.

10 THE WITNESS: So Patel teaches that's
11 where the calculation has to be done. That's
12 where you need to at least put it in memory.

13 So if the transceiver device has a
14 memory limitation, there would be a trade-off.
15 Right? How much of that sensor data do you
16 keep around and for what you can do with it?

17 Patel-2009 was describing a system
18 with capabilities, both processing power and
19 certainly memory capabilities, given that the
20 use case in Patel-2009 was to send finish --
21 completed glucose data to a variety of
22 receiving devices.

23 So it's intuitive to a POSITA that
24 that would require sufficient data storage
25 capability and memory on the transceiver.

1 BY MR. CARROZZA:

2 Q And you just mentioned a variety of
3 devices, but your opinions on claim 1 is based on a
4 combination of Patel-2009 and the Paradigm, right?

5 A For Ground 1, that's correct.

6 Q Okay. And so despite Patel-2009's
7 disclosure of a variety of devices, it's your
8 opinion that it's the insulin pump that would be
9 communicating with Patel-2009's transceiver, right?

10 MR. MASON: Objection. Form.

11 BY MR. CARROZZA:

12 Q In your combination for Ground 1.

13 A So referring back to the Ground 1
14 combination, referencing page 52 of my disclosure,
15 you can see the Patel-2009 sensor transceiver, radio
16 link, and ability to communicate to display systems
17 and monitoring system is what I'm counting on for
18 Patel.

19 I'm using the Paradigm ability to know that
20 it's missing data and to detect conditions by which
21 it can at least alert to the user that there's
22 information that may be missing.

23 Q And that is all based on your understanding
24 that the Paradigm is transmitting calibrated glucose
25 values to its insulin pump, right?

1 MR. MASON: Objection. Form.

2 THE WITNESS: I don't think that's what
3 I've said. The fact that Paradigm is sending
4 finished glucose is a convenient matter and it
5 would be a logical implementation plan. Patel
6 doesn't limit whether it's holding onto the
7 current or to the finished glucose values in
8 its construction.

9 And again, tying it back to if
10 someone needed to build a glucose monitoring
11 system, in the presence of these components and
12 these behaviors, it's a trade-off that one
13 would have to design to. But ultimately
14 there's no limitation, from my perspective,
15 and, in fact, holding onto raw data can be very
16 valuable.

17 BY MR. CARROZZA:

18 Q And so basically they would implement it
19 the way the claims are written in the '056 patent;
20 is that right?

21 MR. MASON: Objection. Form.

22 THE WITNESS: The teachings here suggest
23 that the calibration data needs to be preserved
24 on the transceiver for some period of time.
25 That could be to generate -- it could be to

1 generate a calculated glucose value. It could
2 be until the sensor has exhausted its life. It
3 could be a lot of things.

4 But the bottom line is in order to do
5 the calculation, it needs to be stored on the
6 transceiver.

7 BY MR. CARROZZA:

8 Q Now, with respect to claim 1 of the '056
9 patent, it's your opinion that it would have been
10 obvious to a person of skill in the art to use
11 Bluetooth in the Patel-2009 Paradigm combination,
12 right?

13 A In fact, Patel-2009 in the Provisional
14 calls for Bluetooth as a regular link suitable for
15 this glucose monitoring system.

16 Q Besides Bluetooth, there are plenty of
17 wireless communication protocols that could have
18 worked at that time, right?

19 MR. MASON: Objection. Form.

20 THE WITNESS: There are a few that would
21 be suitable for this type of data, with this
22 type of distance, with this type of power
23 consumption.

24 BY MR. CARROZZA:

25 Q Certainly, the Paradigm didn't use

1 Bluetooth, right?

2 MR. MASON: Objection. Form.

3 THE WITNESS: So at the time Paradigm was
4 using a different spectrum of ISM, which was
5 not yet established as the Bluetooth 2.4
6 protocol or a protocol area, range, spectrum.
7 And there were some challenges with that,
8 including a variety of reasons why it would be
9 logical to move off of that ISM spectrum.

10 BY MR. CARROZZA:

11 Q So in the Paradigm system, the user has an
12 insulin pump that is attached to their body, right?

13 MR. MASON: Objection. Form.

14 THE WITNESS: That is the usual use case
15 as far as I know.

16 BY MR. CARROZZA:

17 Q And there's a picture of it, in fact, on
18 the Paradigm materials that shows the pump being
19 worn on the belt. And it's a pretty typical way to
20 have an insulin pump attached to a patient, right?

21 MR. MASON: Objection. Form.

22 THE WITNESS: So I think we agree that the
23 Paradigm literature shows the insulin pump
24 being body-worn.

25 ///

1 BY MR. CARROZZA:

2 Q I mean, there's a tube that goes into a
3 person at an insertion site, right, for an insulin
4 pump?

5 MR. MASON: Objection. Form.

6 THE WITNESS: The Paradigm REAL-Time
7 system does show an insulin pump with an
8 administration set.

9 BY MR. CARROZZA:

10 Q And the CGM transmitter is also on the
11 person's abdomen, right?

12 MR. MASON: Objection. Form.

13 THE WITNESS: Again, the Paradigm user
14 documentation shows suitable places for the
15 glucose sensor to be placed.

16 BY MR. CARROZZA:

17 Q So the distance -- for an average adult,
18 the distance between -- I almost can't say this with
19 a straight face.

20 The distance between one side of their
21 abdomen to another is on the order of a foot or two,
22 right?

23 MR. MASON: Objection. Form. Maybe we
24 just all need lunch. I don't know.

25 ///

1 BY MR. CARROZZA:

2 Q Let me rephrase.

3 In the Paradigm system, the insulin pump is
4 generally within about 2 to 3 feet of the
5 transmitter, right?

6 A So during normal operations, that's, I
7 think, accurate.

8 Q And at the time in 2009, another protocol
9 was Zigbee; are you familiar with Zigbee?

10 A Yes, I am.

11 Q There are also multiple access techniques
12 like code-division multiple access; are you familiar
13 with that?

14 MR. MASON: Object to form.

15 THE WITNESS: In the context of a det
16 (phonetic) system?

17 BY MR. CARROZZA:

18 Q I'm sorry, a det?

19 A Bidirectional symmetrical bandwidth
20 utilization, if that's what you're referring to.

21 Q It is. What I'm referring to is an RF
22 technology that use a multiple access technique to
23 make sure there weren't collisions, such as
24 code-division multiple accessing; are you familiar
25 with that?

1 MR. MASON: Objection. Form.

2 THE WITNESS: So I'm not sure I'm familiar
3 with code-division multiple access. I can
4 share that there were a small number of
5 available radio technologies that were
6 appropriate for this type of an application.

7 BY MR. CARROZZA:

8 Q Right. And so it's not that a person of
9 skill in the art would have necessarily used
10 Bluetooth, it's that they could have, right? Is
11 that what your opinion is? A person could have used
12 Bluetooth?

13 MR. MASON: Objection. Form.

14 THE WITNESS: So there are at least a
15 bunch of reasons why Bluetooth was the logical
16 implementation for a CGM transceiver that
17 certainly Patel describes, including the fact
18 that you want to talk to things other than
19 glucose -- I'm sorry, insulin pumps, such as a
20 consumer electronic device, you know, a PDA or
21 a cell phone, a computer.

22 By 2007 these devices were already
23 coming on market with Bluetooth. And, in fact,
24 the Bluetooth technology by 2009 was stable
25 enough to ensure that the data load that the

1 sensor transceiver has could be easily
2 off-loaded to a receiver. As opposed to a
3 Zigbee, which is more of a mesh radio, which
4 has a different set of challenges in both
5 pairing and in maintaining the data integrity.

6 So if you want to write a lot of code
7 to support Zigbee in a CED or a
8 computer-electronic device, that may have been
9 an option, but it wouldn't have been the
10 logical one, given that these devices, even
11 today, I'm not aware of a cell phone that has a
12 built-in Zigbee radio. They're all Bluetooth.

13 But at the time, it would have been
14 the obvious selection, given the target devices
15 had already been committing Bluetooth in their
16 roadmaps.

17 BY MR. CARROZZA:

18 Q The Paradigm was an established functioning
19 CGM system, right?

20 MR. MASON: Objection. Form.

21 THE WITNESS: At what time you're
22 referring to?

23 BY MR. CARROZZA:

24 Q As of 2009.

25 A So Paradigm was a functioning system years

1 before that. It was commercially available years
2 before that.

3 Q And it was a functioning system, right?

4 A I'm not sure what you mean by --

5 Q It was a commercial product, I guess is
6 what I'm saying.

7 A Yes. It was a medical device available on
8 market years before 2009.

9 Q And it didn't use Bluetooth?

10 MR. MASON: Objection. Form.

11 THE WITNESS: So Paradigm RT was operating
12 in a lower spectrum ISM. And at the time, the
13 Bluetooth specification was not yet stable or
14 mature enough to consider implementing in the
15 2.4 gigahertz range, in my opinion. It would
16 have been a big risk for the design team to try
17 to implement Bluetooth years before 2009.

18 BY MR. CARROZZA:

19 Q Okay. Why is that?

20 A There's a multitude of reasons. The first
21 being the chipsets did not have Bluetooth built into
22 them in 2006 or '5 or '4, when they were making
23 their design tradeoffs for Paradigm REAL-Time.

24 What was available was unlicensed spectrum
25 that at least limited the number of radio options to

1 two or three, given that Paradigm REAL-Time was a
2 global product.

3 So the reason why they were choosing
4 specific spectrum is likely because some spectrum
5 was not legally available in other geographies. So
6 at that time, that was essentially what was
7 available to them to provide at least a robust radio
8 communication off body to the insulin pump.

9 There are power considerations. There were
10 ease of pairing and unpairing considerations.
11 There's a list of things that make Bluetooth really
12 the motivator, including the fact that there's more
13 bandwidth available. So the likelihood of collision
14 moving from this ISM spectrum into the 2.4 gig
15 spectrum was much, much lower.

16 Q Are you familiar with the term "Bluetooth
17 Low Energy"?

18 A Yes.

19 Q What is Bluetooth Low Energy?

20 MR. MASON: Objection. Form. Scope.

21 THE WITNESS: So Bluetooth Low Energy is
22 an option in the protocol that allows lower
23 emission energy for close proximity
24 communication.

25 ///

1 BY MR. CARROZZA:

2 Q And do you know when Bluetooth Low Energy
3 was first established as a protocol?

4 MR. MASON: Objection. Form.

5 THE WITNESS: I don't recall off the top
6 of my head, but I don't believe it was in
7 Bluetooth 2.1. I think it came later in
8 Bluetooth 3.0.

9 BY MR. CARROZZA:

10 Q If I told you June 2010, would you believe
11 me?

12 MR. MASON: Objection. Form.

13 THE WITNESS: I have no reason to
14 disbelieve you.

15 BY MR. CARROZZA:

16 Q And as far as current CGM products, are you
17 familiar with any of DexCom's products?

18 MR. MASON: Objection. Form. Scope.

19 THE WITNESS: With regards to what?

20 BY MR. CARROZZA:

21 Q Just familiar with them in anything -- I'm
22 going to ask detailed questions. I'm trying to ask
23 if you're familiar with these products first before
24 I ask questions about them.

25 A I'm not intimate with the portfolio of

1 products from DexCom.

2 Q Okay. Are you familiar with the fact that
3 the FCC requires companies that sell products that
4 have RF emissions that they have to comply with FCC
5 regulations?

6 MR. MASON: Objection. Form.

7 THE WITNESS: Did you ask if FDA requires
8 or FCC requires?

9 BY MR. CARROZZA:

10 Q FCC. FCC.

11 A Yes. I'm familiar with that. We marketed
12 a portfolio of patient-worn transceivers. I'm
13 familiar with some of the FCC requirements there.

14 Q And so when a product that is going to have
15 RF emissions is going to be sold, the manufacturer
16 has to have certification done to make sure that
17 they're compliant with FCC regulations, is what I'm
18 getting at, right?

19 MR. MASON: Objection. Form.

20 THE WITNESS: Yeah. The regulatory
21 landscape for FCC compliance changed over time,
22 but your statement is fair. There would be
23 some type acceptance for the radio unit in
24 order to be a certified radio.

25 ///

1 BY MR. CARROZZA:

2 Q Are you familiar with the idea that a
3 manufacturer can ask for a waiver from certain FCC
4 regulations concerning RF emissions?

5 MR. MASON: Objection. Form.

6 THE WITNESS: Can you describe which part
7 of the FCC regulations?

8 BY MR. CARROZZA:

9 Q Sure. So let's say that a company wanted
10 to provide a product that had RF emissions, but the
11 power levels were going to be slightly higher than
12 what the FCC regulations are. That party can ask
13 the FCC for a waiver.

14 Are you familiar with that process?

15 A I've never --

16 MR. MASON: Objection. Form.

17 THE WITNESS: I've never executed that
18 process.

19 BY MR. CARROZZA:

20 Q Okay. Are you familiar with it?

21 A It's plausible that there is such a
22 regulatory exemption, but I'm not personally
23 familiar with how that process works, what the
24 permissive spurious emission requirements are, on
25 band, off band, and under what protocols you're

1 allowed to request an exemption.

2 Q I think now is a good time to break for
3 lunch.

4 MR. MASON: Okay.

5 (Off record from 11:46 a.m. to 12:40 p.m.)

6 BY MR. CARROZZA:

7 Q Mr. Gross, during any of the breaks today
8 have you talked about your testimony with counsel at
9 all?

10 A No.

11 Q Did you overhear counsel talking amongst
12 themselves about your testimony?

13 A No.

14 Q Let's look at paragraph 108 of your
15 declaration. It's on page 70. Now, paragraphs 108
16 and 109, that's referring to your opinion that the
17 Paradigm displays a data gap on the pump display,
18 right?

19 A Yeah. 108 describes a sophisticated
20 network of safety checks that notify the conditions
21 that would result in weak signals and calibration
22 errors. The user sees that on the user interface.
23 And then lost communications as a cause for
24 glucose -- loss of glucose monitoring data as
25 described in the Paradigm REAL-Time document 1011.

1 Q Now, Patel-2009, which is your other
2 reference in Ground 1, that does not disclose
3 displaying data gaps, right?

4 MR. MASON: Objection. Form.

5 MR. CARROZZA: What's the form objection?

6 MR. MASON: It's vague as to displaying
7 disclosed data gaps.

8 BY MR. CARROZZA:

9 Q Well, let me short-circuit this.

10 In paragraphs 108 and 109, you're not
11 referring to Patel-2009 at all, are you?

12 A So in this claim, Patel-2009 is the
13 transceiver, is the sensor, is the radio
14 transmitter, and does serve as the display
15 monitoring component of the system.

16 Q And so in your opinion the Paradigm is
17 going to display a data gap when it has failed to
18 receive data from the transmitter, correct?

19 A So referring to the Paradigm Exhibit 1011,
20 Paradigm REAL-Time discusses sophisticated safety
21 checks and network checks for the system, detects
22 anything unusual, notifies you of the condition that
23 requires immediate attention.

24 And later, on page 72 to 76, Paradigm
25 REAL-Time describes a condition where it's lost

1 communication with the sensor for some period of
2 time, it hasn't received data; tells the user
3 there's a weak signal.

4 And in the diagram below that descriptor of
5 the weak signal, there is an example of what the
6 Paradigm infusion pump display would show indicating
7 that there is no data since the weak signal
8 condition, in this image, since 3:16, where the
9 current time is 3:22, as the REAL-Time clock is
10 displayed at the top of the display.

11 So in this case, I think, in my opinion,
12 it's clear that Paradigm REAL-Time detects the
13 condition where glucose data is not available to the
14 display, notifies the user, and generates this
15 cessation of trend data or graphical trend data
16 which essentially is a gap in the data that's called
17 for in this claim.

18 Q The message of a weak signal is referring
19 to the wireless signal, correct?

20 A It is at least the wireless signal that
21 could cause the weak signal condition. That's
22 further exemplified --

23 Q There's no question pending.

24 A I'm sorry. I'm just continuing my
25 explanation.

1 Paradigm REAL-Time describes the use of an
2 antenna icon on the main display of the insulin
3 pump. And they described the icon changing from
4 solid to hollow in the presence of this weak signal
5 condition. Which, in combination with the FAQ about
6 having the transmitter out of range, I think it's
7 pretty clear they're talking about irregular
8 communication as at least one cause for this
9 condition.

10 Q On page 74 of Exhibit 1011 there's a number
11 of other types of errors that can occur, right?

12 A On page 74?

13 Q Yes.

14 A Okay.

15 MR. MASON: Are you referring to page 74
16 of --

17 MR. CARROZZA: Exhibit 1011.

18 THE WITNESS: Oh, sorry.

19 BY MR. CARROZZA:

20 Q It just coincided -- all right.

21 A So yes. 1011, page 74. There are a
22 variety of other conditions that are called out as
23 part of the troubleshooting alarm section.

24 Q And that's also true for pages 75 and 76,
25 those additional errors that can occur?

1 A Again, these are all present in the user
2 guide for troubleshooting and alarms. So this
3 section, I believe, is intended to help the user
4 identify the cause to error conditions and what to
5 do to correct them.

6 Q And on each of those pages, 74, 75, and 76,
7 the little windows on it, right, those are the alert
8 messages that will appear in the display unit,
9 right?

10 MR. MASON: Objection. Form.

11 THE WITNESS: Again, you're on 1011 or
12 you're on the declaration?

13 BY MR. CARROZZA:

14 Q Yes, on Exhibit 1011.

15 A Okay.

16 MR. MASON: Same objection.

17 THE WITNESS: Yeah, so these do appear to
18 be messages that can appear on the display of
19 the insulin pump, part of the Paradigm
20 REAL-Time system.

21 BY MR. CARROZZA:

22 Q And going back to your declaration which is
23 Exhibit 1008, and looking at paragraph 108 again.
24 And if you go to page 71 of your declaration, are
25 you there?

1 A Page 71 of my declaration. Are you talking
2 about paragraph 108 or page 71?

3 Q Paragraph 108 that carries on to the top of
4 page 71.

5 A Okay.

6 Q You say that lost communication causes
7 failed reception of the continuous glucose
8 monitoring (CGM) data, right? It's the last
9 sentence of paragraph 108.

10 A Right. This is referencing the claim that
11 talks about the glucose monitoring system is
12 configured to detect an adverse condition, where the
13 adverse condition results in the receiver displaying
14 a data gap such that the first line graph displayed
15 on the receiver unit has an end corresponding to a
16 time associated with the start of the adverse
17 condition.

18 And 108 talks about the Paradigm REAL-Time
19 having this ability to detect system unusual
20 conditions and notifies the user to take appropriate
21 action, such as weak signal and calibration errors.
22 And in this case, the insulin pump is changing its
23 icon to help the user understand that it's a weak
24 signal that's causing this interruption in
25 communication.

1 Q Thank you. If communication was lost, is
2 that a detected system malfunction, in your opinion?

3 MR. MASON: Objection. Form.

4 THE WITNESS: What do you mean by
5 "detected system malfunction"?

6 BY MR. CARROZZA:

7 Q Are you able to answer my question without
8 me further explaining it?

9 A Well, detected system malfunction could be
10 a lot of things. Just trying to get clarity on what
11 you're asking about.

12 Q Your answer's fine so far. Let me ask a
13 follow-up.

14 If communication is lost, is that a
15 detected error, in your opinion?

16 MR. MASON: Objection. Form. Scope.

17 THE WITNESS: So with regards to the
18 Paradigm REAL-Time, clearly the insulin pump
19 knows that it does not have communication with
20 the transceiver.

21 BY MR. CARROZZA:

22 Q How does it know that?

23 A It knows that because it told the user weak
24 signal and it changed its radio icon to a different
25 graphical representation such that, referring back

1 to the user instructions, when that happens, the
2 user should move the pump closer to the transmitter
3 or move the transmitter and pump to a new location
4 on your body as a mitigation to this weak signal
5 condition.

6 Q So if a receiver doesn't receive data from
7 a transmitter when it expected to, you would agree
8 that that is a detected adverse condition within the
9 scope of claim one?

10 MR. MASON: Objection. Form.

11 THE WITNESS: So claim 1 calls for the
12 glucose monitoring system to continue to detect
13 an adverse condition whereas the condition
14 results in the receiver unit displaying a data
15 gap. And here what we see in the Paradigm
16 REAL-Time is a clear indication in the user
17 documents that when the weak signal is
18 indicated, the icon changes to a hollow icon.
19 And the Paradigm documentation indicates that
20 the change occurs when the sensor is connected
21 to the transmitter and was communicating with
22 the pump, but this communication has been lost.

23 So I would infer and I would
24 understand that to mean, and a POSITA would
25 understand that to mean, that the display

1 device of the insulin pump has knowledge that
2 it's lost communication with the CGM
3 transceiver.

4 BY MR. CARROZZA:

5 Q And it has that knowledge, at least,
6 because it hasn't received the data that it was
7 expecting during that communication interval; is
8 that right?

9 A Perhaps. It's not the only way that that
10 could be implemented, but it is at least one.

11 Q Fair. Now, if communication was lost, does
12 that result in an inability of the Paradigm system
13 to display or output process data in your opinion?

14 MR. MASON: Objection. Form.

15 THE WITNESS: So the analysis here
16 describes the adverse condition that is called
17 for in claim 1(i). It results in the receiver
18 unit displaying the end of the data trend from
19 the first line. And an end to the
20 corresponding time associated with the start of
21 the adverse condition.

22 So I -- so I'm not sure how your
23 question is applicable here. Maybe I don't
24 understand what you're asking.

25 ///

1 BY MR. CARROZZA:

2 Q If the receiver does not receive data when
3 it expects it, in your opinion does that result in
4 an inability of the system to display or output
5 process sensor data?

6 MR. MASON: Objection. Form.

7 THE WITNESS: So with regards to the
8 Paradigm REAL-Time system, the lack of the
9 communication with the transceiver does result
10 in an inability of the receiving device to
11 display the data that it didn't receive.

12 It's clearly indicated in the figure
13 at the top of page 72 where the time of the
14 communication event is displayed for the user,
15 the inoperative condition or weak signal
16 condition is displayed and the user cannot
17 traverse to the gap data. The only place that
18 they can traverse to is where the data ended.
19 So it's fairly clear that there's the cessation
20 of trended data on the display in this case.

21 MR. MASON: May the record reflect, I
22 think the witness was gesturing toward page 72
23 of his declaration, not 72 of Exhibit 1011.

24 MR. CARROZZA: That's fair. The page
25 numbers just coincide. You're right.

1 BY MR. CARROZZA:

2 Q Let's move on to another claim. Claim 17.
3 And this is paragraph 125 of your declaration.

4 A I'm sorry. Page what of the declaration?

5 Q Page 81 of your declaration. It's
6 paragraph 125.

7 A So claim 17 calls for the glucose
8 monitoring system of claim 1, wherein the adverse
9 condition provides a data unavailability condition;
10 is that the claim you're asking?

11 Q Yes. Thank you. Now, the first thing I'd
12 like to understand, if you can take a moment and
13 read to yourself, your paragraph 125 which consists
14 of two sentences, not including the parenthetical,
15 and explain, what's the difference between the first
16 sentence and the second sentence?

17 A So on paragraph 125, the first paragraph
18 discloses and recants the weak signal condition from
19 which the glucose data is unavailable for display.
20 I also reference paragraph 58 of my declaration as
21 well as 121 above.

22 And in addition, I'm making a recollection
23 that a POSITA would have recognized that failed
24 glucose reception of data of -- failed reception of
25 glucose data would be a cause for data

1 unavailability that they would need to design to.

2 Q So if a --

3 A I'm sorry. Let me also reference back to
4 58 where that, I think, is more clear. Where POSITA
5 would have known that failed communication could be
6 caused by a variety of errors including
7 transmission, reception or signal and the like;
8 malfunctions with the system, transceiver, monitor;
9 and that failed communication would cause data to be
10 unavailable and lead to the inability to display the
11 data. This is on page 35 of my declaration.

12 So I think it's very clear in this section
13 how I think a POSITA would recognize that there are
14 going to be causes for data communication problems.
15 And in that case, the POSITA would definitely want
16 to, when possible, bring the missing data to the
17 user. That's a very important thing for the care
18 and for the use of their system.

19 So I think it would be obvious for a POSITA
20 that this is at least one condition that you need to
21 design to. And in the correction of this condition,
22 you would need to give views of the data that you
23 didn't have at the time of the radio interference or
24 the radio weak signal condition.

25 Q So you're interpreting data unavailability

1 condition to mean that the data is simply not
2 received by the receiver?

3 A Yeah. I believe that the condition when
4 the display device does not receive the data, this
5 results in a data unavailability condition as
6 required in claim 17.

7 Q So you wouldn't construe data
8 unavailability condition to be limited to a
9 calibration failure, right?

10 MR. MASON: Objection. Form.

11 THE WITNESS: So in claim 17, the radio
12 communication -- radio communication weak
13 signal condition is at least one example of
14 what could be causing this data unavailability
15 condition that would be recognized by the
16 POSITA.

17 BY MR. CARROZZA:

18 Q All right. Let's take a look at your
19 paragraph 127 in your declaration. It's on page 82.

20 A Thank you. Paragraph 127.

21 Q Are you there?

22 A Yes. Regarding claim 19, the glucose
23 monitoring system of claim 1, wherein the receiver
24 unit is further configured to a predetermined period
25 of time after the correction of the adverse

1 condition before displaying the second line graph.

2 Q Yes. Thank you. And you refer to the term
3 "lag" a few times in paragraph 127. And we spoke
4 about lag earlier today, do you recall that?

5 A Our discussion previously was with regards
6 to physiologic delays in interstitial glucose and
7 blood glucose, and then processing delays from the
8 sensor electronics to the creation of a glucose
9 measurement and then finally to the display; is
10 that --

11 Q Good recollection. Yes. Thank you.

12 A Okay.

13 Q And now, the Paradigm system, itself,
14 transmitted glucose values every five minutes,
15 right?

16 A That's what the user documentation clearly
17 indicates and it would store up to 40 minutes, 40
18 minutes of data when it could not communicate to the
19 display insulin pump.

20 Q And now in paragraph 129 of your
21 declaration you say, POSITAs would have found it
22 obvious to wait a predetermined time, for example,
23 one, two, three update cycles, before displaying
24 repopulated glucose data; do you see that?

25 A Correct. With reference to paragraph 44?

1 Q Right. And so the three update cycles,
2 that would be, what, 15 minutes in the Paradigm
3 system?

4 MR. MASON: Objection. Form.

5 THE WITNESS: For the Paradigm system, it
6 would be up to 15 minutes, correct.

7 BY MR. CARROZZA:

8 Q So in paragraph 129 you're saying that a
9 person of skill in the art would have found it
10 obvious for the receiver to receive the missing data
11 and then wait one, two, or three cycles before
12 displaying into the user, right?

13 MR. MASON: Objection. Form.

14 THE WITNESS: So that reference is with
15 regards to that the glucose data repopulation
16 happens on a five-minute interval. So if
17 the -- so the lag between synchronizing glucose
18 data and Paradigm REAL-Time display of
19 repopulated data is predetermined when the
20 failed reception occurs. That's what I'm
21 saying in paragraph 128.

22 BY MR. CARROZZA:

23 Q And then in paragraph 129 you're saying it
24 also would have been obvious to wait up to three
25 update cycles before displaying it, right?

1 A So the -- I think the context is said in
2 paragraph 127 to that statement. Where I talk about
3 the results in the display of the update lag
4 resulting in that gap of no data.

5 And the POSITA would recognize that this
6 lag will occur from the most recent five-minute
7 update and that the data is going to be repopulated
8 no sooner than five minutes beyond that. So from
9 the first minute to the second minute to the third
10 minute, that's the update delay that I'm referring
11 to here in 129.

12 Q I don't think I understood your answer.
13 Could you please clarify?

14 A So you asked if the one, two, and three
15 cycle updates are 15 minutes. And while that is --
16 that's accurate, what I'm describing here is the
17 update lag from when the last five-minute
18 measurement was received 'til when the next
19 five-minute measurement would have been received.

20 And that is what is causing this update lag
21 to occur in the trend data.

22 Q All right. Let's use an example because I
23 still don't understand what you're saying.

24 Paragraph 129 says, POSITAs would have
25 found it obvious to wait a predetermined time before

1 displaying repopulated glucose data.

2 Did I read that right?

3 A That is correct.

4 Q And repopulated glucose data is data that
5 was missing from some time period, right?

6 A Correct.

7 Q Let's take a look at paragraph 51 of your
8 declaration which is on page 31.

9 A Okay.

10 Q And in paragraph 51 you provide a
11 definition of a person of ordinary skill in the art.
12 And I just want to ask you a few questions about it.

13 So first, with regard to education level,
14 it's your opinion that a person of ordinary skill in
15 the art would have had a bachelor degree, Bachelor
16 of Science degree in biomedical engineering or
17 similar field such as electrical or software or
18 computer engineering; as far as educational
19 background, that's your opinion, right?

20 MR. MASON: Objection. Form.

21 THE WITNESS: So in the contextualization
22 of a member of a multidisciplinary team that I
23 describe in 52 below, this is typically the
24 education level of the people on these teams.

25 In addition to someone of more

1 experience to help manage the design trade off
2 space.

3 BY MR. CARROZZA:

4 Q And as far as experience goes in your
5 opinion, according to paragraph 51, a person of
6 ordinary skill would have two years of industry
7 experience or research working with medical devices
8 in systems for measuring biomedical signals, right?

9 A That's what paragraph 51 states, yes.

10 Q Are you familiar with an EEG signal or
11 electroencephalogram?

12 A I am.

13 Q That's from brain activity, right?

14 A It's from -- serves as electro detection of
15 electro potentials that is sourced by both muscles
16 and the brain. They need to be demodulated, but
17 yes.

18 Q That's a little more descriptive.

19 A I just want to be clear. It's more than
20 just brain activity. Go ahead.

21 Q But it is a biomedical signal?

22 A It is.

23 Q Are you familiar with an EMG signal?
24 Electromyogram.

25 A I am.

1 Q And that's also a biomedical signal?

2 A As is blood pressure and pulmonary
3 compliance, yes.

4 Q So I want to make sure I understand this.
5 In your opinion, a software engineer with two years
6 of industry experience working with medical devices
7 and systems for measuring EEG signals, that would be
8 a person of ordinary skill in the art in the field
9 of the '056 patent?

10 MR. MASON: Objection. Form.

11 THE WITNESS: So in order to do product
12 development, you would have to have the right
13 skill set on your team. And when I build teams
14 looking for specific domain expertise, for
15 example someone who understands electrochemical
16 sensors, someone who understands microprocessor
17 control and signal processing, someone who
18 understands RF communication, I would be sure
19 that their knowledge set was competent in the
20 domain I needed to build a team with.

21 So I would not necessarily look at
22 somebody who is doing EEG signal acquisition
23 unless there's some application to the
24 technology that I am developing where it would
25 be useful.

1 MR. CARROZZA: We're going to shift gears
2 a little bit and I have a new exhibit.

3 (Exhibit 2012, US Patent 9,577,934, was
4 marked.)

5 BY MR. CARROZZA:

6 Q Mr. Gross, do you recognize Exhibit 2012
7 that's been handed to you?

8 A This appears to be a copy of a patent that
9 I have been granted with Royal Phillips. Or
10 Phillips, Koninklijke.

11 Q How do you pronounce that?

12 A I'm not Dutch.

13 Q Okay. I should say, when's the last time
14 you've seen this patent?

15 A Probably shortly after it was filed.

16 Q Do you recall what it was about by
17 taking -- take a minute to look it over. I just
18 want to make sure you recall this specific patent.

19 A Take a moment.

20 Q Have you reviewed enough to understand your
21 recollection about what it was about?

22 A I've got four more pages. Sorry. The
23 font's a little small.

24 I thank you for the time. It's been some
25 time since I've reviewed this.

1 Q You remember this invention now?

2 A I recall. Review is helpful.

3 Q I understand. So what I want to discuss
4 about this patent is the general idea here is that
5 in a hospital network environment you can throttle
6 the data to prioritize different types of data.

7 Would you agree that that's sort of an
8 accurate overall summary?

9 A That's part of what's being proposed here.

10 Q And if we go to figure 1 of Exhibit 2012,
11 there's a block that's labeled 25 in the top right
12 corner; do you see that?

13 A Block is other physiologic device in
14 patient data?

15 Q Yes. Do you see that?

16 A I do.

17 Q Now, within that block 25, would that
18 include a glucose monitoring system?

19 MR. MASON: I'm going to object on form
20 and scope. I think the witness -- this is not
21 discussed in his declaration.

22 MR. CARROZZA: It's in his CV.

23 MR. MASON: It's cited in the CV. It's
24 not discussed in his declaration. He, himself,
25 said he has not seen it in over ten years. I

1 think you, yourself, alluded to the fact that
2 this is part of an ongoing litigation.

3 So I'll allow a couple basic
4 questions, but getting into the merits here, we
5 might have to call the Board. Because this
6 seems to just be fishing and asking questions
7 related to litigation.

8 I mean, if you can establish a
9 connection to this IPR proceeding, I'm
10 certainly willing to entertain these questions.
11 But right now, given that the witness has not
12 reviewed this in over ten years, it's not part
13 of his declaration.

14 Yes, it's listed on his CV as one of
15 his accomplishments, but there's been no
16 indication that he's considered this in forming
17 his opinions.

18 MR. CARROZZA: Am I allowed to impeach the
19 witness?

20 MR. MASON: If you're using this for
21 impeachment purposes, then hopefully that's
22 made clear quickly. But otherwise, we might
23 have to call the Board just to get clarity.

24 MR. CARROZZA: Right. So let's establish
25 a few facts about it.

1 BY MR. CARROZZA:

2 Q If you'd turn to page 1, the cover sheet of
3 this patent. The PCT filing date is February 2nd,
4 2009, right? It's field 22.

5 A Yeah. 22, PCT filed February 2, 2009.

6 Q And in this particular IPR the priority
7 date of the '056 patent is 2009, agree?

8 A The '056 patent?

9 Q Yes.

10 A That looks like it was filed August 25,
11 2021.

12 Q The priority date. I'm sorry?

13 A I'm sorry. Priority date.

14 Q There's a provisional application that's
15 referenced that was filed in April of 2009?

16 A Provisional application 61/173600 filed
17 April 29, 2009.

18 Q Okay. And so your patent, based at least
19 just on filing dates and priority dates, is just two
20 months before the '056 patent, right?

21 MR. MASON: Objection. Form. Scope.

22 THE WITNESS: So based on the PCT filing
23 date and claim provisional application filing
24 date?

25 ///

1 BY MR. CARROZZA:

2 Q They're within two months of each other?

3 MR. MASON: Same objections.

4 THE WITNESS: It appears that that's the
5 case.

6 BY MR. CARROZZA:

7 Q And in your declaration, Exhibit 1008,
8 submitted in this IPR, you express opinions
9 throughout that a person of skill in the art would
10 have found it obvious to display data gaps on a
11 display, correct?

12 A Are you referring to a section of my --

13 Q I'm referring to your declaration in
14 general.

15 MR. MASON: Objection. Form.

16 THE WITNESS: So I state in my declaration
17 that a POSITA would have known to store sensor
18 signals and other data used by the processor in
19 performing any of the processing routines
20 described above.

21 BY MR. CARROZZA:

22 Q Tell you what. Let me withdraw the
23 question. You don't have to answer because I'll
24 direct you to a very specific paragraph in your
25 declaration.

1 A So while you're hunting, paragraph 58 of my
2 declaration, page 35.

3 Q We can turn to paragraph 11 of your
4 declaration. You see that?

5 A Paragraph 11 on page 14, I relied on my
6 professional experience in formulating opinions
7 expressed in this declaration.

8 Q Yes. Do you see that?

9 A Yes, I do.

10 Q And is the patent that's been marked
11 Exhibit 2012 part of your professional experience?

12 A So given that this patent was based on work
13 I was doing while employed at Phillips and Phillips
14 is my professional experience, I would say yes, the
15 patent is part of my professional experience.

16 Q Thank you. So now if we go back to
17 figure 1 of Exhibit 2012. The box in the top right
18 corner is marked 25, as we discussed. And my
19 question was whether that would include a glucose
20 monitoring system.

21 MR. MASON: I'm going to object as to form
22 and as to scope. And again, I mean, here
23 you're asking him to interpret a document that
24 he hasn't looked at in over a decade. Again,
25 if you want to point him to a specific passage

1 in the document --

2 MR. CARROZZA: I pointed to a specific --

3 MR. MASON: -- and ask how this relates to
4 this proceeding in some way.

5 MR. McANDREWS: Andy, you're doing a fair
6 amount of coaching.

7 MR. CARROZZA: Let's stop with the
8 speaking objections. You made your objection.
9 If you want to call the Board, we can call the
10 Board. He just testified his opinions in the
11 declaration are based on his professional
12 experience. This patent is part of his
13 professional experience.

14 If you want to take this to the
15 Board, we can stop and go call. Otherwise,
16 stop with the speaking objections.

17 MR. MASON: I just want to make sure my
18 objection is on the record. Maybe we can go
19 off the record and the three of us can speak
20 with the witness out of the room just to --
21 because if you can tie it to things clearly,
22 and I understand where you're going with
23 impeachment, then I'll let it proceed.

24 But otherwise -- I mean, you,
25 yourself -- I'm going to stop right now. Let's

1 go off the record.

2 MR. CARROZZA: Yeah. Let's go off the
3 record.

4 MR. MASON: And Mr. Gross can leave the
5 room.

6 MR. CARROZZA: Yes.

7 (Off record from 1:39 p.m. to 2:04 p.m.)

8 BY MR. CARROZZA:

9 Q Welcome back, Mr. Gross.

10 Before the break we were talking about
11 Exhibit 2012 which is US Patent No. 9,577,534. And
12 let's make sure we are on the same page.

13 You are the inventor on this patent, right?

14 A That is correct.

15 Q And you've had a chance to review this
16 patent, at least for a little while, during today's
17 deposition?

18 A Briefly, yes.

19 Q I want to direct your attention to two
20 things and we'll talk about it. First is figure 1
21 and second is column 4 of Exhibit 2012. Now, in
22 figure 1 there's a block in the top right corner
23 that's labeled number 25; do you see that?

24 A I do.

25 Q And the text inside that block says, Other

1 physiologic device and patient data, right?

2 A Correct.

3 Q Now, if you go to column 4 at the very top
4 of Exhibit 2012 there's a reference to element 25;
5 do you see that?

6 A Physiologic devices and/or patient data 25
7 that describe patient parameters, heart rate, blood
8 pressure, respiration rate, SpO2, or other
9 parameters that can be monitored or used in
10 conjunction with monitoring for clinical decisions
11 and alerting, including patient demographics and
12 reports. And further, these devices provide data
13 from the processor 16 to the hospital network.

14 Q Okay. Thank you. And so using figure 1 as
15 a figure for us to look at, the data would flow from
16 block 25 through the hospital network and ultimately
17 to the central server which is labeled 13, right?

18 MR. MASON: Objection. Form. Scope.

19 THE WITNESS: So data would propagate from
20 the source through the processor, either
21 through a gap buffer, an output buffer, and
22 then over the hospital network depending on
23 available bandwidth.

24 BY MR. CARROZZA:

25 Q Very good. And element 25, that would

1 encompass also glucose monitoring systems, right?

2 MR. MASON: Objection. Form. Scope.

3 THE WITNESS: Insofar as the glucose
4 monitoring system is broadcasting data over the
5 hospital network, it could.

6 BY MR. CARROZZA:

7 Q And what would be on the other side of the
8 hospital network? Like a nurses' station?

9 MR. MASON: Objection. Form. Scope.

10 BY MR. CARROZZA:

11 Q Well, strike that. You don't have to
12 answer that question. I want to ask a more specific
13 question.

14 In this invention there are instances when
15 the data from a device within box 25 may be
16 deprioritized over other data and therefore withheld
17 for a period of time before it's sent over to the
18 hospital network, right?

19 MR. MASON: Objection. Form. Scope.

20 THE WITNESS: So the idea here is that
21 monitoring available bandwidth in a shared
22 contentious network gives you the opportunity
23 to decide what's critical to broadcast across
24 and keep track of what the receiving clients
25 have not yet received. Such that when

1 available bandwidth is present or when
2 available congestion or congestion cases are
3 reduced, the system can autonomously requeue
4 that data that hasn't been sent such that the
5 receiving client, whatever that is, can consume
6 it.

7 BY MR. CARROZZA:

8 Q And when that data is requeued, I think you
9 said, that would form sort of a temporary data gap
10 in the data stream, is that the idea?

11 MR. MASON: Objection. Form. Scope.

12 THE WITNESS: For data that's been
13 deprioritized or decimated, describe decimating
14 high fidelity wave data and then just sending
15 an 8-bit version of that until later, so at
16 least the downstream algorithms can consume it
17 and could continue to provide the surveillance
18 that they're intended.

19 BY MR. CARROZZA:

20 Q And so if element 25 encompassed a glucose
21 monitoring system, for example, there could be
22 instances when the glucose data is held for a period
23 of time before it's sent to the hospital server,
24 right?

25 MR. MASON: Objection. Form. Scope.

1 THE WITNESS: So the example list is not
2 exhaustive. If a glucose monitoring system is
3 part of a monitoring system within the hospital
4 network, it could participate in the system.

5 BY MR. CARROZZA:

6 Q So there could be instances when, according
7 to this invention, it would make sense to
8 temporarily hold back the glucose data because other
9 data may have higher priority, right?

10 MR. MASON: Objection. Form. Scope.

11 THE WITNESS: Yeah. Conceptually, closing
12 data gaps is what's novel -- is not what's
13 novel.

14 What's novel is how to deprioritize
15 and how to monitor the contentious shared
16 network so that you can be smart about what
17 data you provide into the transmission queue
18 such that the receiving client can take these
19 discrete chunks of information and then
20 reassemble them as if it had the required
21 bandwidth to process all the data as requested.

22 I refer you back to my declaration
23 where I describe that providing data gap
24 closure is common practice in many domains,
25 including the monitoring domain that I operated

1 in for this period of time. And bringing it
2 back to the declaration, you know, if you have
3 available data that's intended to be shown on a
4 display, it's obvious that it should be shown
5 on that display when the receiving client can
6 get access to that data.

7 BY MR. CARROZZA:

8 Q Right. And according to your invention in
9 Exhibit 2012, that data may be glucose data that's
10 held back for a period of time before it's sent over
11 the hospital network, right?

12 MR. MASON: Objection. Form. Scope.

13 THE WITNESS: Insofar as that is a case of
14 physiologic device data that participates in
15 the system, it could be.

16 We also discussed that the duration
17 of time within the environment that I was
18 operating CGM glucose data was not participant
19 in the infrastructure.

20 MR. MASON: Are we done with 2012? For
21 now. Sorry. Just wondering if I can set it
22 aside.

23 BY MR. CARROZZA:

24 Q Okay. Let's move on to page 113 of your
25 declaration.

1 A So I'm on page 113 of my declaration. This
2 describes the combination motivation for the
3 Shahmirian, Causey, Mastrototaro and Patel-2008; is
4 that right?

5 Q This is about Ground 3.

6 A Okay.

7 Q So on page 113 you have -- there's a figure
8 on page 113, do you see that?

9 A Yes. Highlighted and annotated in red for
10 the Mastrototaro component, green for the Causey
11 component, and blue for the Shahmirian component.

12 Q So the part of figure 1 -- well, what's
13 shown on page 113 is figure 1 from Patel-2008,
14 right?

15 A Can I have the question?

16 Q I can repeat. I may not have asked it so
17 clearly.

18 On page 113 in the figure it says figure 1.
19 That's figure 1 of Patel-2008, right?

20 A So part of it is Patel-2008, the part that
21 talks about the computer electronic device, the
22 device relay, and the blood glucose transceiver
23 system.

24 Q And so what you're showing there in the
25 red, for example, is that the Mastrototaro

1 transceiver and sensor would be used in place of
2 Patel-2008's transceiver and sensor?

3 MR. MASON: Objection. Form.

4 THE WITNESS: So the incorporation of
5 Mastrototaro, Shahmirian and Causey is
6 essentially part of Patel-2008, from my
7 understanding. These were special incorporated
8 references. And they're effectively parts of
9 Patel-2008. So they're explicitly contained
10 within the joint or the combined embodiment.
11 So when we talk about figure 1, although I
12 pointed out to where Shahmirian, Mastrototaro,
13 and Causey talk about these components, my
14 understanding is it's all 2008, Patel-2008.

15 BY MR. CARROZZA:

16 Q You're not a patent attorney, right?

17 A That's correct. It was described to me as
18 by incorporation it becomes or it is reflected back
19 to Patel-2008.

20 Q But you don't have legal training to know
21 whether or not that is correct, legally speaking,
22 right?

23 A Paragraph 189 of my declaration,
24 petition -- counsel for petitioner has informed me
25 that the disclosures of Mastrototaro, Shahmirian,

1 Causey are incorporated and effectively part of
2 Patel-2008.

3 Q And it's possible that your counsel was
4 wrong, right?

5 MR. MASON: Object to form. Scope.

6 THE WITNESS: Anything is possible,
7 Counsel.

8 BY MR. CARROZZA:

9 Q Now, the references of Causey,
10 Mastrototaro, Shahmirian and Patel-2008, I think we
11 established earlier in this deposition, those were
12 references that were pointed out to you, you didn't
13 find them on your own, right?

14 A That's correct.

15 Q And they were given to you as the
16 references to consider for Ground 3?

17 In other words, they were grouped together,
18 these are the four references that should go
19 together for Ground 3, right?

20 MR. MASON: Objection. Form. Scope. And
21 I'll counsel the witness to not disclose work
22 product privilege communications with counsel.

23 MR. CARROZZA: Well, to alleviate
24 counsel's concerns, let me rephrase the
25 question.

1 BY MR. CARROZZA:

2 Q Did you decide that these four references
3 should be grouped together for Ground 3?

4 MR. MASON: Same caution.

5 THE WITNESS: Counsel, I'm just going to
6 refer back that counsel for petitioner informed
7 me that the disclosures of Mastrototaro,
8 Shahmirian and Causey were part of Patel-2008;
9 and that I was to opine this Patel-2008 as part
10 of my declaration.

11 BY MR. CARROZZA:

12 Q Now, Patel-2008 discloses a transceiver and
13 a sensor, right?

14 A Yes.

15 Q And it's shown in figure 1 as element 125,
16 do you see that?

17 A That's at least one implementation of a
18 glucose sensor and transceiver.

19 Q And you're suggesting that you would
20 replace the transceiver and sensor with a different
21 transceiver and sensor from Mastrototaro; is that
22 right?

23 A Again, that Patel-2008 reference includes
24 Mastrototaro, as I've indicated in the incorporation
25 of Mastrototaro, Shahmirian and Causey.

1 Specifically, 182, Mastrototaro discloses a
2 telemetered characteristic monitor transmitter
3 coupled to a sensor set adapted for use in
4 subcutaneous tissue, referencing Exhibit 1019.

5 And further, that embodiment sensor set 10
6 transmitter 100 are connected by a cable 102 with
7 sensor connector 104. And later on page 107 you see
8 that that sensor set cable has been replaced and
9 indeed the sensor set is connected into the housing
10 of the transceiver unit as declared in figure 15 of
11 Mastrototaro. Again, Exhibit 1019.

12 Q Okay. And so again, you're replacing
13 Patel-2008's transceiver and sensor shown in
14 figure 1 with a transceiver and sensor from
15 Mastrototaro, right?

16 MR. MASON: Objection. Form.

17 THE WITNESS: I think I've answered that.
18 Patel-2008 includes Mastrototaro's sensor
19 configuration as described in Exhibit 1019.

20 MR. CARROZZA: I don't think you're
21 answering my question, but that's fine. Can we
22 take a short break?

23 MR. MASON: Okay.

24 (Off record from 2:22 p.m. to 2:39 p.m.)

25 MR. CARROZZA: Mr. Gross, thank you for

1 your time today. We have no further questions.

2 MR. MASON: Okay. Let's go off the record
3 for a minute.

4 (Off record from 2:40 p.m. to 2:43 p.m.)

5 MR. MASON: I have no questions today.

6 MADAM COURT REPORTER: Counsel, just to
7 confirm, you're receiving the original
8 transcript and a rough draft and you would like
9 it on Monday?

10 MR. CARROZZA: Yes. As quick as you can.
11 Monday is fine.

12 MADAM COURT REPORTER: As quick as I can.
13 Okay. And Mr. Mason, you're receiving a copy
14 with your realtime.

15 MR. MASON: Oh. Yes, standard delivery is
16 fine.

17 (Proceedings ended at 2:43 p.m.)

18 (Signature reserved.)

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1 REPORTER'S CERTIFICATE

2 I, VICTORIA A. GUERRERO, Certified Shorthand Reporter,
3 Registered Diplomat Reporter, Registered Merit Reporter,
4 Certified Realtime Reporter, in and for the State of Oregon
5 do hereby certify that, pursuant to notice, BRIAN D. GROSS
6 personally appeared before me at the time and place
7 mentioned in the caption herein; that the witness was, by
8 me, first duly sworn/affirmed under oath and examined upon
9 oral interrogatories propounded by counsel;

10 that said examination together with the testimony of
11 said witness was taken down by me in stenotype and
12 transcribed through computer-aided transcription; I further
13 certify that I am not a relative or employee of any attorney
14 of the parties, nor financially interested in the action;
15 and the foregoing transcript, pages 1 through 166,
16 review requested by the witness or a party, constitutes a
17 full, true, and correct record of such testimony adduced and
18 oral proceedings had and of the whole thereof.

19 WITNESS MY HAND AND DIGITAL SIGNATURE this Sunday, May
20 5, 2024.



21 Victoria A. Guerrero, CSR, RMR, CRR
22 Thompson Court Reporters
23 Oregon CSR No. 14-0428 (exp. 6-30-2023)
24 Washington CCR No. 3293 (exp. 3-15-2024)
California CSR No. 8370 (exp. 3-15-2024)
Hawaii CSR No. 490 (exp. 12-31-2023)

1 CASE NAME : DEXCOM vs ABBOTT

2 DEPOSITION OF: BRIAN GROSS

3 DATE TAKEN: MAY 2, 2024

4

5 This is to certify that I have read the
6 transcript of my Deposition taken in the above-entitled
7 cause and that the foregoing transcript accurately
8 states the questions asked and the answers given by me
9 as they now appear.

10 Please check one:
11 _____ I made no corrections

12 _____ Number of corrections made

13 _____
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CORRECTION PAGE

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DEPOSITION OF: BRIAN GROSS
DATE TAKEN: MAY 2, 2024

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