UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.

Petitioner

v.

ABBOTT DIABETES CARE INC.

Patent Owner

CASE NO. IPR2023-01409

U.S. PATENT NO. 11,202,591

DEPOSITION OF KARL R. LEINSING, MSME, PE

THURSDAY, OCTOBER 17, 2024

9:04 A.M. - 2:28 p.m.

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BOSTON, MASSACHUSETTS

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ROUGH DRAFT

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(NO EXHIBITS MARKED)

P R O C E E D I N G S

KARL R. LEINSING, MSME, PE,

Deponent, having first been satisfactorily identified by the production of his New Hampshire driver's license and duly sworn by the Notary Public, was examined and testified as follows:

EXAMINATION

BY MR. MASON:

Q. Good morning. Can you please state your name for the record?

A. Yes, it's Karl Robert Leinsing.

Q. Could you please state your address for the record, please, as well?

A. It's 77 Spur Road in Dover, New Hampshire.

Q. Have you been deposed before, Mr. Leinsing?

A. Yes.

Q. Roughly how many times have you been deposed?

A. Approximately 50, 60 times.

Q. And when was the most recent time?

A. I don't recall a date, but it

would have been a couple times this year, I would think.

Q. Okay. So do you feel you understand the deposition process?

A. Yes.

Q. And do you agree to testify truthfully today?

A. Yes.

MR. HANSEN: Objection as to form. He just was sworn in.

BY MR. MASON:

Q. Do you agree to testify --

MR. HANSEN: That's in appropriate.

MR. MASON: Leland, you can withhold the speaking objections or we're going to call the PTAB.

MR. HANSEN: These aren't proper questions.

BY MR. MASON:

Q. Do you agree to testify accurately today?

MR. HANSEN: Objection to form, argumentative.

MR. MASON: No speaking observations today, Leland. You can object as to form, that's it, unless I ask you what the form of objection is.

MR. HANSEN: Andy, we're going to do the same thing that you did at my depositions last week, and I'm going to make my proper objections, and you're not going to badger the witness by asking him --

MR. MASON: Leland --

MR. HANSEN: He just took oath.

MR. MASON: Leland, I'm going to call the board.

MR. HANSEN: Okay. Let's do. I want to do to call the board. No, I want to do it right now. Let's clear this up. You're not going to badger my witness. He took an oath. He swore an oath.

You don't need to state, Are you going to tell the truth? Are you going to testify accurately? He took an oath. These questions are inappropriate.

They're intended to --
BY MR. MASON:
Q. Is there anything that would impair or impede your ability to testify truthfully today?
A. No.
Q. Is there anything that would impair your ability to testify accurately today?
A. No.
Q. Do you understand that the rules of the USPTO forbid you from communicating with counsel about the substance of your testimony during breaks today?
A. That's my understanding, yes.
Q. And do you agree to follow those rules today?
A. Yes, I will.
Q. And do you have in front of you today some exhibits from this IPR?
A. Yes.
MR. MASON: And, for the record, that's IPR 2023-01409.
BY MR. MASON:

Q. And do you have in front of you today your declaration that was submitted in that IPR, Mr. Leinsing?
A. Yes, I do.
Q. If I could invite you to page 177 of that declaration.
A. Okay.
Q. Is that your signature on page 177?
A. Yes, it is.
Q. And do you also have an Appendix A to your declaration?
A. Yes.
Q. And is Appendix A your CV?
A. Yes.
Q. And do you also have Appendix B there with your declaration?
A. Yes.
Q. And does Appendix B span from page B1 to page B26.
A. Yes.
Q. And do you understand that this declaration with your July 19th, 2024, signature on page 177 and Appendices A and B

was filed as Exhibit 2002 in IPR 2023-01409?

MR. HANSEN: We'll stipulate for the record that it was so submitted.

A. Yes, along with the exhibits that I mention in the body of the declaration.

BY MR. MASON:

Q. Okay. Thank you.

And can we agree to just refer to that as your declaration today?

A. Yes, that's fine.

Q. Okay. Am I correct that you use the term "POSA," P-O-S-A, in your declaration to refer to a person of ordinary skill in the art?

MR. HANSEN: Objection as to form, accuracy.

A. Yes, that's correct, I use the phrase "POSA" to stand for a person of skill in the art.

Q. And are your opinions in the declaration intended to reflect the viewpoint of a POSA?

A. Yes.

Q. Can I invite you to paragraph 160

of your declaration on page 63?

A. Okay.

Q. And in paragraph 160, do you see about eight lines down there's a sentence that begins, "For example, accurate sensor placement is critical"?

A. Yes, I see that.

Q. Is it your opinion that a POSA would know that accurate sensor placement is critical to ensure that electrical chemical sensor can appropriately and correctly monitor glucose levels?

A. Can you repeat that, please?

Q. Yes. Is it your opinion that a POSA would understand that accurate sensor placement is critical to ensure that the electrochemical sensor can appropriately and correctly monitor glucose levels?

A. That's one of many important things to assure that you get accurate and reliable glucose readings.

Q. And what do you mean by, quote, "accurate sensor placement," end quote?

A. Well, as I say further in my

declaration, it's important that it's placed straight into the patient without wobble, without causing tissue drama, without damage to the tissue and other reasons that I mention in my declaration.

Q. Is there anything else you mean by "accurate sensor placement"?

MR. HANSEN: Objection as to form.

A. That it's placed by a stable system that allows the sensor to be placed, again, without tissue trauma, damage to the sensor, a very fragile sensor, any wobble or other factors that would cause an inaccurate or unreliable reading -- glucose reading.

Q. What other factors might cause an inaccurate or unreliable glucose reading?

MR. HANSEN: Objection as to form.

A. Again, as I say in my paragraph 160 of my declaration, not just the sensor issues but there's concerns with the on-body unit itself. It needs to prevent from moisture, since a patient will wear the device for multiple days. You don't want

other contaminants to interfere with accuracy. In addition to all the requirements for properly placing the sensor, as I mentioned.

BY MR. MASON:

Q. Does accurate sensor placement have anything to do with the depth of the sensor underneath the patient's skin?

A. It depends on the sensor but the depth will matter. You can't put a sensor halfway in, for example, or pull it -- push it into the patient and then pull it slightly out and then push it back in. There would be some tolerances that would impact the accuracy of the sensor regarding depth.

Q. And what tolerances regarding depth would impact the accuracy of the sensor?

MR. HANSEN: Objection as to form.

A. I wouldn't be able to tell you that off the top of my head, and it would depend on the particular sensor.

BY MR. MASON:

Q. Would a POSA understand that there was a appropriate depth of sensor placement?

MR. HANSEN: Objection as to form.

A. Depends on the sensor, and I believe that kind of research is still even ongoing today.

BY MR. MASON:

Q. Sitting here today, do you have -- strike that.

Do you have any opinion as to what the appropriate depth of sensor placement is in the context of, quote, "accurate sensor placement"?

MR. HANSEN: Objection as to form.

A. It would need to be sufficient in order to get proper analyte readings from a patient or to get proper glucose readings, and it would depend on the sensor. Placing a sensor into a patient to get accurate readings is very important, as I mention in my declaration.

BY MR. MASON:

Q. And how would appropriate sensor

depth depend on the particular analyte sensor?

MR. HANSEN: Objection as to form.

A. Different sensors have different technologies. There some two-conductor, three-conductor sensors. Depends on how long the sensor is, how much needs to be exposed to get proper analyte exposure and to measure the glucose. It's very sensor dependent, but once that's determined, it needs to be placed accurately and properly with a stable insertion system.

BY MR. MASON:

Q. And do you know if there's an appropriate minimum depth of sensor placement.

MR. HANSEN: Objection as to form, asked and answered.

A. Depends on the sensor, and it's not just a requirement of depth but all of the other factors I mention in my declaration with stability preventing wobble, inserting the sensor without damaging it. It's a very

fragile small sensor.
BY MR. MASON:
Q. So is it your opinion that the appropriate sensor depth varies from sensor to sensor?
MR. HANSEN: Objection as to form.
A. It can vary but that doesn't mean at some point there might be a standard that -- that is determined for sensors across all different CGM devices.
BY MR. MASON:
Q. Are you aware of any such standard?
A. No, not at this time, no.
Q. Are you aware of the sensor depth of any particular CGM sensors?
MR. HANSEN: Objection as to form.
A. I studied a lot of different sensors and analyzed them. I don't recall the distances off the top of my head.
BY MR. MASON:
Q. Was 10 millimeters a known acceptable sensor depth -- was 10 millimeters

a known acceptable sensor depth with respect to accurate sensor placement?

MR. HANSEN: Objection as to form.

A. Again, I don't recall the exact lengths of sensors or depth requirements off the top of my head so I can't answer that.

BY MR. MASON:

Q. And do you see about four lines down from the top of paragraph 160, Mr. Leinsing, you refer to, quote, "proper placement"?

A. You're looking again in paragraph 160?

Q. Yes. On the fourth line down, there's a sentence that ends "and proper care requires care and precision"?

A. Yes, I see that.

Q. Are you referring here to proper placement of the sensor?

A. Of the sensor, which then also requires proper placement and securement of the insertion system of the device.

Q. By "proper sensor placement," do

you mean the same thing as quote, "accurate sensor placement" later in the same paragraph?

A. I wouldn't say it's the same. I would say proper would encompass more broader requirements such that the sensor is placed with -- without causing wobble or tissue trauma inserted in a linear fashion and without damaging the sensor.

Q. I believe those are things you mention with respect to be accurate sensor placement.

But, nonetheless, my question is, are there any other differences that you can recall between proper placement of the sensor and the term "accurate sensor placement"?

MR. HANSEN: Objection as to form, colloquy, characterization.

A. I would say there's some overlap between proper placement and accurate sensor placement, but as I mention here in paragraph 160 it is important to have proper placement, which includes placing the sensor accurately in the patient with consistent depth for a

particular sensor, without causing any wobble, tissue trauma, and damage to the sensor that can last a period of time that is indicated by the CGM.

BY MR. MASON:

Q. What do you mean by "consistent depth"?

A. A particular sensor will have a depth requirement with some tolerance and therefore the insertion system would need to insert a sensor each time for each patient over millions of patients that depth within that tolerance every time.

Q. And, sitting here today, is it your testimony that you can think of no particular depth requirement?

A. For this declaration, we're looking at a patent and alleged prior art that would invalidate that patent and that was not the requirement of writing this declaration, and I don't recall those depths or tolerances off the top of my head. That's a manufacturer's specific device requirement and irrelevant to my analysis.

Q. And just to clarify, so your testimony is that the appropriate depth of a given sensor is irrelevant to your analysis in this IPR; is that correct?

A. That's not correct.

The depth -- the accuracy and the depth place, as I mentioned earlier, is important. The specific depth and tolerance that you're asking me about about a particular sensor is not relevant, because this is talking about the accurate sensor placement, whichever it might be, whether it's for whatever company or whatever manufacturer, they're going to have their own specific depth and tolerance requirements in order to be able to get accurate readings from every patient the sensor is inserted into.

Q. And would a POSA understand any general requirement or a specific depth requirement?

A. I don't understand your question.

Q. I'll strike that again and ask a different one.

Was there any known required range of depth to a POSA.

MR. HANSEN: Objection as to form, asked and answered.

BY MR. MASON:

Q. With respect to sensor placement?

A. A person of skill in the art for a particular sensor will know the requirements of that specific sensor and the tolerance and then would adjust the sizes appropriately, such as the '591 patent, to then accurately and properly place that sensor.

Q. And for a person of skill in the art designing a CGM device, would there be a known minimum depth for sensor placement?

MR. HANSEN: Objection as to form, asked and answered.

A. Again, it depends on the sensor, and that particular sensor will have a proper depth and tolerance to get an accurate and reliable reading and the '591 patent teaches how to do that and make sure that that sensor is inserted properly.

BY MR. MASON:

Q. Where does the '591 patent teach how to get a proper depth of the sensor?

A. So the '591 patent teaches how to easily and accurately place a sensor with reliability. It does not give exact dimensions. So a person of skill in the art would adjust the dimensions for depth or accuracy as they needed for their particular sensor, then the '591 patent would teach how to then assure stability and help prevent wobble or damage to the sensor, either in packaging or during insertion so that the user can insert it easily and properly.

Q. Do you recall mentioning wobble earlier in your testimony today?

A. Yes, and I mention that in my declaration as well.

Q. What do you mean by "wobble," in the context of sensor placement?

A. To insert the sensor without wobbling or wiggling into a patient, which would either cause damage to the sensor or tissue trauma to the patient.

Q. Would a POSA know to avoid wobble

during sensor placement?

A. The '591 patent would teach a person of skill in the art, particularly where the claims talk about inserting linearly into the patient, and around this time the inventors of the '591 were discovering amounts of wobble and tissue trauma that would cause a sensor to be inaccurate.

Q. And does it state in the '591 patent that the alleged inventors were discovering amounts of tissue trauma caused by wobble?

A. If we read the prior art even, it talks about how it's important for accurate placement of the sensor. So a person of skill in the art at the time of the patent knows that it's important to insert a sensor accurately and properly so you don't have wobble or tissue trauma.

Q. Did a POSA know that it was desirable to avoid tissue trauma during insertion CGM?

A. Can you repeat that question?

Q. Did a POSA know that it was desirable to avoid tissue trauma during CGM insertion?

A. The inventors of the '591 patent knew it.

Q. And my question was did a POSA know that it was desirable to avoid tissue trauma during CGM sensor insertion?

A. I would need to look back at the prior art to see if they mention tissue trauma. I know they mention multiple times the critical or importance of having proper and accurate sensor placement, whether or not they use the tissue trauma, I don't recall.

Q. And when you say "they," are you referring to prior art?

A. Correct. And I mention some of the prior art in my declaration, stating that it was known that sensors require more delicate insertion than an infusion cannula.

Q. Do POSAs know how to implement inserters that properly -- inserted sensors for CGM devices?

MR. HANSEN: Objection as to

form.

A. For a CGM with a OBU attached to the sensor, I do not think so until the '591 patent came about.

BY MR. MASON:

Q. With respect to CGM devices generally, did a POSA know how to implement inserters for injection of the sensor to a proper depth?

MR. HANSEN: Objection as to form.

A. I don't understand your question.

MR. MASON: Can you repeat the question, please, Sandy.

THE STENOGRAPHER: Yes.

"With respect to CGM devices generally, did a POSA know how to implement inserters for" -- vehicles? -- "of the sensor to a proper depth?

MR. MASON: I don't think it was vehicles.

BY MR. MASON:

Q. I'll just ask a different question. Did POSAs know how to implement

CGM inserters so as to properly and accurately place the sensor of a CGM device?

MR. HANSEN: Objection as to form.

A. Yeah, I can't answer that question. I don't know what you mean by "properly." That's something outside the scope of what I was doing for my declaration that involves further analysis into other type CGM devices, and I can't answer that.

BY MR. MASON:

Q. You do agree, though, that you use the term "proper placement" with respect to CGM sensors, correct?

MR. HANSEN: Objection as to form.

A. Yes, and it's particularly in the context of the '591 patent which is of an IBU -- OBU -- sorry -- attached to a sensor.

Q. And by "OBU," do you mean on-body unit?

A. Yes, that's correct.

Q. Sitting here today, you have no opinion as to whether POSAs would know how to insert CGM sensors in an accurate manner?

MR. HANSEN: Objection as to

form.

A. We could talk about specific ones. I'm thinking of ones that actually made it to the market and worked with patients. The Abbott Navigator was a product that worked, and then I believe Dexcom also had some manual syringe-type inserter.

It would help if we talk about more specific devices or patents.

Q. You mentioned the Abbott Navigator and the Dexcom product, are there any other prior art products that you can think of that would inform your opinions on proper sensor placement and the knowledge of a POSA?

MR. HANSEN: Objection as to form, scope.

A. Again, it's difficult to answer your question. You're saying "proper sensor placement." I don't know what you mean by -- sensors alone, sensors later connected with an OBU, sensors previously connected with an OBU.

My analysis and declaration is specific to the '591 and the prior art that

Dr. Fletcher asserted against it.
BY MR. MASON:
Q. Is it your testimony that accurate sensor placement is dependent on how the sensor is connected to any circuitry?
MR. HANSEN: Objection as to form.
A. It's more difficult, and in the ways that the '591 describes it, it had not been done before.
BY MR. MASON:
Q. What had not been done before?
A. Everything that's described by the claims of the '591 patent, namely Claims 1 and 19, independent claims, in addition to the dependent claims.
Q. What with regard to, quote "accurate sensor place," end quote, as you use that term in your declaration, as reflected in the '591 patent.
A. Well, we can step through each of the claim elements of Claim 1, but it would be Claim 1 as a whole is what allows for accurate sensor placement, as well as the other claims of the '591 patent.

Q. Is there anything in particular about Claim 1 that relates to accurate sensor placement?

MR. HANSEN: Objection as to form, omnibus.

A. Again, it would be the claims as a whole and then some particular things that help address that is the, for example, line 30, Column 23 of the '591 patent, it talks about advancing the on-body unit and the sharp in a linear direction from the first position to a second position, such that the sharp pierce of the skin of the user and the housing of the on-body unit is secured to the skin of the user in a second position. That element, along with the rest of the elements of the claim, are what allow a sensor and on-body unit to be placed accurately and reliably to a patient that's easy and inexpensive for the patient.

Q. And outside of the '591 patent, did a POSA know how to implement a CGM inserter to avoid trauma?

MR. HANSEN: Objection as to

form.

A. They knew of other ways, but not the way the '591 and the specification and the claims of the patent teach it.

BY MR. MASON:

Q. And outside of the '591 patent, did a POSA now how to implement a CGM device to avoid ingress of contaminants into the inserter.

MR. HANSEN: Objection as to form.

A. If you have a particular piece prior art to look at, I can answer that. That's too broad of a question for me to answer. I don't really understand the scope of your question.

BY MR. MASON:

Q. Do you have an understanding of the concept of a POSA?

A. Can you ask that again?

Q. Yeah. Do you understand what "POSA" means?

A. A person of skill in the art.

Q. And do you feel that you have a

solid understanding of what is meant by the term "person of skill in the art"?

A. Yes.

Q. And in forming your opinions, did you -- strike that.

In this IPR, do you have an opinion as to the knowledge and skills of a POSA?

A. Yes.

Q. Outside the context of the '591 patent, did a POSA know how to implement a CGM device to avoid ingress of contaminants into the on-body unit?

MR. HANSEN: Objection as to form, scope.

A. It depends what you mean for "on-body unit," whether the on-body unit is a separate device that's attached to a sensor or whether it's a preattached. I wouldn't want my answer to be misunderstood for being a global answer over all on-body units.

BY MR. MASON:

Q. Outside the '591 patent, did POSAs know how to implement a CGM device to avoid

ingress of contaminants into the on-body unit when that on-body unit was added after the fact?

MR. HANSEN: Objection as to form, scope.

MR. MASON: I'll strike that. I'll ask it again. I'll rephrase my question.

BY MR. MASON:

Q. Outside the '591 patent, did POSAs know how to implement a CGM device with a separately attached on-body unit so as to avoid ingress of contaminants into the on-body unit?

MR. HANSEN: Objection as to form, scope.

A. Can you repeat that question again, please?

MR. MASON: Sandy, could you read that back for me?

THE STENOGRAPHER: "Outside the '591 patent, did POSAs know how to implement a CGM device with a separately attached on-body unit so as to avoid

ingress of contaminants into the on-body unit?"

MR. HANSEN: Same objection.

A. And that's outside the scope of my analysis. I believe there was some prior art that talked about knowing that contaminants wouldn't be desirable in the on-body unit, so I believe they knew that was something they needed to obtain. Whether they were successful at doing that, I didn't do that analysis.

Q. Do you recall the Stafford prior art in this device, which was introduced as Exhibit 1004?

A. Yes.

Q. Does Stafford describe a manner of implementing a CGM device with an integrated on-body unit and sensor so as to avoid ingress of contaminants into the on-body unit?

MR. HANSEN: Objection as to form, scope.

A. Can you point to me where you're reading in Stafford that says that?

BY MR. MASON:

Q. I'm just asking a question here.

A. So what was your question about Stafford again?

Q. Does Stafford describe a manner of inserting a sensor of a CGM device so as to avoid ingress of contaminants into the on-body unit?

MR. HANSEN: Objection as to form.

A. I don't recall if it specifically talks about that. I would need to read it again to see or do a word search on my computer.

BY MR. MASON:

Q. In your opinion, sitting here today, would the CGM insertion process described by Stafford avoid ingress of contaminants into the on-body unit?

MR. HANSEN: Objection as to form.

A. Can you repeat that, please?

BY MR. MASON:

Q. Is it your opinion, sitting here today, that the CGM insertion process described by Stafford would avoid ingress of

contaminants into the on-body unit?

A. I didn't make or test for the enablement of Stafford. Stafford talks about different aspects of the invention where it would prevent the moisture or contaminants that may compromise the functions and operations of the data processing unit, but it's not the same device as taught in the '591 patent.

Q. But is Stafford a device in which the on-body unit and sensor are integrated with one another prior to the insertion of the sensor beneath the skin?

MR. HANSEN: Objection as to form.

A. Yes, but not as a complete device using the inserter and other components as taught by the '591 patent.

BY MR. MASON:

Q. Outside the '591 patent, then, did POSAs know how to implement CGM devices with an integrated sensor and on-body unit so as to avoid ingress of contaminants into the on-body unit during insertion?

MR. HANSEN: Objection as to form,

scope.

A. I don't understand your question. Can you break it apart a little bit?

BY MR. MASON:

Q. What don't you understand about the question?

A. Well, if I understood it, I could explain to you. I don't understand the question. There's a lot of broad terms and terms that need to be more specific to understand your question.

Q. Earlier were you distinguishing between CGM devices in which the on-body unit was combined with a sensor after insertion and CGM devices in which the on-body unit was combined with the sensor prior to insertion?

A. Yes, we talked about those two particular types of CGMs.

Q. And so with respect to the latter of those types of units in which -- those in which the on-body unit was combined with the sensor prior to insertion, would a POSA know how to implement a CGM so as to avoid ingress of contaminants into the inserter -- sorry --

into the on-body unit during insertion?

MR. HANSEN: Objection as to form, scope.

A. Not when it's part of an insertion device in the way that the '591 patent teaches.

BY MR. MASON:

Q. And outside the '591 patent, did POSAs know how to implement a CGM so as to accurately place the sensor?

MR. HANSEN: Objection as to form, scope.

A. I didn't do that analysis. I can't answer that question sitting here.

BY MR. MASON:

Q. So you have no opinion today on whether POSAs knew how to implement a CGM system that would accurately place the sensor; is that correct?

MR. HANSEN: Objection as to form, characterization.

A. I would need to look at the prior art and what a POSA knew at the time frame of the patent in 2009 to answer that question.

I didn't do that for my declaration.
(Recess taken at 10:00 a.m. to 10:11 a.m.)
BY MR. MASON:
Q. Mr. Leinsing, we while were on break, did you communicate with counsel regarding the substance of your testimony?
A. No, I did not.
Q. Did you communicate with counsel at all regarding your declaration in this IPR?
A. No, I did not.
Q. Could I invite you to paragraph 256 of your declaration?
Actually, you know what, pause before that. There's one thing I wanted to circle back on.
Do you recall prior -- during your prior testimony discussing the Abbott Navigator and the Dexcom product that was around prior to 2009?
A. Yes, I may be mistaken on the dates, which is why I said I didn't do that analysis of the time period of a person of skill in the art. What I did do was an

analysis of the prior art that was presented by Dexcom in this IPR proceeding, and that is -- and the results of that are in my declaration.

Q. Yeah. And what made you mention the Abbott Navigator device?

A. Because I believe when I was looking at some prior art there may be a patent that was related to the navigator in that time frame, but, again, I don't recall the exact dates without looking at the patent.

Q. And just for my edification, what do you mean by the "Abbott Navigator"?

A. I'm not sure how to explain that to you. I would need to, again, look at the prior art that was there. I forget the inventor's name that has the patents of the navigator product but that's a device that's different from what the '591 is teaching.

Q. Do you recall mentioning the Abbott Navigator earlier today?

A. Yes, you asked me that. I said, again, I don't recall the dates. And I also

don't think that G5 went back that far, so I think I misspoke on that if I said that was in the 2009 time frame.

Q. What do you mean by "G5"?

A. The Dexcom G5 product, I don't believe goes back to 2009 time frame.

Q. And I'm just trying to get understanding.

What did you mean by the Abbott Navigator in your testimony earlier today?

MR. HANSEN: Objection as to form, scope.

A. I don't understand your question. I think you asked me about a particular feature about a CGM product that was outside the scope of the '591 patent that had some features. We'd have to look back at your question, and I mentioned the Abbott Navigator.

BY MR. MASON:

Q. And maybe I've overcomplicated the question. But my question just is, what is the Abbott Navigator?

MR. HANSEN: Objection as to form,

scope.
BY MR. MASON:
Q. That you referred to earlier. What is the Abbott Navigator?
A. It's a CGM device that was developed by Abbott, that it's different than the '591 patent.
Q. How is the Abbott Navigator different from the '591 patent?
A. Dr. Fletcher didn't bring that prior art forward. I don't have those patents in front of me. What I did do is analyze what Dr. Fletcher brought forward in prior art, so I can't answer that question sitting here without looking at it, and I didn't refresh my memory on what's different.
Q. Are you familiar with the Abbott Navigator product?
MR. HANSEN: Andy, we're going to need to go off the record if you're going to continue with this.
MR. MASON: I'm just trying to get a -- he testified about something as being prior art. And I'm just asking

him what his familiarity with this prior art --

MR. HANSEN: Okay. We need to go off the record.

MR. MASON: Okay. Well, we should -- yeah, let's call the board then.

MR. HANSEN: Yeah, let's do it.

MR. MASON: So you're telling the witness -- you're not going to let the witness answer any questions with regard to prior art --

MR. HANSEN: Andy, you know what you're doing. Okay. It's a product. It's not paper art. It cannot be considered as prior art in this proceeding. You asked questions to get the witness to bring it up earlier. I have objections to the questions now.

If you're going to continue to ask about prior art, it's beyond the scope of an IPR, then yes, let's talk to the board and let's get you reigned in.

BY MR. MASON:

Q. Mr. Hansen, was the Abbott Navigator a well-known CGM system?

MR. HANSEN: Okay. We're not going to -- let's talk about to board. Let's talk to the board.

MR. MASON: Okay. Let's call the board. You want their number?

MR. HANSEN: You can call them.

MR. MASON: If you're instructing the witness not to answer, it's your call --

MR. HANSEN: I'm not instructing him not to answer. I'm telling you that your questions are improper, and if we need to go to the board to seek a protective order, we will.

MR. MASON: I mean, if you're instructing him not to answer, the burden is on you to call the board, make your request to the board as to what relief you're asking for. I'm not going to call the board. I'm asking the witness questions. Either you allow him

to answer or you go off the record and we call the board.

MR. HANSEN: Let's go off the records, and we call the board.

MR. MASON: Off the record.

(Recess taken at 10:19 a.m. to 10:26 a.m.)

BY MR. MASON:

Q. Are you ready to resume your deposition, Mr. Leinsing?

A. Yes, I think so.

Q. Can I invite you to paragraph 256 of your declaration?

A. Okay.

Q. And in paragraph 256 to your declaration, do you discuss, quote, "low-profile on-body unit"?

A. Yeah, let me read the paragraph to refresh my memory.

Okay. What was your question? It does talk about low-profile on-body units.

Q. And do you also discuss such units being, quote, "more tolerable and convenient for the user"?

A. Yes, a lower-profile on-body unit

would make it more tolerable for the user and the '591 patent describes ways to achieve that design.

Q. And you also discuss the -- strike that.

You also discuss the ultra-low profile allowing for the device to be discretely and comfortable worn by users?

A. Yes, and the '591 patent teaches how to do that.

Q. And outside the '591 patent, did a POSA know that a lower-profile device was more tolerable for a user?

A. Stafford talks about low profile, but it was lacking the other features than that the '591 patent teaches.

Q. And my question is just in terms of your understanding of a POSA in this IPR, and so I'll state my question.

My question is, would a POSA know that a lower-profile device was more tolerable for a user?

A. My answer is the same. That's my understanding of a POSA.

Q. And would a POSA know that a lower-profile device was more convenient for a user?

A. It was more convenient, but it wasn't until the '591 patent that you could do that with all the features as claimed by the '591 patent.

Q. Aside from the '591 patent, did a POSA know that a lower-profile device was more convenient for users?

A. They may have known that it was more convenient as discussed by Stafford and some others, but actually enable and show how to do it, it was not known until the '591 patent, in addition to all the other claim features.

Q. And outside the '591 patent, did a POSA know that a lower-profile device was more discrete for a user?

A. I think a person of skill would know that they would want it discrete, but until the '591 patent, they weren't able to achieve the claimed design of the '591 patent.

Q. And outside the '591 patent, did a POSA know that a lower-profile device was more comfortable for a user?

A. I think they would know that it would be more comfortable to do it, but then to do it with all the other features as claimed by the '591 patent, that was not known.

Q. Where does the '591 patent describe how to achieve a ultra-low profile device?

A. So in lots of different places, keeping in mind that it's a low-profile device in combination with all the other claimed elements, and particularly an on-body unit that is attached to a sensor, and as we step through the '591 patent, you can see teachings from the spec and the figures how to place the PC board with examples of overmolding, how the components are arranged on the -- on the PC board.

Figure 23 of the '591 patent shows how to position the battery, how the openings allow the alignment of the PC boards such

that it can be low profile, how the sensor is connected with the angles so that it can be low profile, and then all of the other figures and specification together all teach how to achieve the claimed invention of the '591.

Q. Is it your testimony that POSAs would not know how to place the PC board in a manner that created a low profile?

A. They would not know how to do it in combination with all of the other features of the claimed invention, the '591. There was nobody else prior to the '591 that has done all of features.

Q. And I understand your testimony with regards to the claimed invention as a whole.

But my specific question is, setting aside the claim as a whole, would POSAs know how to place the components on a PC board so as to achieve a low profile?

A. I can't answer that because it wouldn't be proper to look at all these features absent looking at the claims as a

whole. It's achieving that low profile in combination with all the other features that has not been done before, which is why we don't have an anticipatory argument.

Q. So you are unable to answer today whether a POSA knew how to place a PC board components in a manner that created a low profile; is that correct?

A. They would know how to place components in a low profile but they would not know how to place components in a low profile attached to a sensor along with all the other features in the claims of the '591 patent.

Q. So is it also -- go ahead.

A. And achieve a successful device that's accurate, reliable, inexpensive to use, easy to use and that works for millions of patients.

Q. So is it your testimony that a POSA would not know how to implement a CGM system that attached a sensor to a electronics in a manner that achieved a low profile?

MR. HANSEN: Objection as to form, asked and answered.

A. I think I answered that question.

BY MR. MASON:

Q. You described, quote, "How the sensor is connected with the angles," end quote.

Do you recall discussing that in your testimony today?

A. Yes.

Q. What did you mean by that?

A. Well, when you look at the '591 specification, it teaches the sensor and then how its attached to the on-body unit and talks about the specific -- some example embodiments, and then that, along with all of the other elements of the claimed invention, they're able to achieve an easy-to-use, accurate, stable system that's cost effective for the user.

This is an invention that has to work for millions of people and be accurate every single time, and if it's inaccurate, can be very dangerous to the user, to even

death. It has to be very reliable and accurate for millions of millions of times.

Q. Would a POSA know of CGM devices in which -- strike that.

Would a POSA know how to implement a CGM device with a sensor connected with angles to the electronics?

A. Not in the way that all of the claimed inventions of the '591 are achieved, and that's clear because Dr. Fletcher was not able to find that, even in his combination of Stafford and Cote. All of the elements are not present.

Q. You have the '591 patent there in front of you, correct?

A. Correct.

Q. Can I invite you to Figure 23? If you look at what's been labeled 14 on Figure 23.

Do you see that?

A. Yes.

Q. And is 14 along with 48 and 30 what you understand to be the sensor in this figure?

A. That's portions of the sensor, 14, 30 and 48, and then there's other aspects of the invention that allow it to be enabled to meet the claimed invention.

Q. And when you were discussing earlier an angled sensor so as to reduce the profile, were you referring to this 90-degree bend here that's shown between the sensor 14 and the sensor 30? I'm just trying to get an understanding of what you're referring to.

A. I'm going to point you to the specification that talks about that, that enables the '591 invention.

So, for example, one of the many portions of the '591 patent Column 12, lines 37 and to 56 talks about the sensor or a example of an embodiment of a sensor that enables the claimed invention.

Q. Can you repeat that portion of the patent again for me, which column?

A. '591 patent, Column 12, lines 37, to 56. It's just one example. And then it goes onward with Figure 5, and then it talks about other embodiments, and then Figure 6

talks about some more embodiments, and that combined with other parts of the specification, a person of skill in the art is enabled on how to make an on-body unit connected with a sensor, such that it can be low profile to at least what is claimed in the '591 patent.

Q. And prior to the '591 patent, would POSAs know to implement a sensor such that it could be positioned in two substantially perpendicular intersecting planes so as to reduce the profile of the on-body unit?

A. Not while meeting all of the other elements of the claimed invention.

Q. But is it your testimony that a POSA would know how to implement be -- strike that.

But is it your testimony that a POSA would know to implement a sensor in this fashion so as to reduce profile?

A. Well, Stafford Exhibit 1004 describes a sensor that's attached to the OBU, but it's lacking many other elements of

the '591 patent.

Q. And are you referring --

A. Five elements of the claims of the '591 patent.

Q. And are you referring to Stafford because Stafford uses a sensor that permits the sensor to bend and therefore be positioned in two substantially perpendicular intersecting planes?

MR. HANSEN: Objection as to form.

A. I would need to read Stafford to answer that question. You're asking about bending and other aspects that are not in what Mr. Fletcher analyzed. I don't believe he analyzed bending and other words you asked in your question.

BY MR. MASON:

Q. Yeah, I'm just trying to understand why you referred to Stafford when I asked the question about a sensor that was bent at a 90-degree angle to reduce the profile.

MR. HANSEN: Objection as to form,

characterization.

A. That was not in your question. Stafford doesn't talk about bending a sensor in a particular way or do the teachings as the '591 patent. You asked about, I believe, a sensor perpendicular to the OBU unit, and Stafford has a sensor -- or discusses one, but is missing many other elements of the '591 claims.

BY MR. MASON:

Q. And do you have Stafford there, Exhibit 1004, in front of you?

A. Yes.

Q. And looking at Stafford Figure 1, do you have an understanding of how a user would insert the needle and sensor of Stafford.

A. Can you repeat that question?

Q. Yeah. Do you have an understanding of how a user would insert the needle and sensor of Stafford?

A. Yes, I have an understanding of Stafford and how its introducer would place the sensor in the user.

Q. And in Stafford, does the user just press the needle down into their own skin?

A. They press the OBU with the needle already inserted into it and press both up against the user's skin.

Q. And is that like pushing a thumbtack into the skin?

A. I wouldn't describe it that way.

Q. How would you describe it?

A. I would describe it as inserting a OBU with a very small needle and sensor into the user.

Q. Would a POSA recognize that insertion in that manner would allow for wobble of the device?

A. I don't think a person of skill in the art reading and that Stafford would teach that. It would allow wobble in its needle, which is, I think, partially why it's shown with a short needle and short sensor.

Q. Just to make sure I understand your testimony. Is it your testimony that a POSA would understand that the Stafford

introducer would allow wobble during insertion?

MR. HANSEN: Objection as to form, asked and answered.

A. A person of skill in the art would read the reference and what it teaches and does not indicate any problems and neither did Dr. Fletcher indicate that Stafford would have any indications of allowing wobble that would create any kind of motivation to combine with anything to prevent it.

BY MR. MASON:

Q. So is it your testimony today that the Stafford system would prevent wobble during insertion?

MR. HANSEN: Objection as to form.

A. I think without getting into enablement, a person of skill in the art would understand that; and, again, Dr. Fletcher did not mention that as issue or any kind of motivation to be combined with anything else, so a person of skill in the art would understand that Stafford would not

have wobble.

MR. MASON: Can you read back the end of that last answer, Sandy?

THE STENOGRAPHER: "Dr. Fletcher did not mention that as issue or any kind of motivation to be combined with anything else, so a person of skill in the art would understand that Stafford would not have wobble."

BY MR. MASON:

Q. And would a person of skill in the art understand that the Stafford system might not allow for straight insertion of the sensor?

MR. HANSEN: Objection as to form.

A. So it was my test to review what Dr. Fletcher analyzed in each of these prior art and what he identified as any potential issues, and I don't recall him identifying that as an issue.

BY MR. MASON:

Q. And aside from Dr. Fletcher's -- strike that.

Aside from your characterization of Dr. Fletcher's testimony, would a POSA recognize that Stafford might allow the sensor to enter at something other than a straight angle?

MR. HANSEN: Objection as to form, asked and answered.

A. It's my understanding it's not my burden to identify what the weaknesses are of the prior art in terms of creating motivation that Dr. Fletcher should analyze. I don't believe he talked about that, so I did not address that in my declaration. A person of skill in the art would understand that it did not cause that issue, therefore there would be no motivation to combine with any other prior art.

BY MR. MASON:

Q. So is it your testimony, then, that the Stafford system would deliver the sensor in a straight fashion?

MR. HANSEN: Objection as to form, scope, asked and answered.

A. Not in the way that the '591

patent teaches it and as claimed with all the other elements.

BY MR. MASON:

Q. In Stafford -- strike that.

Do you understand -- strike that.

In Stafford is the user inserting a bare needle into his or her skin?

MR. HANSEN: Objection as to form.

A. It's inserting a small hypodermic needle with a sensor inside of it into the patient or the user.

BY MR. MASON:

Q. And is that hypodermic needle exposed prior to insertion?

MR. HANSEN: Objection as to form.

A. No, it has a guard segment 104 or a cover.

BY MR. MASON:

Q. And the guard segment remains on the needle during insertion. Is that your testimony?

A. It remains on the needle before and after insertion but not during insertion.

Q. What happens during insertion? Is that guard needle -- strike that.

Is the needle guard removed by the user prior to insertion?

MR. HANSEN: Objection as to form.

A. Yes, it's removed.

BY MR. MASON:

Q. And upon removal of the needle guard is it just a bare needle that the user then has holding in their hand?

MR. HANSEN: Objection as to form.

A. It is a small, short needle with a sensor inside that's inserted into the user. But then is missing all of the other components when combined with that to meet the '591 claims.

BY MR. MASON:

Q. Do you think that inserting such a bare exposed needle into the skin would cause anxiety for at least some users?

MR. HANSEN: Objection as to form, scope.

A. Stafford is aware of ways to do

that and solve the solution with the guard cover 104.

BY MR. MASON:

Q. Do you think that inserting a bare needle into the skin would cause a user more anxiety than a system in which the needle was hidden during insertion?

MR. HANSEN: Objection as to form, scope.

A. Patients who use these devices are diabetic patients that are used to using needles. The prior art that Dr. Fletcher has presented has different ways of addressing that pain and anxiety with needles. Stafford chooses a cover, and yet there are other ways that Dr. Fletcher could have looked at to address that problem, but instead cherry picks another solution that has that same issue addressed in a different way.

BY MR. MASON:

Q. Do you think at least some patients would have less anxiety with a device that hid the needle during insertion as opposed to Stafford's device in which the

bare needle was exposed during insertion?

MR. HANSEN: Objection as to form, asked and answered.

A. Stafford shows so many other advantages with not having a separate inserter or other components that are thrown away, lower costs, maintaining the lower profile, and many other features, and even considers other inserters or other ways to protect the needle; but in order to reach the objective, they choose a needle guard, like other systems, to address that pain and anxiety.

It would be like giving away the farm to sell a corn of the cob. You're not going to get -- try to address this one feature and then add all kinds of other costs and things that Stafford already knew about and considered when coming up with its invention.

Q. So is it your opinion that the Stafford insertion method is preferable to that method for insertion described in the '591 patent?

A. So that one particular feature, depending on who you ask, might be better, but then you lose all of the other benefits that Stafford showed. So it wouldn't make sense to gain one small advantage to a group of users that are used to needles to then lose multiple other advantages that Stafford teaches, such as the low cost, not creating waste, low profile, and everything else that Stafford mentions, which is why even the combination of prior art with Cote has the same needle exposures presented by Stafford.

Q. What did you mean by "one small advantage" in that last answer?

MR. HANSEN: Objection as to form.

A. It's a small advantage because the combination that Dr. Fletcher talks about with Stafford and Cote, he chooses an embodiment of Cote that is a manual insertion of a needle. So you still have that same anxiety, so the only small advantage would be is potentially not seeing the needle but then you lose all of the other advantages of

Stafford, such as the low profile, low cost, less waste, and everything else taught by Stafford, when specifically Stafford teaches away from those other types of separate inserters.

Q. So is it your opinion that factors such as cost and waste would outweigh other factors, such as user convenience?

MR. HANSEN: Objection as to form.

A. I don't know what you mean by "user convenience." But cost is a big factor for users. It's almost on the news weekly about cost of medical supplies and devices, so that they're affordable for millions of people to use them.

BY MR. MASON:

Q. And accepting that cost -- or understanding that cost -- your opinion is that cost is a concern, is it your opinion that cost would outweigh other factors in the design of a CGM device?

MR. HANSEN: Objection as to form, scope.

A. I don't know what you mean by

"other factors."
BY MR. MASON:
Q. Let's start with user convenience.
Is it your opinion that cost would outweigh user convenience in design of a CGM device?
MR. HANSEN: Objection as to form, scope.
A. I don't know what you mean by "user convenience." If you're talking about just being able to see or not see a needle --
MR. HANSEN: The PTAB is calling us.
MR. MASON: We can go off the record momentarily and maybe you want to step out, Mr. Leinsing.
(Recess taken at 11:04 a.m. for conference call with the Patent And Trademark Appeals.)
(Transcript of conference call with the Patent And Trademark Appeals under separate transcript.)

MR. MASON: We can go back on the record.

BY MR. MASON:

Q. Are you ready to resume your deposition, Mr. Leinsing? 11:44 AM

A. I was ready 20 minutes ago.

Q. And while we were on break, did you have any communications with counsel about the substance of your testimony?

A. No, I did not. 11:45 AM

Q. Did you have any communications with counsel about your declaration in this matter?

A. No, I did not.

Q. So do you recall prior to our break -- and thank you for your patience -- that we were discussing cost as one factor of CGM design? 11:45 AM

A. Yes, I remember us talking about that and other features. 11:45 AM

Q. And is your testimony that cost would you outweigh user convenience in the design of a CGM system?

MR. HANSEN: Objection, form,

asked and answered.

MR. MASON: That was more than one word, Leland.

MR. HANSEN: Two separate objections. One word for the first objection. Two words for the second one. Short, concise, not coaching, unlike your objections in many these depositions in these matters. 11:45 AM

BY MR. MASON: 11:46 AM

Q. Do you understand the question, Mr. Leinsing?

A. I totally forgot it now. If you could please repeat it.

Q. So the question is, is your testimony that cost would outweigh user convenience in the design of a CGM system? 11:46 AM

A. I did not do an analysis to weight each one of those, but there are many features, in particular talking about Stafford in the ones that are mentioned in that patent while still addressing the sharp that would not create any motivation to combine with Cote or that alone would meet 11:46 AM

the claims of the '591 patent.

Q. Is it your opinion that a separate sensor introducing device was undesirable?

A. If you're referring to Stafford in your question, Stafford did specifically address that a separate sensor introducing device would be undesirable because of the cost, the bulk of the materials, and the recycling of plastics that was recognized and which would also relate to cost, the low profile and other features that Stafford was teaching. He was teaching away from doing that, therefore no motivation to combine in and either alone or in combination do not meet the '591 patent claims. 11:47 AM 11:47 AM 11:48 AM

Q. Do the Libre devices that you opine on use a separate sensor introducing device as described by Stafford?

MR. HANSEN: Objection as to form.

A. Yes, they use a separate introducer device as claimed by the '519 patent as I outline in my Appendix B. 11:49 AM

BY MR. MASON:

Q. Is it your opinion that a POSA

would view the Stafford method of insertion is preferable to the separate sensor introducing device in the Libre devices that you opine on?

A. That's the prior art that Dr. Fletcher presented and Sanford -- Stafford -- sorry -- discusses the different options and weighs the cost of the separate introducer and presents a better concept, and I -- 11:49 AM 11:50 AM

Q. So is it your opinion that Stafford presents a better concept than was later used in the Libre device?

A. I did not do that analysis or do any kind of market study on which is better than the other, but Stafford addresses the concerns of having a separate one and teaches a way to reduce the cost; and based on all the complaints, I'm aware of a separate introducer with waste, as I mentioned with cost, it's even a current concern today, and likely might go full circle back to a Stafford-type design. 11:50 AM 11:50 AM

Q. I'm sorry. Do you have an opinion

on whether the Stafford method of insertion would be preferable to the method of insertion of the Libre devices described in your report?

MR. HANSEN: Objection as to form, scope. 11:51 AM

A. I don't have an opinion on that. That's not what I was asked to do in writing my declaration.

BY MR. MASON: 11:51 AM

Q. Do you have an opinion on whether the Stafford method of insertion would be preferable to spring-loaded automatically retracting methods of insertion?

MR. HANSEN: Objection as to form, scope. 11:51 AM

A. That's not the task I was asked to do. I was asked to look at what Dr. Fletcher had presented for prior art and whether or not that covered the claims of the '591 patent. That would be outside the scope of my analysis. 11:51 AM

BY MR. MASON:

Q. Do the Libre devices discussed in

your declaration integrate sensor introducer mechanism and data processing unit into a single assembly that does not need a separate inserter?

A. Say that again, slow, that was a long question. 11:52 AM

MR. HANSEN: Objection as to form.

BY MR. MASON:

Q. Do the Libre devices discussed in your deposition integrate a sensor introducer mechanism and data processing unit into a single assembly that does not need a separate inserter? 11:52 AM

MR. HANSEN: Objection as to form, compound. 11:53 AM

A. I can't answer that question. If you could break it up for me, that would make it easier.

BY MR. MASON:

Q. Can I invite you to paragraph 132 of your declaration? 11:53 AM

A. Okay.

Q. And in paragraph 132, do you see where and you have a block quoted passage?

A. Yes.

Q. And do you see how the beginning of the block quoted package begins, "Furthermore, by integrating the analyte sensor, the introducer as well as the data processing unit into a single assembly..." 11:53 AM

Do you see that?

A. Yes.

Q. So do the Libre devices that you discuss in your declaration integrate the analyte sensor, the introducer, as well as the date processing unit into a single assembly? 11:54 AM

A. Yes. And then in addition to other features as claimed by the '591 patent. 11:54 AM

Q. Do the Libre devices need a separate inserter?

MR. HANSEN: Objection as to form.

A. I didn't address whether or not they need one. They have a separate inserter and embody the claims of the '591 patent, as I outlined in Appendix B. 11:54 AM

BY MR. MASON:

Q. So is it your opinion that those Libre devices use an insertion mechanism that is inferior to the Stafford thumbtack approach?

MR. HANSEN: Objection as to form, scope. 11:55 AM

A. I did not do an analysis of which design would be better than the other. Clearly Stafford made a decision and notes that a separate introducer like the Libre products would be more expensive and, you know, bulkier as a complete assembly for packaging and other issues that Stafford mentions. 11:55 AM

BY MR. MASON: 11:55 AM

Q. And do you have any opinions on why the designers of the Libre system used a bulkier design with more packaging as opposed to the simpler design of the Stafford system that you opined on? 11:55 AM

MR. HANSEN: Objection as to form, scope, speculation.

A. I don't agree with the phrasing of your question. You're making conclusions

about what Stafford is saying in the way you phrased your question.

BY MR. MASON:

Q. What conclusions do you disagree with? 11:56 AM

A. Well, you're saying that one would be simpler than the other. I didn't do that analysis between the two. The '591 patent clearly has claims of a specific device that became world changing. It was a device that 11:56 AM won an award over 50 years of medical devices. It's changed the lives of millions of millions of people. It's been a huge step in terms of control of those with diabetes.

It's a different device. It made 11:57 AM it, you know, less expensive than other devices that were on the market at the time, easy to use. Whether or not it's better than Stafford, that's not the analysis I did. Does Stafford cover the '591 patent and all 11:57 AM of its elements? No, either alone or in combination with any of the prior art that Dr. Fletcher brings forward.

Q. Is it your opinion that any awards

supposedly received by the commercial products that you discuss in your declaration were due entirely to the alleged invention claimed in the '591 patent?

MR. HANSEN: Objection as to form. 11:57 AM

A. I would not say entirely. I would say that they're associated to the claims of the '591 patent.

BY MR. MASON: 11:58 AM

Q. You if your answer is not entirely, then what else led to those awards?

MR. HANSEN: Objection as to form.

A. I didn't do that analysis. I just looked at the Libre products against the claims of the '591 patent and then the awards that were received, and those features of the claims are associated, at least partly contributable to that success. 11:58 AM

BY MR. MASON:

Q. What do you mean by "at least partly contributable to that success"?

A. Well, they're not entirely, so

they're at least partly contributable to that success. The '591 patent, based on the fact that Dr Fletcher specifically could not find any other prior art was world changing. It was a device that was not done before, was 11:59 AM
put into the Libre set of products. It changed the world for many people. They won awards for it. I think close to 10 awards. It was it was a long-felt need. It had never been satisfied before and the Libre -- and 11:59 AM
the success of the Libre products is proof of that.

MR. MASON: Object and move to strike everything -- as nonresponsive everything after contributable to that 11:59 AM
success.

BY MR. MASON:

Q. So my question to you can you identify anything --

MR. HANSEN: Objection to the 11:59 AM
colloquy.

BY MR. MASON:

Q. Can you identify anything today, Mr. Leinsing, in those Libre products

discussed in your report that led to your awards, aside from the alleged invention of the '591 patent?

MR. HANSEN: Objection as to form, scope.

12:00 PM

A. Can you repeat that, because you guys we're talking over each other and then you said your awards. They're not my awards.

BY MR. MASON:

Q. Do you recall mentioning awards with respect to the Libre devices discussed in your report?

12:00 PM

A. Yes, I talk about, I think, approximately ten awards.

BY MR. MASON:

12:00 PM

Q. And is it your testimony -- strike that.

Can you identify anything other than the alleged invention of the '591 patent that led to the those awards?

12:00 PM

MR. HANSEN: Objection, form, scope.

A. I did not do that analysis of all of the other things that would be

attributable to those awards and that success, but it's clear from my analysis in Appendix B that the Libre products map onto the claims of the '591 patent, and based on the fact that they're successful and that there wasn't anything in the prior art like it, as Dr. Fletcher found, that addresses the commercial success and the long-felt need and meeting that -- that need in the market. 12:01 PM

Q. So is it your testimony that you did not do any analysis as to whether the alleged success of the Libre products were due to something other than the alleged invention of the '591 patent? 12:01 PM

MR. HANSEN: Objection, characterization, form. 12:02 PM

A. I did a mapping, as shown in Appendix B of my declaration that shows that the products that were, in fact, the recipients of many awards were, in fact, covered by the claims of the '591 patent, that helps to show the nexus and satisfying the secondary considerations of nonobviousness in my analysis. 12:02 PM

BY MR. MASON:

Q. What do you mean by "nexus"?

A. That there's a connection between the claimed inventions and the success of the device. 12:02 PM

Q. All I'm trying to get at here is whether you think that any alleged success of the Libre products discussed in your declaration were fully attributable to the '591 patent or whether there were other 12:03 PM things that led to that success.

So with that in mind, my question is, is the alleged success of the Libre products discussed in your declaration fully attributable to the alleged invention of the 12:03 PM '591 patent?

MR. HANSEN: Objection, form, scope, compound, asked and answered.

A. I think I answered that question.

BY MR. MASON: 12:03 PM

Q. What was your answer?

A. Can you read back my answer?

Q. I don't think you answered that question, so I'll -- can you repeat my

question for him?

THE STENOGRAPHER: "All I'm trying to get at here is whether you think that any alleged success of the Libre products discussed in your declaration were fully attributable to the '591 patent or whether there were other things that led to that success.

"So with that in mind, my question is, is the alleged success of the Libre products discussed in your declaration fully attributable to the alleged invention of the '591 patent?" 12:02 PM 12:03 PM

A. I would refer to the answer previously, which I had said is not fully. I think the '591 is largely contribute contributable to those are awards, as I mapped out in Appendix B, and as I explain in my declaration, the association of the claimed invention of the '591 to those awards. 12:04 PM 12:04 PM

BY MR. MASON:

Q. And is it your testimony that, sitting here today you cannot identify any

other factors that contributed to the alleged success of these Libre products in your declaration?

A. It's my understanding -- that's not my task, that's not my job to do that. 12:05 PM
If Dr. Fletcher wants to point to something else that he thinks was the cause of those awards, then I can address those as he brings forwards, but he has not done so. But it's clear that the device was a world-changing 12:05 PM
device. It won many awards.

And even if he's to dispute one, there's ten different awards that this device looked at. I've won similar awards in my medical devices, and I didn't even receive 12:05 PM
ten on some of my awards. I only received one or two in that group. So it's pretty significant to show nonobviousness of the '591 patent.

Q. So you agree that you cannot think 12:05 PM
of any other factors that contributed to the alleged success of these Libre products?

MR. HANSEN: Objection, form, asked and answered.

BY MR. MASON:

Q. Is that correct?

A. I did not do that analysis, and I'm not going to speculate to what the other contributing factors might be for those awards. But, as I said, it's at least partly, if not largely, to the '591 claims as I mapped out in Appendix B, and as I discuss in my declaration. 12:06 PM

Q. Could I invite you to paragraph 139 of your declaration? 12:06 PM

A. Okay.

Q. Are you there?

And in paragraph 139, do you discuss needle guards? 12:07 PM

A. Yes, that's correct.

Q. Is it your opinion that a needle guard was an effective way to prevent needle sticks?

MR. HANSEN: Objection as to form. 12:07 PM

A. Yes, that's one way to prevent needle sticks.

BY MR. MASON:

Q. Were there other ways to prevent needle sticks known to POSAs?
A. Yes.
Q. What were those other ways?
A. Well, there's all kinds of different ways. What I found interesting was that even with all those other ways present and that Dr. Fletcher reviewed, he picks ones that are only chosen because of the alignment with the patent claims and not ones that would -- that would be more automatic, for example. 12:08 PM
MR. MASON: Object and move to strike as nonresponsive.
BY MR. MASON: 12:08 PM
Q. My question is, what were those other ways that you indicated that were effective ways to prevent needle sticks?
MR. HANSEN: Objection, asked and answered, argumentative, colloquy. 12:08 PM
A. So, for example, Dr. Fletcher was looking at Stafford for saying it wasn't sufficient and there's motivation to look for other ways to protect the needle better than

what Stafford has, and instead of choosing something fully automatic or an embodiment that was fully automatic, say in Cote, for example, he chooses one that was cherry-picked to try to map it with the claims of the patent. 12:09 PM

So if it was such an issue to change it, even though Stafford clearly states it's aware of other solutions to protect the needle, and it chooses not to do it because of cost and other reasons, Dr. Fletcher still chooses other solutions that he feels are aligned with the claims, which they end up not being aligned with the claims anyway. So that's just more evidence that Stafford was, in fact, sufficient to protect the needle, and that there's no need to combine it with any other reference, there's no motivation to do that. 12:09 PM

Q. Is it your opinion that a POSA implementing a CGM system would not seek out improved ways to avoid needle sticks? 12:10 PM

MR. HANSEN: Objection, scope, form.

A. Stafford already is aware of those other introducers that are known to a person of skill in the art and purposely and teaches away from those other means in order to reduce the profile and improve the cost of its device. There's no motivation to combine Cote with Stafford for that reason. 12:10 PM

BY MR. MASON:

Q. And my question is, as a skilled artisan -- do you understand the term "a skilled artisan"? 12:10 PM

A. I think so. If you want to explain your understanding so it's not --

Q. We'll use your words.

My question is would a POSA implementing a CGM system not seek out improved ways to avoid needle sticks? 12:10 PM

MR. HANSEN: Objection, asked and answered, Form.

A. A POSA would not seek out other ways to improve it if they're not motivated to do. 12:11 PM

THE STENOGRAPHER: Seek out other ways to?

THE WITNESS: To improve needle protection, specifically when Stafford already addresses those other ways and teaches against those other ways for the reasons that Stafford mentions. 12:11 PM

BY MR. MASON:

Q. Is it your opinion that if a POSA has an accepted design for a given problem, then they would not be motivated to improve that particular feature? 12:12 PM

MR. HANSEN: Objection, form, scope.

A. They would not be motivated to do that when you look at all of the other benefits that Stafford teaches with 12:12 PM eliminating those other parts or other needle protection means because of cost, bulkiness, and other reasons that Stafford mentions.

BY MR. MASON:

Q. And I'm not limiting this to 12:12 PM Stafford.

So my question is, without regard to stafford is it your opinion that if a POSA has an accepted design, then she would not be

motivated to improve it?

MR. HANSEN: Objection, scope, asked and answered.

A. That would be outside the scope of my analysis. I was presented with prior art that Dr. Fletcher felt was best to cover the claims of the '591 patent, and specifically with Stafford and Cote, there's no motivation to take Stafford and combine or cherry pick with Cote for something that Stafford explicitly says that they're aware of and teaching away from for the reasons Stafford mentions. 12:13 PM

BY MR. MASON:

Q. Was a POSA aware of CGM systems on the market in 2009 and earlier? 12:13 PM

MR. HANSEN: Objection, scope, form.

A. The hypothetical person of skill in the art would know what was on the market and would be technically all-knowing of patents and everything else that's out there. 12:14 PM

BY MR. MASON:

Q. Would a POSA know about the Abbott

Navigator system that you mentioned earlier?

MR. HANSEN: Objection, form, scope.

A. I did not do that analysis, and I would withdraw my previous answer on the Navigator as I don't know the dates of the Navigator patents and when they actually came forward, and I may have misspoke in my earlier answer. 12:14 PM

All I did was analyze the prior art patents and information that Dr. Fletcher presented and whether or not those prior art, either in combination with one or two or knowledge of a person of skill in the art, covered the claims of the '591 patent, and I concluded that they do not for the reasons mentioned in my declaration. 12:14 PM 12:15 PM

Q. So is it your testimony today that you don't know if the Abbott Navigator system was on the market in 2008? 12:15 PM

A. I'm not a hundred percent sure of that, standing here today, no.

Q. If the Abbott Navigator system was on the market in 2008, would a POSA have

known about it?

MR. HANSEN: Objection, form, scope.

A. They would have known about that, but that was not a piece of prior art that Dr. Fletcher brought forward and was not something that I analyzed to be able to answer your questions today regarding the Navigator. 12:15 PM

BY MR. MASON: 12:16 PM

Q. Do you recall discussing insertion of CGM sensors using a needle or sharp?

MR. HANSEN: Objection, form.

A. I don't recall. I think you need to be more specific or ask a different question. 12:16 PM

BY MR. MASON:

Q. Would a POSA have known that any needle used to insert a sensor would become contaminated with biological fluids? 12:16 PM

MR. HANSEN: Objection, scope, form.

A. I think a POSA at the time of 2009 would know that a needle inserted into a

human would have biological contaminated fluids on it.

BY MR. MASON:

Q. Would a POSA know that CGM sensors would sometimes be inserted into a patient by a caregiver? 12:17 PM

MR. HANSEN: Objection, form, scope.

A. Yes, they would know that that would be one possibility. 12:17 PM

BY MR. MASON:

Q. And would a POSA know that there were regulations that related to handling a needle that had contacted biological fluid?

MR. HANSEN: Objection, form, 12:18 PM scope.

A. Yes, a person of skill in the art would know that, and Stafford addressed that their way and would also know that the diabetic patients were used to handling 12:18 PM needles with sharps, containers and other ways of disposing them properly and safely.

BY MR. MASON:

Q. Did you consider those regulations

in forming your positions related to Stafford and the acceptability of its needle guard approach?

MR. HANSEN: Objection, form.

A. Yeah, I don't understand your question. 12:19 PM

BY MR. MASON:

Q. Did you consider the regulations that you just testified about in forming your opinions related to the acceptability of Stafford's needle guard? 12:19 PM

A. What regulations are you asking about?

Q. My question previously is, would a POSA know that there were regulations that related to handling a needle that had contacted a biological fluid, and you responded yes. 12:20 PM

And so I'm just wondering -- my question is, did you consider regulations related to handling a needle that had contacted biological fluids in forming your opinions regarding Stafford's needle guard? 12:20 PM

MR. HANSEN: Observation, form,

characterization.

A. Yes. And Stafford has an acceptable form of needle protection putting a cover over a needle, which is still done today in hospitals or other caregiver environments where the needle is covered and then disposed in a sharp's container. 12:20 PM

BY MR. MASON:

Q. Okay. So your answer is that you did consider those regulations related to needle disposal? 12:20 PM

MR. HANSEN: Objection, form, asked and answered.

BY MR. MASON:

Q. Correct? 12:20 PM

A. I did not review those regulations specifically in writing my declaration. I just know, as a person of skill in the art and putting myself in 2009, that those were -- that that was known and that Stafford, as it clearly explains with a protective guard or cover on its needle, would be the same as covering a needle on a syringe or other sharp, and then you would 12:21 PM

dispose in a container, just as you would even the '591 patent requires the same type of care and disposal.

Q. To your knowledge, was the Stafford insertion mechanism ever commercialized? 12:21 PM

A. I did not do that research or determine if it was or not.

Q. Is it fair to say that an automatic inserter like that discussed -- strike that. 12:22 PM

Is it fair to say that an automatic inserter, like that in the Libre products discussed in your declaration, had different features and benefits from Stafford's proposed insertion technique? 12:22 PM

MR. HANSEN: Objection, form, compound.

A. That's a long question. If you can break that up, and I didn't agree with some of the statements in your question. 12:22 PM

BY MR. MASON:

Q. All right. What did you disagree with?

A. Well, it's kind of long, so I can't repeat off my memory everything that was there. But you were just making lots of statements in your question.

Q. Would you characterize the Libre products discussed in your declaration as having an automatic inserter? 12:22 PM

MR. HANSEN: Objection, form, scope.

A. I would call it a semi-automatic inserter. 12:23 PM

BY MR. MASON:

Q. What do you mean by semi-automatic?

A. Meaning that the Libre products used a threshold-type force system that uses the force of the user to insert the needle and then automatically retract the needle with the spring. So therefore I consider it a semi-automatic system. 12:23 PM 12:23 PM

Q. And just so I understand, do you refer to it as semi-automatic because the manual forces use for insertion but it's a spring or some other automatic mechanism

that's used to then retract the needle from the user; is that correct?

MR. HANSEN: Objection, asked and answered, characterization, form.

A. Can you repeat that? 12:24 PM

MR. MASON: Sandy, can you repeat that?

THE STENOGRAPHER: "And just so I understand, do you refer to it as semi-automatic because the manual forces 12:23 PM use for insertion but it's a spring or some other automatic mechanism that's used to then retract the needle from the user; is that correct?"

A. It's too difficult to answer that 12:25 PM question. There's too much bundled in that question. That's not the analysis that I was doing. The only thing I analyzed between the Libre was the Libre product against the claims of the '591 patent, and then any 12:25 PM secondary considerations of nonobviousness against it did not opine on any kind of, you know, specific operation of it, other than what is claimed in the '591.

BY MR. MASON:

Q. Did the semi-automatic inserter of those Libre products have benefits over Stafford's proposed insertion technique?

MR. HANSEN: Objection, form, scope. 12:26 PM

A. It had all the benefits as outlined by '591 patent and as claimed by the '591 patent.

BY MR. MASON: 12:26 PM

Q. And I'm just talking about the automatic inserter of the Libre product.

So would a POSA recognize any benefits of those Libre products over Stafford's proposed insertion technique? 12:26 PM

A. The '591 patents are not limited to whether it's semi-automatic or automatic. So that's not relevant to my analysis.

Q. Oh, and I'm not asking about the '591 patent here, Mr. Leinsing. I'm just asking, would a POSA recognize any benefits of the Libre products discussed in your declaration over the proposed insertion technique of Stafford? 12:26 PM

MR. HANSEN: Objection, scope, form.

A. Asked and answered.

The '591 patent claims are all of the benefits over Stafford. Stafford does not show or demonstrate or describe all of the claimed or elements -- elements or claimed features of the '591, so therefore all of what's claimed in the '591 is in the free-style Libre products, and as a result of all of those elements being in the free-style Libre products resulted, in a world-changing device that won many awards. 12:27 PM 12:27 PM

BY MR. MASON:

Q. Setting aside the '591 patent, would a POSA recognize any benefits of semi-automatic sensor insertion over the proposed insertion technique of Stafford? 12:28 PM

MR. HANSEN: Objection, form, asked and answered. 12:28 PM

A. Since the claims of the '591 patent are not limited to whether it's automatic or manual insertion, I did not do that analysis. I just overlaid the claims of

the '591 patent and determined whether or not the Libre family of products, as described in Appendix B, cover those claims and then looked at the success of the Libre product.

So the '591 is different, is found in the Libre products, and at least at the time of this invention and the time those products were released, it had features that were better than the Stafford -- the Stafford teachings. 12:28 PM 12:29 PM

Q. So is it true that you have no opinion as to whether a POSITA would recognize the benefits of semi-automatic sensor insertion over the proposed insertion technique of Stafford? 12:29 PM

MR. HANSEN: Objection, form, asked and answered, argumentative.

A. I think I've answered that question. Stafford is a different product from the Libre products, and the Libre products are successful for the -- for the reasons I mentioned earlier and for the claimed inventions of the '591 patent. 12:29 PM

BY MR. MASON:

Q. And I'm not asking about the Libre products or the '591 patent.

My question is, would a POSA recognize any benefits of semi-automatic sensor insertion over the sensor insertion technique of Stafford? 12:30 PM

MR. HANSEN: Andy, since you stated you're not asking about Libre, you're not asking about '591, could you please -- 12:30 PM

MR. MASON: Leland, this is a speaking objection.

MR. HANSEN: Then we --

MR. MASON: If you want to go off the record, we can discuss it, but there's a question pending and the witness needs to answer the question unless you're -- 12:30 PM

MR. HANSEN: We can go off the record because it is clear to me that you're trying to -- 12:30 PM

MR. MASON: Leland, you're --

MR. HANSEN: -- take discovery for a different matter.

MR. MASON: This has nothing -- this has everything to do with this matter.

MR. HANSEN: It has nothing to do with this matter. 12:31 PM

BY MR. MASON:

Q. Mr. Hansen, can you answer the question, please?

MR. HANSEN: Objection as to form, asked and answered. 12:31 PM

THE WITNESS: My last name is Leinsing.

BY MR. MASON:

Q. I apologize for mispronouncing it up to now. Thank you for correcting me. 12:31 PM

A. No, you said it right. But you said Mr. Hansen, will you answer the question?

Q. Okay. Sorry. Yeah.

A. So do you want him to answer it or do you want me to answer it? 12:31 PM

Q. Oh, no, I want you to answer it.

A. Oh, you said, "Mr. Hansen, can you answer the question?"

MR. HANSEN: Same objections.

A. Can you repeat the question?

BY MR. MASON:

Q. Yeah. So my question is -- every question I've asked is -- you brought it back to the '591 patent and Libre products, but I'm just asking for a POSITA, would a POSA -- strike that. 12:31 PM

My question is, would a POSA recognize any benefits of a semi-automatic sensor insertion device over the proposed insertion method of Stafford? 12:31 PM

MR. HANSEN: Objection, form, asked and answered.

A. So my task was to review the prior art that Dr. Fletcher put forward. He did not identify which ones he would think are semi-automatic or automatic or identify that term. If you're referring to Cote, and asking -- and whether they would choose Cote and put that on to Stafford, we've talked about that, and there's no motivation to modify Stafford to add features of Cote and then even if you did, Cote still does not 12:32 PM 12:32 PM

satisfy the elements of the claim or therefore the entire claims of the '591 patent.

BY MR. MASON:

Q. In your opinion, does Cote describe a semi-automatic sensor insertion process? 12:32 PM

MR. HANSEN: Objection, form, scope.

A. Not in the way I describe the Libre products, no. It -- 12:33 PM

BY MR. MASON:

Q. How does the Cote insertion process differ from the Libre products?

A. Significantly. First, it's a manual insertion with a spring retraction. It has a sleeve that pulls away from the user prior to retraction of the needle and other things. But those are the major differences. 12:33 PM

Q. Would a POSA recognize any benefits to Cote's spring retraction over the manual extraction described in Stafford? 12:33 PM

MR. HANSEN: Objection, form, scope.

A. No, because Cote has the features that Stafford explicitly teaches away from. Cote also has a system that doesn't allow for the needle to remain stable during insertion and retraction as the claims of the '591 require. 12:34 PM

BY MR. MASON:

Q. So is it your testimony that a POSA would see no benefits in Cote's insertion -- strike that. 12:34 PM

Is it your testimony that a POSA would see no benefits to Cote's insertion process over the insertion process described in Stafford?

MR. HANSEN: Objection, form, asked and answered. 12:35 PM

A. Cote has features that Stafford clearly teaches away from doing. Stafford already has a solution to a problem and then Cote's device itself would not address what is known in the prior art, meaning to do an accurate and stable insertion of the sensor and then removal of the needle, such that you don't damage the sensor and you place it 12:35 PM

properly so that it's accurate and reliable, keeping in mind the device has to work for millions of millions patients and work every time.

Cote pulls away a sleeve prior to retraction of the needle and that would be really bad for a sensor insertion device. There is no benefits of Cote, as described by Dr. Fletcher. 12:35 PM

Q. So is it your testimony then, that there are no benefits in Cote over the insertion process of Stafford? 12:36 PM

MR. HANSEN: Objection, form, asked and answered.

A. There are no benefits that outweigh everything that Stafford teaches. 12:36 PM

BY MR. MASON:

Q. But there are some benefits. Is that your testimony?

MR. HANSEN: Objection, form, asked and answered. 12:36 PM

A. There's no benefits with Cote, as I said in my previous answers. It tries to solve a problem that's already solved in

Stafford, but then creates other problems that Stafford teaches away from and that a person skilled in the art wouldn't be motivated to use Kote because it creates more issues than it solves. 12:37 PM

BY MR. MASON:

Q. Yeah, and my only -- it seems like your answers have been sort of perhaps inconsistent, so I just want to clarify.

MR. HANSEN: Objection, objection. 12:37 PM

No. No. No. No.

MR. MASON: Mr. Hansen.

MR. HANSEN: No. We're going to go off the record before you ask your question. 12:37 PM

MR. MASON: Are you instructing the witness not to answer?

MR. HANSEN: No. We're going to go board.

MR. MASON: We're not going off record. 12:37 PM

MR. HANSEN: No, we're going off -- no, you haven't ask a question. We're going to go to the board right

now.

MR. MASON: Okay. You can go to the board right now.

MR. HANSEN: Okay. Go out.

(Recess taken at 12:37 p.m. to 1:22 p.m.) 01:22 PM

BY MR. MASON:

Q. Are you ready to resume your deposition, Mr. Leinsing?

A. Yes.

Q. Great. While we were on break did you discuss the substance of your testimony with counsel? 01:22 PM

A. No.

Q. Did you discuss your declaration or its substance with counsel while we were on break? 01:22 PM

A. No.

Q. Can I invite you to paragraph -- strike that.

Yeah, in your declaration, you note that Cote is described as an inserter for cannula-type devices; is that correct? 01:22 PM

A. It can -- repeat that, please.

Q. Yeah. In your declaration, do you

know that Cote -- strike that.

In your declaration, you characterize Cote as describing an inserter for cannula-type devices.

A. Yes, a cannula or infusion set-type device, yes. 01:23 PM

Q. And is it your testimony that a POSA would not know how to adapt a cannula inserter to insert a CGM sensor?

MR. HANSEN: Objection, form. 01:23 PM

A. Yes, absolutely. A sensor -- a glucose sensor in particular are very fragile and inserting a -- as I say in my declaration, inserting a catheter or cannula is much different than inserting a fragile electronic sensor, and if it was obvious to do that, it would have been done a long time ago. 01:23 PM

BY MR. MASON:

Q. So is it your testimony that no one has ever adapted a design for a cannula inserter for use in insertion of a CGM sensor? 01:24 PM

A. I didn't do that particular

analysis. I know that there's some references that casually mention that, but there are clearly, and not the references we looked at particularly in this case or the prior art, but it's very different, as I mention in my declaration, to insert a sensor compared to a catheter or cannula. 01:24 PM

Q. Would a POSITA know -- strike that.

Would a POSA know how to adapt a CGM sensor inserter for insertion of a cannula device? 01:24 PM

A. If you are asking the reverse, if you could go from a CGM inserter to a catheter or cannula device, that would be more likely than the reverse, for all the reasons I mention in my declaration. 01:25 PM

Q. And indeed in Column 14, does the '591 patent itself say that its inserter can be used interchangeably for a cannula or a sensor? 01:25 PM

A. Which line was it in Column 14?

Q. Column 14, line 57.

A. Yes, it would take some changing,

obviously, but it would be more likely that you would be able to do that than the reverse, I think as demonstrated by I think the history of devices and the prior art as described or presented by Dr. Fletcher. 01:26 PM

Q. Other than sensor sensitivity, can you identify any other issues that, in your opinion, would prevent a POSA from adapting a cannula-type inserter for use with CGM sensors? 01:26 PM

MR. HANSEN: Objection, form, omnibus.

THE WITNESS: What does that mean?

BY MR. MASON:

Q. We don't need to discuss what that means. 01:27 PM

A. Oh, okay.

In particular -- can you repeat the question? I'm sorry.

Q. Yeah. Other than -- 01:27 PM

MR. MASON: Can you repeat the question, Sandy? Sorry, the real-time is less than crystal.

THE STENOGRAPHER: "Other than

sensor sensitivity, can you identify any other issues that, in your opinion, would prevent a POSA from adapting a cannula-type inserter for use with CGM sensors?" 01:26 PM

Q. Other than sensor fragility, can you identify any other issues in your paper that would prevent a POSA from adapting a cannula-type inserter for use of CGM insertion? 01:27 PM

A. Yes. In Cote, for example, it's pulling away a sleeve before removing or retracting the needle, which is something you wouldn't want to do with placement of a sensor. 01:28 PM

BY MR. MASON:

Q. Are you referring to what you called the overtravel in Cote?

A. Yes, that's correct.

Q. And do you understand that manual force is what leads to the overtravel that you describe as happening in Cote? 01:28 PM

MR. HANSEN: Objection, form.

A. I don't agree with your

characterization of the way Cote operates or my understanding of it. But what is important is that the sleeve is pulled away from the skin prior to or before the needle is retracted, and that is why the Cote reference is not invalidating prior art to the '591 patent. 01:29 PM

BY MR. MASON:

Q. Do you have an opinion on whether the manual force applied by the user is what powers the overtravel in the Cote insertion device? 01:29 PM

MR. HANSEN: Objection, form, scope.

A. Again, I don't agree with your characterization of the operation of the Cote device in your question. Manual force starts the operation or steps of the Cote device, but then it talks about a overtravel, which I believe is -- comes from the spring, and then that overtravel is what triggers the retraction of the needle. 01:30 PM

So that removal of the distal end of the inserter occurs before needle

retraction. It's a necessary step of the device, which is not directly from manual. It's after the -- a manual operation, but it's not using force from the user.

BY MR. MASON: 01:31 PM

Q. Okay. So is it fair to say that your understanding of Cote is that the spring then is what is causing the overtravel that you describe in your declaration?

A. I don't want to speculate on the 01:31 PM operation. It's not really clear from Cote, but seeing as the direction of movement is opposite the direction of movement of the way the user places the inserter to the skin or towards the skin, it would only make sense, 01:31 PM to me, that more likely than not that it's the spring that would cause that overtravel or pulling away of the sleeve prior or before the retraction of the needle, which is why the device does not invalidate the claims of 01:32 PM the '591 patent.

Q. And for the aspects of Cote at issue here, do you understand that the user is pressing down on the insertion device

throughout the entire time of insertion and retraction?

A. That is my understanding, which is why I feel it's the spring that pulls back the sleeve prior to retraction of the needle, and it's the overtravel or retraction of the sleeve that triggers the needle to retract. So it's a necessary step before retracting the needle, therefore it does not invalidate the claims of the '591 patent. 01:32 PM 01:33 PM

Q. Is that because it's your opinion that the overtravel causes the distal end of the Cote inserter to move away from the skin?

A. That's correct.

Q. How is that possible when the user's hand is pressing down on the proximal end of the Cote inserter during the overtravel? 01:33 PM

THE STENOGRAPHER: Could you keep your voice up? 01:33 PM

A. That's a good question.

So if you look at the figures, in particular 81A to 81C of the Cote reference, Exhibit 1005, there's a -- I'll see if the

there's a number pointing to that component -- but there's a support -- I think it's 1120, that is around the infusion set hub and that is remaining up against that hub, as you can see during Figure 81C, the 01:34 PM
retraction of the sleeve is occurring, but the force is continuing to push the cannula, and keeping in mind that is for an infusion set, so it's holding that against the skin as the sleeve is being retracted or what's 01:34 PM
called overtraveled.

BY MR. MASON:

Q. And is it your opinion that in that instance the skin would lay flat in a completely planer position during that 01:34 PM
retraction of the outer edge of the distal portion of the inserter?

MR. HANSEN: Objection as to form.

A. That's the way the Cote reference 01:35 PM
depicts it. But we would know that the skin is not necessarily going to be perfectly flat, but what the Cote reference teaches is that there's a small amount of overtravel or

retraction, which must be sufficient in order to shear the adhesive, so it would need to be away from the skin in order for that to happen before it retracts the needle, which is why it doesn't cover the claims of the '591 patent. 01:35 PM

BY MR. MASON:

Q. So is it your testimony that during this overtravel process the skin would not deform and thus remain in contact with that peripheral portion of the distal portion of the inserter? 01:36 PM

MR. HANSEN: Objection, form.

A. That is not my testimony. It could deform; it could be flat. But Cote talks about it pulling away sufficient enough away from the skin, and I think -- and it mentions some distances, even if small, is away from -- in the direction away from the skin, such that the adhesive would shear, and that operation would be before the needle is retracted, therefore not being covered by the '591 claims. 01:36 PM 01:36 PM

BY MR. MASON:

Q. Where, Mr. Leinsing, does Cote discuss pulling away slightly from the skin?

A. Paragraph 0210.

Q. And is there any other disclosure in Cote that you believe describes the distal portion pulling away slightly from the skin? 01:38 PM

MR. HANSEN: Objection, form, omnibus.

A. Paragraph 0209 of the Cote reference, in conjunction with the described figures, as well as other parts of the spec -- or specification. 01:38 PM

BY MR. MASON:

Q. What are those other parts of the specification? 01:39 PM

A. If you want, I can read through each one of them, but the figures and reading the whole spec you can understand the, quote/unquote, "overtravel" anywhere it talks about the overtravel. But specifically paragraphs 0209 says, "As the housing 1110, the cylinder hub 1120, and needle hub 1130 are displaced further in the direction A, it is preferable that the needle hub 1130 is 01:39 PM

positioned so that a lower portion of the site 1800 travels slightly beyond the second end, 1442, of the sleeve, 1140, as shown in Figure 81C.

This, quote, "overtravel," unquote, assures that the adhesive portion 1160 is properly sheared away from the surface 1449 of the sleeve, 1140, and allows for coupling of the cite, 1800, to the adhesive portion 160," and this operation would be before the retraction of the needle, so it would not satisfy the claims of the '591 patent. 01:40 PM 01:40 PM

Q. Did you account for possible deformation of the skin in forming your opinions relating to Cote's overtravel? 01:40 PM

MR. HANSEN: Objection, form.

A. Yes.

BY MR. MASON:

Q. Did you perform any testing of the Cote-like device to confirm those opinions? 01:41 PM

A. No, I did not need to do that because Cote is teaching this step and a person of skill in the art reading this spec

would understand that you would need to pull away from the skin in order to do this step in the Cote reference.

A person of skill in the art can adjust the sizes or whatever is needed to achieve this step, and then regardless, this step is a required step in order for the needle to retract in the mechanism, as disclosed, which would make it not an invalidating piece of prior art to the '591 patent. 01:41 PM 01:42 PM

Q. Is it your understanding that in CGM devices that wirelessly transmit other units, that data is received from the analyte sensor before transmission to a receiving device? 01:42 PM

A. So it's my understanding that analog information, what I think you called data, is received from the sensor and then is converted to digital and then transmitted to another device or control unit. 01:42 PM

Q. And in order to transmit that digital data from the on-body unit to another device, would a POSA understand that the data

would have to be stored somewhere on the on-body unit?

A. No, and in particular the references that Dr. Fletcher discussed, particularly the reference Say, with a capital S, mentions that data storage would be optional, and as a person of skill in the art, I understand that you can take analog information, convert it to digital and transmit it without a data storage unit. 01:43 PM

Q. So your understanding is that transfer of digital data wirelessly from one device to another can occur without any type of storage; is that correct?

MR. HANSEN: Objection, scope, form. 01:44 PM

A. Sorry -- I don't -- I don't agree with your particular characterization of data or data storage. It talks about a data storage unit. You're talking about any data. I'm not sure what you mean by your question. But the Say reference that was brought forward by Dr. Fletcher says that it's an optional feature that can be added to such 01:44 PM

devices indicating clearly that CGMs do not require data storage unit.

BY MR. MASON:

Q. And what do you understand the term "data storage unit" to mean in the context of '591 patent? Strike that. 01:44 PM

What would a POSA understand the term "data storage unit" to mean in the context of a '591 patent?

MR. HANSEN: Objection, form, scope. 01:44 PM

A. I take the plain and ordinary meaning to a person of skill in the art. It's a unit that stores data.

BY MR. MASON: 01:45 PM

Q. Could that be any type of data?

MR. HANSEN: Objection, form scope.

A. The specification is not limiting to any specific type of data. 01:45 PM

BY MR. MASON:

Q. Is the specification limiting as to any particular type of unit?

MR. HANSEN: Objection, form,

scope.

A. No.

BY MR. MASON:

Q. Is it your opinion that a device can wirelessly transmit digital data to another device without buffering that dedicate in memory? 01:46 PM

MR. HANSEN: Objection, form, scope.

A. Can you please repeat your question? 01:48 PM

BY MR. MASON:

Q. Is it your opinion that a device can wireless transmit digital data to another device without buffering that data in memory? 01:48 PM

A. Yes, that's my understanding, and Say talks about the data storage unit being optional.

Q. What portion of Say are you relying on? 01:49 PM

A. It's in my declaration.

Q. While you're looking at that, so I understand, is it -- I'm going to withdraw that question.

Is it your recollection then that Say describes a data storage unit as an option?

THE STENOGRAPHER: Counsel, keep your voice up, please. 01:50 PM

MR. MASON: Did you get that?

THE STENOGRAPHER: Yeah. I'm struggling to hear every word.

A. Yes, and if you give me time to look for it, Say does say it. I actually 01:50 PM confirmed this even last night. That it says there's optional features and data storage unit was specifically mentioned in Say as being optional, and that's in my declaration somewhere around page 125 and onward. 01:51 PM

BY MR. MASON:

Q. Is the term "sensor hub," as used in the Claims 15 and 28 of the '591 patent, a term of art, in your opinion?

MR. HANSEN: Objection form. 01:52 PM

A. I did not do that analysis for my work on analyzing Dr. Fletcher's prior art. I took the plain and ordinary meaning of all the terms and not determine whether any such

term was a term of art.
BY MR. MASON:
Q. Are you aware of any particular meaning in the art for the phrase, quote, "sensor hub," end quote? 01:52 PM
MR. HANSEN: Objection, form, asked and answered.
A. I did not do an analysis to determine whether any of the terms in the claims or in the prior art were terms of art. 01:52 PM
It's outside of the scope of my assignment.
BY MR. MASON:
Q. Does the '591 patent define the term "sensor hub"?
A. The '591 patent does not act as 01:54 PM
its own lexicography to expressly define sensor hub. It only points to a sensor hub in 123 of the '591 patent and a person of skill in the art looking at that term would understand the plain and ordinary meaning as 01:54 PM
understood by a person of skill in the art in view of the specification.
Q. Can I invite you to paragraph 321 of your declaration, Mr. Leinsing?

A. Okay.

Q. Is it -- and you see there where you opine that "Dr. Fletcher appears to assert that the claimed sensor hub is a 'separate support structure' used to hold, support and/or guide the sensor...into the correct position"? 01:55 PM

A. Yes, I see that.

Q. Yeah. And do you agree that a sensor hub -- or strike that. 01:55 PM

Is it your opinion that a sensor hub is a structure for holding or supporting an analyte sensor?

A. So yes, as I state here and in my declaration, I read Dr. Fletcher's understanding of sensor hub, and for the purpose of my analysis I adopted his understanding of the term, just for the purposes of this declaration. 01:55 PM

Q. And do you agree with that understanding of sensor hub? 01:56 PM

A. I agree with it only for the purposes of this analysis of the '591 patent in view of the prior art that Dr. Fletcher

brought forward.

Q. So is it fair then that -- for purposes of this IPR, you offer no opinions on the meaning of the term "sensor hub"?

A. No, I do not offer my own opinion on the meaning of "sensor hub." I merely adapt his for the purposes of this analysis and this IPR only. 01:56 PM

Q. Can I invite you to paragraph 406 of your declaration? 01:57 PM

A. Okay.

Q. Do you opine in paragraph 406 that "None of the prior art described a complete solution to these problems as discussed above"? 01:57 PM

MR. HANSEN: Objection, form.

A. Yeah, I just read the paragraph. What was your question again?

BY MR. MASON:

Q. Do you opine that, quote, "None of the prior art described a complete solution to these problems as discussed above," end quote? The very end of the paragraph 406. 01:58 PM

A. Yes, that's correct, and I discuss

that earlier.

Q. And what aspects of these problems did Stafford supposedly not solve?

A. All of the claims and claim elements of the '591 patent that I mention in my declaration. 01:58 PM

Q. Did Stafford describe an easy-to-use insertion assembly?

MR. HANSEN: Objection to form.

A. The hypothetical person of skill in the art at the time of Stafford, that's what Stafford felt was an easy-to-use device that was cost-effective but did not think of all of the combination of elements and claims as the '591 patent. 01:59 PM

BY MR. MASON:

Q. Is it your opinion that a POSA would view Stafford as easy to use?

MR. HANSEN: Objection, form, asked and answered. 01:59 PM

A. At the time of the Stafford patent and that hypothetical person of skill in the art, it would be easy to use as that invention describes but is not easy to use

with all of the other features of the '591 patent to claims -- in claim elements.

Q. And would a POSA view Stafford as reliable for insertion of a CGM sensor?

MR. HANSEN: Objection as to form. 02:00 PM

A. Stafford would view it as reliable as a person of skill in the art in that time would know, but it would not be re- -- it would be reliable but would not have all of the features as claimed in the '591 patent 02:00 PM while being reliable.

BY MR. MASON:

Q. Setting aside the '591 patent, would a POSA recognize any shortcomings in Stafford? 02:01 PM

MR. HANSEN: Objection, form, scope.

A. Being that a hypothetical person of skill in the art in the time frame of the Stafford patent, they would think that was a 02:01 PM viable solution at that time, but it's hard to say. It's outside the scope of the '591 patent because that's what this IPR is about. It would be lacking, again, those claim

features that would also be very reliable and have other features and benefits that are -- are desirable for a CGM device.

BY MR. MASON:

Q. I'll ask a slightly different question just to make sure it's clear. 02:01 PM

Without looking at the '591 patent, would a POSA recognize any shortcomings in Stafford?

MR. HANSEN: Objection, asked and answered, form, scope. 02:02 PM

A. Again, that hypothetical person of skill in the art looking at Stafford where Stafford even considers multiple different features that could be added to his invention would see that invention as easy to use, simple and reliable. But, again, it wouldn't meet the '591 claims. 02:02 PM

BY MR. MASON:

Q. So is it your opinion, then, that a POSA would not recognize any shortcomings in Stafford without consulting the '591 patent? 02:02 PM

A. It's not about the '591 patent

showing that it has shortcomings. The '591 patent has features that the Stafford invention, either alone or in combination with any of the reference that Dr. Fletcher brought forward, would have. 02:03 PM

Q. And you recall earlier today our discussion about the Abbott Navigator?

A. Yes.

Q. Okay. Did the Abbott Navigator allow one-handed operation? 02:03 PM

MR. HANSEN: Objection, scope, form.

BY MR. MASON:

Q. You may answer.

A. I can't answer any questions. I told you I withdraw all my questions with the Navigator. I don't have the patents in front of me to look at dates. I don't have a Navigator in front of me. I wasn't asked to analyze the Navigator. Dr. Fletcher did not identify the Navigator. It's outside the scope of my report and cannot answer any further questions regarding the Navigator. 02:03 PM

Q. So is it your testimony here today

that you have no knowledge of the Abbott Navigator system?

MR. HANSEN: Objection, argumentative, scope, form.

A. I know the Navigator was an initial product of Abbott and that's all I can recall, and it's outside the scope of my declaration, and I'm not prepared to answer any further questions, other than I know it was a CGM product of Abbott that they sold some time in the past, and I don't recall the dates. 02:04 PM

BY MR. MASON:

Q. Do you recall if the Abbott Navigator allowed one-handed operation? 02:04 PM

MR. HANSEN: Objection, form, scope, asked and answered.

BY MR. MASON:

Q. All I'm asking is do you recall whether it did or not? 02:04 PM

A. You already asked me that, and I cannot answer any further questions on the Abbott Navigator.

Q. And am I that you cannot answer

because you do not know? Is that your testimony?

A. I do not know for sure to be able to answer your questions accurately. I didn't prepare for this deposition and refresh my memory of the operation of the Abbott Navigator device. 02:05 PM

Q. So at one time you did have knowledge of the operation of the Abbott Navigator device? 02:05 PM

MR. HANSEN: Objection, scope, form.

BY MR. MASON:

Q. Is that correct?

A. Again, I don't know for sure. 02:05 PM I've seen devices that look like the Abbott Navigator. I'm not sure if they were the Abbott Navigator. I need to go back and look at the pictures in my files to see if they were the Navigator and then refresh my memory 02:05 PM on the device in order to answer any further questions on the device.

Q. So do you know if the Abbott Navigator was spring powered?

MR. HANSEN: Objection, scope, form.

A. Again, if you want to present me with a patent that was -- describes the Navigator, you know, I can look at it, but I would need to analyze that patent; I would need to analyze the device and take some time to look at it carefully and then answer your questions. 02:06 PM

That was outside the scope of this declaration. Dr. Fletcher did not bring up the Navigator, I don't believe in any way, shape or form, so I did not refresh my memory on that device. 02:06 PM

Q. Would a -- do you know if a POSA would understand the state of the art for the CGM sensor inserters to include spring-powered inserters? 02:06 PM

MR. HANSEN: Objection, scope, form. 02:07 PM

A. If they existed, then it would be Dr. Fletcher to present those to me for analysis to review, and I don't recall that he's brought such device forward for

analysis.
BY MR. MASON:
Q. Did the state of the art to a POSA include inserters that automatically retracted the sharp into the inserter after the sensor was deployed. 02:07 PM
MR. HANSEN: Objection, scope, form.
A. Can you repeat your question, and if it's something Dr. Fletcher brought up, then if you could highlight that part of it declaration, then I would be happy to answer questions regarding that. 02:07 PM
BY MR. MASON:
Q. No. My questions are only as to your understanding of the knowledge of a POSA. 02:08 PM
And with that my question is, would a POSA understand the state of the art to include inserters that automatically retracted the sharp into the inserter after the sensor was deployed? 02:08 PM
A. Not that would meet all of the elements and claims of the '591 patent.

Q. But the state of the art would include automatically retracting inserters outside of that caveat; is that correct?

MR. HANSEN: Objection, form, scope, speculation. 02:08 PM

A. I can't recall sitting here. If you want to point to me a piece of prior art that might demonstrate that true or not, I cannot answer that off the top of my head. That would be something Dr. Fletcher would need to do in research and present that to me for analysis. 02:09 PM

BY MR. MASON:

Q. So, sitting here today, you are not certain whether the state of the art to a POSA would include inserters that automatically retracted the sharp into the inserter after the sensor was deployed; is that correct? 02:09 PM

MR. HANSEN: Objection, form, scope, asked and answered. 02:09 PM

A. To at least within the claims as discussed in the '591 patent, they did not exist, nor was it obvious to combine a

reference.
BY MR. MASON:
Q. Yeah. And setting aside all other -- strike that.
And setting aside any other aspect of the '591 patent claims, do you know whether a POSA would understand the state of the art to include inserters that automatically retracted the sharp into the inserter after the sensor was deployed? 02:09 PM 02:10 PM
MR. HANSEN: Objection, form, scope, asked and answered.
A. So you keep saying put the '591 patent aside, and all of my answers and all of Dr. Fletcher's analysis is related to the '591 patent, and what was found as prior art. And no, the '591 patent and the on-body unit with its included sensor or attached sensor was not in the prior art, either single or combined with other references. 02:10 PM 02:10 PM
BY MR. MASON:
Q. And just so I understand, are you saying that you cannot offer testimony on what a POSA knew without tying that to the

claims of the '591 patent?

MR. HANSEN: Objection, form, scope, argumentative.

A. The hypothetical person of skill in the art, at the time of the '591 patent, is to be of all knowing of patents in that area. It's then Dr. Fletcher's task to narrow that scope of prior art to what he feels is best fitting or that would best describe the '591 claims. He brought that forward. I analyzed that very carefully and determined that all of the prior art, with all the combinations and the lack of motivation, do not describe the '591 claims. I cannot give you answers to something -- of all of the entire prior art sitting here analysis Dr. Fletcher has presented that to me for time to analyze. 02:11 PM 02:11 PM

Q. And can you give me answers sitting here today about the knowledge of a POSA without Dr. Fletcher having presented that to you beforehand? 02:11 PM

A. Well, I can tell you that a person of skill in the art at the time of the '591

patent did not know how to put together each of the elements of the claims that come up with the claims of the '591 patent, and Dr. Fletcher could not either, as I demonstrated in my declaration of all the parts that are missing in the claims and his analysis. 02:12 PM

Q. Are you able to opine on the knowledge of a POSITA -- strike that.

Are you able to opine on the knowledge of a POSA without reference to the '591 patent claims? 02:12 PM

MR. HANSEN: Objection, scope, foreman, asked and answered.

A. Where I was able to do that, I've answered that question. Some of your questions are so broad in scope that I can't answer that fully without analysis and reviewing of lots of different patents. 02:12 PM

Dr. Fletcher had opportunity to look at many different patents and prior art and was not able to find something that could invalidate the claims of the '591 patent for all the reasons I describe in my declaration. 02:13 PM

BY MR. MASON:

Q. Did the state of the art -- strike that.

Would a POSA know that the state of the art included CGM sensor inserters that allowed one-handed operation? 02:13 PM

MR. HANSEN: Objection, scope, form.

A. Well, Dr. Fletcher brought forward Stafford, which was a one-handed operation device but was lacking many other features of the '591 patent. So he had to combine with other references; but, unfortunately, those references were still lacking elements of the '591 claimed invention. 02:13 PM 02:14 PM

BY MR. MASON:

Q. Would the POSA know that the state of the art included CGM sensor inserters that hid the sharp from the user's view?

MR. HANSEN: Objection, form, scope. 02:14 PM

A. I think Dr. Fletcher brought forward Brenneman as a very distant secondary reference that hid a spiral-shaped sharp but

Brenneman was lacking many of the other limitations of the claim, therefore was not invalidating prior art alone or in combination with the references he brought forward. 02:14 PM

MR. MASON: I have no further questions.

MR. HANSEN: All right. Let's take a short break, and we'll determine if we have any follow-up questions. 02:15 PM

(Recess taken at 2:15 p.m. to 2:26 p.m.)

MR. HANSEN: So we can go back on. I have no questions, so we can all go home.

THE STENOGRAPHER: Mr. Hansen, you're ordering a copy, correct? 02:26 PM

MR. HANSEN: Yes.

THE STENOGRAPHER: And do you want a rough?

MR. HANSEN: Yes. 02:26 PM

THE STENOGRAPHER: Mr. Mason, you're ordering the original and a rough, correct?

MR. MASON: Yes.

THE STENOGRAPHER: And final as soon as possible?

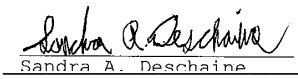
MR. MASON: Yes. Let's just say Monday.

(Deposition concluded at 2:28 p.m.) 11:44 AM

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

I, Sandra A. Deschaine, Registered Professional Reporter and Notary Public within and for the Commonwealth of Massachusetts at large, do hereby certify that the deposition of KARL R. LEINSING, MSME, PE, in the matter of Dexcom, Inc., vs. Abbott Diabetes Care Inc., at Kirkland & Ellis, LLP, Boston, Massachusetts, on October 17, 2024, taken and transcribed by me; that the witness provided satisfactory evidence of identification as prescribed by Executive Order 455 (03-13) issued by the Governor of the Commonwealth of Massachusetts; that the witness is hereby reading and signing, that the transcript produced by me is a true record of the proceedings to the best of my ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken, and further that I am not a relative or employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action, on this 23rd day of October 2024.



Sandra A. Deschaine

Registered Professional Reporter

My Commission Expires:
July 5, 2024