Trials@uspto.gov
571-272-7822

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2023-01251
Patent 11,298,056 B2

Record of Oral Hearing
Held: November 4, 2024

Before JEFFREY N. FREDMAN, RYAN H. FLAX, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

APPEARANCES:

ON BEHALF OF THE PETITIONER:

JOHN VANDENBERG, ESQUIRE
ANDREW MASON, ESQUIRE
Klarquist Sparkman, LLP
121 S.W. Salmon Street, Suite 1600
Portland, Oregon 97204
(503) 595-5300

ON BEHALF OF THE PATENT OWNER:

S. GIRI PATHMANABAN, ESQUIRE
LELAND HANSEN, ESQUIRE
MICHAEL CARROZZA, ESQUIRE
McAndrews, Held & Malloy, Ltd.
500 W. Madison Street, 34th Floor
Chicago, Illinois 60661
(312) 775-8000

The above-entitled matter came on for hearing on Monday, November 4, 2024, commencing at 10:00 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P R O C E E D I N G S

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JUDGE HARDMAN: Okay. Let's go on the record, please. Good morning, everybody. I am Judge Hardman, and this is Judge Flax and Judge Fredman. This is the final oral hearing in IPR2023-01251, *DexCom, Incorporated v. Abbott Diabetes Care, Incorporated*. The patent at issue is U.S. Patent Number 11,298,056 B2.

This hearing is open to the public. I believe we have a public line open. We have a court reporter present. That's Mr. Watson. The Board will issue a transcript in due course.

Okay. Let's start with appearances. Counsel for Petitioner?

MR. VANDENBERG: Good morning, Your Honor. John Vandenberg for Petitioner DexCom. And with me at counsel's table is Mr. Andy Mason, who's lead counsel.

JUDGE HARDMAN: Thank you, sir. Counsel for Patent Owner?

MR. PATHMANABAN: Good morning, Your Honors. Giri Pathmanaban for Patent Owner Abbott. And with me lead counsel Leland Hansen and Mike Carrozza.

JUDGE HARDMAN: Good morning, Counsel. As set forth in our hearing order, each side has 60 minutes to present their case. Petitioner begins with its arguments first and may reserve rebuttal time. Would you like to reserve any rebuttal time, sir?

MR. VANDENBERG: Yes, Your Honor. Twenty minutes for rebuttal, if we may.

JUDGE HARDMAN: And Counsel for Patent Owner, would you like to reserve rebuttal time?

MR. PATHMANABAN: Yes, Your Honor. There are 15 minutes. Thank you.

JUDGE HARDMAN: I'll just set the clock. As you know, the Panel has access to the entire record. So if you're referring to a paper or an exhibit or demonstrative, please let us know what you're referring to so that we can call it up on our side. If you're referring to the demonstratives here, also please let us know which demonstrative so that we have a clear record for Mr. Watson.

Now, our expectation is that counsel for the opposing party will not object during the other side's presentation. If you have any objections, please hold them for when it's your time to speak.

So with that, we have 40 minutes on the clock and you may begin.

MR. VANDENBERG: Thank you. May it please the Board, I'd like to start with a sort of 60-second summary of our grounds 1 and 2. The ground 1 monitor, which is a *Patel-2009-Paradigm* monitor, sometimes receives time-critical glucose information that is slightly delayed. It might be delayed 5 minutes, 10 minutes, up to 40 minutes. And at that point there's two options: either display that data by adding it to the trend graph so that the patient sees this potentially time-critical information they need to act on, or the other option is to hide it, just keep it in the storage in the display device. The *Paradigm* reference teaches the former approach, teaches give this important information to the user, to the patient when it needs it.

Now, as to the dependent claims, most of them address simply different reasons or causes for that slight delay in the data coming from the glucose sensor to the display device. And the references teach that the cause

of the delay does not change the benefits to the patient of having that slightly delayed data added to the trend graph. It's just as important to see, for instance, that 15 minutes ago my glucose level was below a critical level, telling me I need to do a finger stick right away. Drop what you're doing, do your finger stick, it doesn't matter the cost. So those claims 4, 5, 6, and 7 don't affect the benefit and, therefore, the obviousness --

JUDGE FREDMAN: Do you have any record -- excuse me, do you have any record of evidence that says that reasoning? I mean, I know it says backfilling, but evidence that says why they're backfilling.

MR. VANDENBERG: Oh, why they're backfilling. I would submit, Your Honor, that there's both direct evidence, primary evidence from the exhibits as well as from the experts.

JUDGE FREDMAN: Can you point to a couple pieces?

MR. VANDENBERG: Well --

JUDGE FREDMAN: Or can you tell me in the record where they are?

MR. VANDENBERG: The Exhibit 1011 on page 64 has the 24-hour and 3-hour graphs.

JUDGE FREDMAN: Right.

MR. VANDENBERG: And we can point to that. This is our slide. This is the 24-hour graph. This is Petitioner's demonstrative slide 10. And this teaches the first highlighted portion at the top, which I'll note with the laser pointer there, that you have a graph of the most recent 24 hours of data. It doesn't say a graph of some of the most recent 24 hours of data. So the primary purpose of this display device is naturally to display.

JUDGE FREDMAN: Right. And it does mention that the glucose exceeds 310 mgs., (inaudible) which is elevated. Does it ever tell you, though, what to do about it? I mean, is there a reference that says, okay, when you see elevated glucose, I mean, now there's a reason to do something? I'm just curious if there's a reference that says that or a declaration.

MR. VANDENBERG: Well, absolutely for both. But, for instance, on our demonstrative slide 12 that we see here, the *Paradigm* reference Exhibit 1011 teaches the patient what to do with this trend graph information. For instance, it says it shows the effects of meals, exercise, and medication. And then the next slide, slide 18, it tells the patient, hey, this is why we're giving you this trend graph information.

JUDGE FREDMAN: Thank you. That's what I was looking for.

MR. VANDENBERG: Oh, okay. And just while we're on this graph, on this demonstrative, it allowed to be proactive in the diabetes treatment. That's why this time-critical information is uniquely beneficial.

Another secondary optional use of the information is if the patient decides to download the optional CareLink, then days, maybe weeks later, they can look at some downloaded report. That doesn't help you in the moment. And for instance, here, we didn't highlight it, but we see here it says, "You can see if your glucose is trending up or trending down and take action much earlier." Right? So you can only take action much earlier if you get the information immediately.

And I'd like to make things more concrete to give a hypothetical that I was using the ground 1 combination system this morning. And at 8:59 a.m., there was a 30-minute gap in receiving information, whatever the

cause. It might have been a calibration error or it might have been a transmission out of range, transmission interference, but that ended at 9:29. So at 9:30 it's undisputed in the record that the display device received seven data points, six historical points, 9:00, 9:05, 9:10, et cetera, up to 9:25, and then the current point at 9:30. And at that point in time the references teach that you repopulate the pump, and, again, the primary purpose of the pump is to give information. So our position is that at 9:30 this reference teaches, renders obvious, giving me that information. And it's possible that at 9:10 this morning or 9:15 this morning, my glucose level went below a critical level or above a critical level. At which point, if I knew that, I would know because I've been educated by use of CGM, by my doctor, et cetera, I would know I need to take action. I need to do a finger stick to confirm whether or not that reading is actually correct or am I in trouble?

If the gap stayed there, perhaps at 9:30 it had inched up again and I look at just 9:30 and I have this information that's hidden, I don't know that I need to take a finger stick. And that's all over these references, as Dr. Ahmann explains. Dr. Ahmann was our medical expert. And one thing I'll just note here is the both sides had a medical doctor. Our doctor actually worked with these products at CGM back in the time period 2009 because he focused on type 1 diabetes, which was approved back then and earlier to use CGM. Their doctor, Dr. Wright, you know, nothing against him, but he was focused on type 2 diabetes, which did not use CGM. So he didn't use CGM until 2014.

So the only doctor who actually worked with patients and other clinicians on point had a detailed declaration explaining all the reasons why,

one, a POSITA would read these references to disclose adding the delayed data to the trend line and, two, the benefits of doing that.

So without abandoning any argument today, I'm going to address grounds 1 and 2 only. And first is what is the combination for ground 1?

So ground 1 primarily is *Patel-2009*. Even though we already talked mostly about *Paradigm*, most of the combination comes from *Paradigm* -- from *Patel-2009*. So it comes from *Patel*'s -- and I'll just refer to as *Patel* if I may. So *Patel* provides the sensor, the transceiver, and an array of display devices. It could be a bedside monitor that's plugged into, you know, a socket. It could be a PC, it could be a portable device. All of those are disclosed here, for instance, in figure 11 on our slide number 1.

And as we see in *Patel* 086 it talks about that even when a display device is remote and out of range, the transceiver keeps calculating glucose values and stores those values. And in *Patel-2009* there's no limit as far as how long it can store. It doesn't have the 40-minute limit that's in *Paradigm*. So continuing with *Patel*, which is Exhibit 1012, and then it says that when communication is reestablished, the remote device can synchronize data with the transceiver. So you're synchronizing this slightly delayed data with the display device. And, again, the primary purpose of the display device is to display. And so *Patel*'s teaching that you're updating and synchronizing.

And then *Patel* also teaches that all the data that they're displaying includes trends as well as graphs. So *Patel-2009* by itself comes awfully close to disclosing claim elements 1.K and 1.L.

JUDGE HARDMAN: Counsel, can you point us to the paragraphs in *Patel* that talk about the synchronizing the data?

MR. VANDENBERG: Right here on the screen, paragraph 86 and I have by the laser pointer it says, "When communication is reestablished, the remote device can synchronize data with the transceiver and receive glucose values calculated while the remote device was not communicating with the transceiver." And that's the primary that we've pointed to.

JUDGE HARDMAN: Thank you.

MR. VANDENBERG: And in our demonstratives we cite the exhibit, of course, and we also cite at least examples of where our papers had cited to this exhibit in this paragraph for the Board's convenience.

So the combination has, this is the *Patel* from figure 2 and on slide 2, it has the sensor receiver, it has the stored glucose data value. So at 9:29 the sensor stored 9:00, 9:05, 9:10, it couldn't send it to my phone, but it was storing it, it was calculating it. And then it links to the monitor. And we saw on the earlier slide those monitors could be portable, battery-powered, they could be plugged into a wall, PC, whatever, and then the display, and then we supplement that with the *Paradigm* disclosure. And here as an example, we took one of the diagrams from *Paradigm*, Exhibit 1011, that shows the data gap. So at 9:29 in my example, there'd be a data gap from 8:55 up to present time. And this is an example of that data gap. But then it teaches that if then at 9:30 it gets a set of seven data points, it adds those to the trend graph thereby satisfying claim elements 1.K and 1.L.

JUDGE HARDMAN: Counsel, what is -- Patent Owner has pointed out that if this were so obvious how come none of the commercial products on the market at the time were actually backfilling the graphs on the handheld device?

MR. VANDENBERG: A couple of responses to that. First, *Patel* was filed in October 2007, the provisional, and *Patel* had the attempt advance of storing the data during, say, a communication failure. There's no evidence in the record that I'm aware of that earlier devices were storing the data. So when Patent Owner says, oh, look, here are data gaps, those do not show that somehow data was being sent to a display device and then hidden. Rather, the data was missing. The display device cannot obviously display the data if it's not there. If you had an old system, a conventional system that from 9 to 9:29 all it did was it calculated and then it sent it out and that was it, it didn't store it locally, then that wouldn't be this case and that wouldn't contemplate *Patel*. *Patel* disclosed I have the data, I've sent it, I've synchronized it. So that's there. So that's one reason why we submit that, you know, whatever the commercial devices were doing doesn't show they were hiding data. They don't contemplate *Patel-2009*.

JUDGE FREDMAN: So let me ask my question then. My question is a little different. It's do the claims require that the data that is missing that there be a gap shown? And if the data's been reestablished after you've backfilled it, is there any requirement that the backfill be distinguishable from the data in the claim that I'm arguing about -- or questioning about, from the original data?

MR. VANDENBERG: No, the claim does not require that when you backfill that you -- that, for instance, the patient would notice that the information was temporarily missing. It doesn't prohibit it, but it doesn't require it.

JUDGE FREDMAN: And then there's no requirement to show that either really, yeah.

MR. VANDENBERG: I believe the claims do require that there be a gap, that basically when there's information -- it requires you to have a trend graph and then it requires that during the adverse condition there be a gap. And then it requires that once the adverse condition has ended and you have the data to fill in, you fill in the data.

JUDGE FREDMAN: And is there a chart? I mean, so you're drawing a picture from what you said before about having a gap, is that right?

MR. VANDENBERG: The -- right here, this on our slide number 2, this is an example of a gap, but it is undisputed. They have not disputed that *Paradigm-Patel* combination has a gap. That element, in their Patent Owner response, they did not dispute that.

JUDGE FREDMAN: Okay.

MR. VANDENBERG: Now, the issues are rather narrow here. So, again, on ground 1, they in their Patent Owner response did not dispute any element except for 1.K and 1.L, basically filling in, adding the delayed data to the trend graph. They didn't contest or say anything about motivation to combine, nor did they contest reasonable expectation of success.

Now, in the Institution Decision, of course, it was a preliminary decision based on incomplete record and tentatively preliminarily found that *Paradigm* disclosed or suggested and taught the elements that we're talking about, 1.K and 1.L. So that raises the question, what's happened since? And we submit that both parties, not just Petitioner, but Patent Owner, have submitted evidence that support that finding. I'd like to start with Dr. Striegel, their expert, their non-medical doctor expert, Ph.D.

So Dr. Striegel certainly didn't abandon ship for Patent Owner. He doesn't say that, oh, yeah, *Paradigm* disclosed backfilling. But the

individual concessions he made, we support, go a long way toward that finding. So, first, as I was saying, he conceded that if the data were missing from 9 to 9:25, there would be a gap on the screen. And this is our slide 5.

And then going to our slide 6, Dr. Striegel admitted that the POSITA would understand that once the data became available to the pump that it would store the data. He says it would be stored in long-term memory. So that means at 9:30 he's conceding the data points from 9 up to 9:30 would all be stored in long-term memory. So that's seven data points in long-term memory.

And then he says here that -- I think this is how it goes, he says historical data could be downloaded to a personal computer. So we agree with that if the patient got the optional CareLink software. So that's one way the patient who could later or the doctor weeks, days later could look at that. But then he says, "or". He says, "or this historical data," historical data includes 9 to 9:25. He's admitted 9 to 9:25 is stored in long-term memory "or accessed for retrieving discrete data values." That's discrete 9:00, 9:05, 9:10 glucose values, you know, for retrieving discrete data values. And he says those would be in long-term memory.

So the question is, beyond downloading, how does *Paradigm* describe a patient accessing retrieving discrete data values? Well he concedes that as well on slide 8. And we're referring to Striegel declaration, Exhibit 2015. Mr. Mason reminded me to complete the record there. So these last four slides are citing to Striegel's declaration, Exhibit 2015.

And then he concedes that, oh, well, the way you access -- at least one way you access discrete data values is scrolling through a trend graph. And they don't, -- neither Striegel nor Patent Owner identifies any other

way, putting aside downloading, that you can access 9:00, 9:05, 9:10 data values other than by putting them on the trend graph and then scrolling back. And --

JUDGE FREDMAN: I mean, it doesn't -- he doesn't actually say it's a trend graph. He says it's data points. So they could just simply be a list of data points, too, I suppose.

MR. VANDENBERG: But he does not point to that and nor does Patent Owner. Nothing in the record that *Paradigm* gave some list of data points. So based on the record he said, oh, you can access this historical data in two ways: download or the only other --

JUDGE FREDMAN: On an individual basis you have a *Paradigm* device would be the screen essentially with a graph.

MR. VANDENBERG: On the trend graph, yes. And that's just not attorney argument.

The next slide, slide 9, is Mr. Gross and his declaration, Exhibit 1057, and he walks through this. The ellipses are where he's, you know, summarizing basically how it works. And he's citing to Dr. Striegel. He said, "as the patient went between different screens." So when I'm on my phone and I have the system, first I'll get the home screen which won't have any trend data. Then I hit Escape once, I see the 3-hour, hit Escape twice, I'll see the 24 hours. Where does that data come from? It comes from the display buffer. And for instance, Dr. Striegel in deposition, and this is quoted in Exhibit 1057, paragraph 12, says, quote, "The display buffer is what I want to show," which makes sense. It's the display buffer. It holds what you're about to put up on the screen. The display buffer is now contained in slide number 9 of my deck.

So basically, as you go between different ones, 3-hour, home screen, 24 hours, it accesses any needed data from long-term memory and loads that data into the display buffer. And then since the missing data from 9 to 9:25 per Striegel is in the long-term memory, when I go to retrieve that to update my trend graph, it's going to include those data points. And then basically he, again, says, "The display buffer is filled with information from long-term memory and thus includes any data that's been repopulated." So Dr. Striegel didn't abandon ship, but his individual discrete concessions, we submit, as explained by Mr. Gross, support the Board's Institution finding.

Now, returning to slide 10 in the 24-hour graph, this is the primary evidence, this and other Exhibit 1011 teachings. We already noted that it's displaying the most recent 24 hours of data. Our position is that this graph that we see here as continuous teaches the POSITA as well as the patient two situations. One situation is, for whatever reason, there was no data gaps. There was never any interruption in the flow of data from the sensor transceiver to the display. But it also covers the situation where there were short, under 40-minute delays of the sensor data and those have been filled in.

It's also interesting, the other side, Patent Owner talks about historical reports. Well, our position, this is a historical report. The downloads are historical reports, but this is a historical report. And, in fact, they used the word "history" to talk about, in my hypo, the data points 9:25, 9:20, 9:15. They say those are the history. And on the left side here it says, "Sensor glucose data points." Those are the discrete data points that Dr. Striegel conceded could be accessed other than by downloading.

Now, as far as historical report, there's no argument or expert has said the word "report" and this art has some peculiar, you know, unusual meaning. Nor is there any argument by them or any of their experts to say that what we're looking at here, the 24-hour graph, is not a report under the common English meaning of "report." It's a presentation, a structured and detailed presentation of information. It's as much as a report as any weather report.

The term "historical report" is a generic term. It covers the downloaded reports. Even though they don't call themselves historical reports, they do refer to report. They don't say they're historical reports, but obviously they're historical reports because they're reporting historical data. A historical report is a report that reports historical data. It's as simple as that. So our position is this is a historical report. Dr. Ahmann in his deposition, Exhibit 2041 at pages 122 to 126, explained that these are historical reports. And Mr. Gross explained the same to Exhibit 1057, paragraph 47.

So, we'll skip the three-hour graph. The FAQs, we in our petition referred to one as the first FAQ and then there's the second FAQ, or Frequently Asked Question, on slide 12. And basically, you know, it makes the point that if it's out of range a certain distance, the transmitter will hold 40 minutes of the data. Again, *Patel-2009* is part of the combination and doesn't have that restriction. And then it says that it can be repopulated. So basically, the CGM data can be populated in the insulin pump. And this is telling the patient that your CGM data, the data we promised to show you, will be repopulated. If you're out of range 40 minutes, don't worry, you're not going to lose that data. You're going to be able to see that data.

And then in the last sentence, it refers to when reviewing the historic reports, if it's gone more than 40 minutes, so instead of the half-hour postponement, there was an hour, from 8:59, 9:59, you're going to lose 20 minutes or so of data. And he calls that -- they call that here a "data gap." Well, Dr. Striegel referred to data gaps when talking about the display graphs. That's a term that's not limited to the trend graphs, but it covers the trend graph gaps as well.

And then the second FAQ, the first sentence ties it together even more nicely because the first sentence refers to the display, that basically as long as you're within range, you're going to get CGM data displayed on the screen. And then it says if you're out of range, only the last 40 minutes will be repopulated. Well, the last 40 minutes of what? The antecedent is in the first sentence, "the data being displayed." What's being repopulated? The screen. That's the only antecedent. This first sentence here doesn't refer to storage, it refers to the screen. So this is an expressly submit disclosure of claim elements 1.K and 1.L.

And then in the last sentence it refers to historical reports, you would notice a data gap. That's an absolutely true statement referring to the trend graphs. You would notice a data gap if the delay was more than 40 minutes. And it doesn't say downloaded historical reports, it uses the broad generic term here.

So in addition to Dr. Striegel's concessions, in addition to the plain reading of the trend graphs and the FAQs, we also have a design purpose that's taught by these references. And before getting into that, their expert, Dr. Wright, in our slide 14, Exhibit 1053, admitted that in 2009 it was important to provide as much accurate information, glucose data to the

patients with diabetes as possible. And that's secondary evidence, but the primary evidence says the same thing.

And back to our slide 15 from the *Paradigm* Exhibit 1011. It says basically that, you know -- sorry, it says the trend graphs show the effects of meals, exercise, and insulin." Well, if I ate at 9:00 or I ate at 9:10, this -- we submit this would be false advertising. This would be misleading the patients. They'd be lying to the patients because they -- because it wouldn't be showing you the effects of meals even though they had the data. No one says it was incapable of displaying data. It's a display device. It has the data. It knows the data that would tell me what was the effect of that meal I had at 9:10 or the exercise or medication, whatever it is. But they're not going to tell you, they're going to hide it? That would be directly contrary to what they told the patient was -- and this indication here, this is all FDA approved. *Paradigm* was approved for using trend graphs to assist the patient to know -- to see some time-critical information that tells them I need to do a finger stick now. This was all FDA approved.

Now, the next slide, slide 16. This is from again Exhibit 1011, you know, page 9 of Exhibit 1011. We looked at this a bit already earlier, but it's basically, I think the key here is the time-critical nature of this information, taking action much earlier. Hiding the information would be inconsistent with that. The design principle is being proactive. People who are using CGMs, the Medtronic providing the data, it was all about data-driven decision-making. Not simply doing, you know, six or so fingerprint sticks in a day and hoping that somehow you got lucky and they showed you the low point, they showed you the high point, they showed you a troubling trend line. Instead you have 228 data points in the day and you can see on

your 24-hour graph and under the Patent Owner's theory that the data is going to be hidden, that's like a Swiss cheese graphs theory. Let's say you had a 3-hour graph and you had three 30-minute, you know, interruptions, half the graph would be missing. That would be completely contrary to what this is teaching and what the prior slide was teaching for *Paradigm*.

JUDGE FLAX: Counsel?

MR. VANDENBERG: Yes.

JUDGE FLAX: If the prior art is not as explicit as you would like it to be about displaying the gap in data which repopulated, is it your contention that showing that data is mere common sense to the person of ordinary skill in the art or would it have been obvious to do that?

MR. VANDENBERG: Our contention is that it would have been obvious. It was common sense, but we're not relying on the common sense. All that's missing from *Paradigm* is it does not have a before and after picture of the exact same data where there was a data gap and then there wasn't a data gap. It doesn't show the graph at 9:29 and then show the graph at 9:30. So that's no verbatim before and after of the same data. We agree with that.

But that aside, everything else teaches this concept. And, again, they had -- basically there's only two options. It's conceded the data was there. It's evident and taught that the data was critical. The plain reading of the data -- of the page 64, the 24-hour graph says we're showing you the most recent 3-hour data. Well, if it's 9:30 and they're not showing me 9 to 9:25, they're not showing me the most recent three-hour data. And then the FAQ, particularly the second FAQ, ties the display to the repopulating. So we think all of that is way more than a preponderance of the evidence,

acknowledging that there isn't the verbatim before and after of 9:29 and 9:30. Did that speak to your question?

JUDGE FLAX: You did. Thank you.

MR. VANDENBERG: Okay. Thank you.

JUDGE FREDMAN: So let me now go with another question. This is going to Patent Owner's exhibits, I think. They're talking about how backfilling, the reasons you might not want to do it. Can you address that a little bit? Too much power or stale information?

MR. VANDENBERG: Right. The one analogy I came up with that is a smoke alarm. Obviously, if a smoke alarm detects smoke, it is obvious and beneficial to set off a loud alarm. You can always come up with reasons, you know, the downsides of doing that. Perhaps it was a false alarm, perhaps the smoke alarm wasn't working. Perhaps there are people who get triggered at really loud noises. Right? So there's always some reasons that someone can dream up as to why you might not want to do something. And some of these reasons Patent Owner came up with, respectfully, are as absurd as don't set off the sound alarm because it might drain some power. Right? They're saying that we may have time-critical, medical care-critical information, we're going to hide it because it might take more power to show six more pixels? Really? That's the position? We submit some of their positions were so, you know, out there that it really support -- they support our case.

In any event, we have Dr. Ahmann, the only expert who actually -- medical doctor who actually worked with these things in the time period. And his declaration goes on and on explaining all the reasons, the beneficial reasons why you would display the data and went through Dr. Wright's

attempts to come up with reasons you wouldn't do it. For instance, at one point they said, oh, it's stale data. Well, 9:25, 9:29, 9:15, that's not stale data. Particularly if *Paradigm* thinks it's important to show me data 23 hours ago. How could data 5, 10, 15 minutes ago be stale?

They say, oh, it might confuse people because they wouldn't know that they were out of range during that period. Well, their own slides show us how to -- if that were an issue -- and obviously being confused about whether you're out of range pales in comparison with having a health event, but even if you cared about that, you could have the line in color, you could have the filled in gap line with some different color, or you could have it thicker. And they themselves helpfully in their slides you'll see example where they gave a demonstrative and they did both. They made the red --

JUDGE FREDMAN: But they have it in their record to do that, right? And there was prior art. Does Dr. Ahmann say to do it in color or did someone -- there's some record evidence to say why you might do that in a different color or some other markup?

MR. VANDENBERG: I believe Dr. Ahmann said that there could be some theoretical benefit of showing it -- displaying it differently. As far as color and thicker line, I don't recall at this point, but when I get back up, hopefully, I might have be able to point to something on that.

JUDGE HARDMAN: Well, Counsel, doesn't that point cut against you? Because the *Paradigm* documentation nowhere says, hey, the backfilled data will be shown in another color or thicker line or distinguished in some way.

MR. VANDENBERG: Well, no. And because it's a trivial consideration, there is no need to show the fact that it was out of range for

some number of minutes. That isn't a critical consideration compared to what we're seeing, for instance, on slide 16, that you can be proactive in your diabetes treatment, you can take action much earlier, you can manage your diabetes more effectively, you can live a healthier life. All of those benefits teach filling in the data, giving the data, not hiding the data.

JUDGE HARDMAN: These concerns, though, about stale data, back -- confusing data, don't some of those reasons come from your client's own patents and patent applications?

MR. VANDENBERG: Those patent applications and patents which came later mentioned those points. They also disclosed backfilling data. So those patents support our position, although they're late, so we wouldn't have cited them on our own, but they support the position. They say you can disclose -- you can backfill the data or you can choose not to. But it was obvious to backfill data. Here are the benefits of backfilling data and they came up with improvements, ways you could do it. Like for instance, I think one had to do with, like, power and they basically said, well, you can compress the data and then you'd have less data. So they noted these potential problems like, oh, the smoke alarm is too loud, et cetera. And they solve it. So that doesn't -- we don't think that cuts against us somehow.

JUDGE HARDMAN: Before we close out on your time here, could you speak to claim 21, please?

MR. VANDENBERG: Yes. So claim 21, our slide 21, which shows figure 1 of *Patel-2009* and then the sur-reply brief's annotation of figure 8A of *Patel-2009,* and claim 21 requires an integrated housing. So integrated means bringing separate things together to form a whole. That's the plain meaning. And the petition we said, you know, we go under plain meaning.

The Patent Owner has not suggested some unusual understanding of the word "integrated" in this field or in this patent. So we submit that's exactly what *Patel-2009* is doing here. *Patel-2009* takes the sensor set and the transceiver and combines them to form a whole. And we see that in both of these figures.

And I would like to quote from the Institution Decision at page 4, quoted the '056 patent specification's use of the word "integrated." And it was quoting from the Harper '056 patent at columns 5, 54 to 58. And the quote is, "The data processing and transmitter unit 102 may be physically coupled to the sensor unit 101, so that both devices are integrated in a single housing and positioned on the user's body." So the specification used the term "integrated" in that commonsense plain meaning that you bring two things together physically coupled. That's precisely what *Patel-2009* shows here. Also --

JUDGE HARDMAN: The claim language, though, also says "single." So it's a single integrated. So the joining sounds like two housings, but the term "single" suggests that somehow it's just one housing. So are you reading out single with this argument?

MR. VANDENBERG: No. No, Your Honor. The -- we have here, this is their annotation. The result, we submit, is this single housing that -- oh, let me get my corner here -- the single housing that basically once you combine it, it just continues and it's the outer wall of the two devices. It acts as a single housing. For instance, *Patel-2009* describes that basically it acts as a single unit after you've done that.

JUDGE FREDMAN: To the (inaudible) after that.

MR. VANDENBERG: It helps -- it discloses both. It says preferably they're detachable, but it also discloses it doesn't need to be detachable. It also discloses that in terms of acting as a single unit, that you can have adhesive on the sensor part of it and that will stabilize the transceiver as well. So they're being used as a single unit there.

Also, the claim says a single integrated housing. Patent Owner does not argue that there is more than one integrated housing here. It does not argue that the sensor set is an integrated housing. It doesn't argue that the transmitter has an integrated housing. You only have one integrated housing. You might have two housings, but they've been combined to form a single integrated housing. So that satisfies the claim language, the use of the word "single." We're not reading the word "single out." We're reading it in combination with integrated. After you've done your job, you have a single integrated housing.

They sort of make noises that maybe this had to be done at the factory, that it doesn't count because in *Patel*, the patient is integrating the two. But the claim doesn't say that. If they wanted the claim limited that way, they should have moved to amend.

We also see in this illustration from them the pink goes to inside the sensor, really is inside of the transceiver housing. The transceiver has a sensor interface that has to interface with the sensor. And at the *Patel* paragraph 60 it says that the sensor interface "permanently connected" to the server set. And we cited that in our reply at page 26, which, again, reinforces that this is a single unit. It has been integrated.

So just to sort of summarize on claim 1, but briefly on claims -- well, just on summarizing on claim 1, no matter how you slice it, the references

teach elements 1.K and 1.L. If you look at it from a design principle standpoint, it teaches the importance of taking the slightly delayed data and filling in the trend graph. If you look at the plain reading, plain reading and meaning of the terms, of the references, it teaches the same thing. And if you look down at the implementation details, we have Dr. Striegel conceding that that delayed data gets put in long-term memory and that you can access discrete data points from long-term memory without downloading, which means -- which supports our position.

Thank you.

MR. PATHMANABAN: Good morning, Your Honors. Giri Pathmanaban for Abbott again.

JUDGE HARDMAN: I'm sorry, can you say that again?

MR. PATHMANABAN: Giri Pathmanaban for Abbott.

JUDGE HARDMAN: And if you're ready, I will start the clock.

MR. PATHMANABAN: I'm ready, Your Honor.

JUDGE HARDMAN: Thank you.

MR. PATHMANABAN: Thank you. I'd like to start with claim 21. And because Counsel ended with that and Judge Hardman asked a very insightful question, let's start with the claim language.

The glucose monitoring system of claim 1 wherein the data processing and transmitter unit and at least a portion of the glucose sensor are disposed within a "single" integrated housing. Counsel, you are absolutely correct, Your Honor, was leaving out the word "single." And they are absolutely reading out the word "single" from this claim and they're saying any integrated housing effectively would meet this claim. That is not the case.

Now, they have made a -- they have taken a totally shifting sands approach to their arguments as to this claim. And let me just walk you through that. Let's start with what they said in the petition. Let's go to slide 41, Mr. McLean (phonetic).

This is -- I put on slide 41 of our demonstratives the entirety of what the petition said about claim 21, ground 1. *Patel-2009* provides that transceiver 100 fits directly onto and is supported by sensor set 10 itself and have the figure and they have some cites. That's it. They don't say anything about why this even has a housing much less an integrated housing, much less a single integrated housing. They said nothing about it.

And let's go to slide -- we can skip 42 and let's go to slide 43, Mr. McLean. And we pointed out all the flaws with their argument, and specifically *Patel-2009* and, for that matter, *Mastrototaro*, for ground 3 have two separate housings and they are coupled together by the user. The sensor goes in first and then you add the transmitter to it. And that's the opposite of what is claimed in our view. Right?

And so in the reply they come back with this figure from figure 1 of *Patel*. Let's focus on that. And they color in in red and say, oh, the sensor extends into the transmitter housing. They have no support for that. Pure attorney argument. They don't even have their expert supporting them in this report. They don't have a declaration. So this is pure attorney argument that should be disregarded. And of course, it's a brand new argument raised belatedly in their reply. So that should be disregarded.

Today for the first time, let's go to their slide. I heard today for the first time a new argument, which is not even one that they made in their reply. Yes, and this is Petitioner's demonstrative slide 21 on claim 21 and

they focused on our drawing on the right there and said that whole red thing is a single housing. But they have not made that argument at all in their papers, any paper, petition, reply, whatsoever. And no, it's not one housing. Those are two separate housings as we have repeatedly pointed out.

I think Mr. Vandenberg said at one point that Patent Owner doesn't dispute that this is one housing. I'm baffled by that suggestion, Your Honor. We've gone for pages and pages in our papers about that.

These are two separate components. The sensor in *Patel-2009* and the transmitter, they're two separate components. They have separate housings and one goes in and then you put the other on. They're not a single housing. They're not a single integrated housing.

If we can go to slide 44 of our demonstratives, Patent Owner's demonstrators. So all they're relying on with respect to *Patel-2009* and their argument in the reply is attorney argument. And the case law is very clear, Your Honors, that you have -- you cannot give that any weight. And then to the extent they're relying -- I'm not even sure anymore if they're actually relying on what they said in their reply. But to the extent they are, the law is also clear that a drawing -- for a drawing to disclose a claim limitation, the limitation must be shown clearly, and it is far from clear. In fact, it's the opposite of clear what that figure 1 actually shows, and there's no description to support that any portion of that sensor extends into the transmitter housing. There's no description in *Patel-2009*.

JUDGE FREDMAN: Is there a requirement for that in the claim, for the sensor extending into it? Does that matter?

MR. PATHMANABAN: Well, the claim requires that a portion of the sensor and the transmitter, among other things, the data processing unit

as well, all be within a single integrated housing, Your Honors. So as I understood, the argument that they were making in their reply was that, well, the sensor, a portion of the sensor does extend into the transmitter's housing and, therefore, they are single integrated housings. But that's not the case. That's not disclosed at all.

JUDGE FREDMAN: So if I buy a chair from IKEA and I put it together following their instructions, is that an integrated chair, a single integrated chair, or is that a bunch of pieces because I didn't put it together -- because I put it together and it came in a box?

MR. PATHMANABAN: Well, it's obviously a different context, but in that case you could say that's a single integrated chair. Sure.

JUDGE FREDMAN: So by putting something together and they're together and they're covered by a housing that extends over the entire thing, why isn't that a single integrated housing?

MR. PATHMANABAN: Because there is no such thing that extends over the entire thing in this context.

JUDGE FREDMAN: Well, the entire thing is covered in the picture. In figure 1 it's fairly clear that there's objects covering all elements in the claim and that they're integrated together in some way, right?

MR. PATHMANABAN: Sure, but they have two separate housings. It has to be one housing.

JUDGE FREDMAN: What does that mean, to be one housing? Because that's the question I'm asking.

MR. PATHMANABAN: Well --

JUDGE FREDMAN: You're putting a lot of weight on the word "single."

MR. PATHMANABAN: Sure.

JUDGE FREDMAN: And in my chair example, there -- it has a seat and there's legs and there's a back and we're screwing them together and we're attaching them in some way. They become a single thing once they're attached. Why does attachment not make a housing together?

MR. PATHMANABAN: Well --

JUDGE FREDMAN: If I had another medical device and I put together two pieces, is it not a single device at that point or is every device not single unless they're made singly?

MR. PATHMANABAN: Well, I don't want to make a general statement about all medical devices or in this case a chair, but I will say in the context of this medical device that's claimed in the '056 patent and the '056 patent's context, you're talking about a sensor and a transmitter integrated within one housing so that the user can apply it all together. So an example is the Freestyle Libre 3 device, Abbott's device. Right? So a user could buy it and within one press, both the sensor and the sensor electronics all go into the arm together.

In contrast to that is their DexCom's G6 device, for example, which is an older device. And there's an exhibit that we have attached that describes the G6. In that, what happens is the patch with the sensor goes in first and then the sensor electronics is snapped on afterwards. That's what we were trying to distinguish over with this claim, the single electronic -- integrated electronics.

JUDGE FREDMAN: Is there a definition in the spec that clarifies that in the patent (inaudible)?

MR. PATHMANABAN: There is, Your Honor. It's not a definition, but it's very informative. So if we can go to the '056 patent. And actually, Mr. Vandenberg alluded to this, the '056 patent.

JUDGE HARDMAN: Counsel, sorry to interrupt you. While you're calling that up, could you pull the microphone in front? I think the microphone is -- yes. By your right hand.

MR. PATHMANABAN: This one?

JUDGE HARDMAN: Yes. And if you could try not to veer too far from the microphone --

MR. PATHMANABAN: Gotcha.

JUDGE HARDMAN: -- because I understand from our tech folks that we're having an issue with the sound.

MR. PATHMANABAN: Understood. Thank you, Your Honor.

JUDGE HARDMAN: Thank you very much.

MR. PATHMANABAN: So if we can go to '056 at column 5, line 48 through 67. So here you see it states the sensor unit 101 is physically positioned in or on the body of a user whose analyte level is being monitored. That's line 48 to 50. And then I'm going to skip a few lines and it says, starting around line 54, "In certain embodiments, the data processing and transmitter unit 102 may be physically coupled to the sensor unit 101, so that both devices are integrated in a single housing and position on the user's body." And so --

JUDGE FREDMAN: You could imagine that in multiple ways. Right? One could imagine coupling them by simply clicking it on top, where they're clearly not an integrated housing. Or the vision of figure 1. They're kind of -- they look like they're a single thing. They're different

embodiments. It doesn't necessarily imply that they're not two different things clicked together.

MR. PATHMANABAN: Well, respectfully, Your Honor, I think the fact that it says "both devices are integrated in a single housing and positioned on the user's body," that I think in context is talking about positioned together as one piece effectively. And also to the extent there's any doubt, at the bottom of that paragraph, it describes examples of such integrated sensor and transmitter units can be found in, among others, U.S. Patent Application Number 12/698,124, which is incorporated by reference. And if you go to the incorporated by reference application -- let's do that, the ’124 application. There, I'm going to go to paragraph 33.

JUDGE FREDMAN: Which slide number is this?

MR. PATHMANABAN: This is not a slide. I'm just pulling up the incorporated by reference application, Your Honor

MR. VANDENBERG: Can I just inquire what exhibit number that is, please?

JUDGE HARDMAN: Yes, I have the same question.

MR. PATHMANABAN: Unfortunately, it was not submitted as an exhibit because this issue did not come up until they raised it in their reply. And we could not, of course, as you know, file exhibits with our sur-reply.

JUDGE HARDMAN: Okay. So there are no new arguments permitted at a hearing, so I just caution Counsel on that.

MR. PATHMANABAN: I understand, Your Honor. I was trying to be responsive to Judge Fredman's question, but if you go -- I can move on. But the bottom line is, if you go to this application, along with what the '056 patent itself says, it is an integrated sensor And --

JUDGE FREDMAN: Let's move on because exemplary embodiments wouldn't prove anything anyway, right? An example doesn't limit it, so it wouldn't matter even you had it.

MR. PATHMANABAN: I'm not suggesting that it's definitional, but I think it is highly informative in this respect because --

JUDGE FREDMAN: Let's move on. Let's move to another point.

MR. VANDENBERG: Yeah. Whatever's on the slide, I'm intentionally not reading it because it says work product and attorney-client privilege. I'm not sure they have the right thing up on the screen.

MR. PATHMANABAN: Oh, I apologize if that was the case. Let's go to slide 45 of our demonstratives.

JUDGE FLAX: Can I ask you to do something for me?

MR. PATHMANABAN: Yes.

JUDGE FLAX: If you would go back to the image where you had the *Patel* reference figure up and it was highlighted? Do you recall that one?

MR. PATHMANABAN: Of our side?

JUDGE FLAX: Whichever one you were talking about, in pink and it's in yellow.

MR. PATHMANABAN: Okay. So that's --

JUDGE FLAX: Or any one that you prefer actually.

MR. PATHMANABAN: Well --

JUDGE FLAX: That's fine. Can you walk me through the yellow part and the pink part and tell me with respect to your claim 21, what are you arguing is in each part? So where's the sensor there? Where's the transmitter? Where's the receiver? Can you describe that?

MR. PATHMANABAN: Absolutely. So the transmitter is in yellow and the transmitter housing is in red. The outline is in red, and the sensor is in pink or purple, whatever you want to call it. And the outline of that housing is in blue.

JUDGE FLAX: Okay. And where's the -- where would the data processing be? Is that in the yellow part, too?

MR. PATHMANABAN: Correct.

JUDGE FLAX: All right. And then so the claim says that at least a portion of the glucose sensor has to be within that single integrated housing.

MR. PATHMANABAN: Correct.

JUDGE FLAX: And so does it matter to you that some of that is inside of the yellow part?

MR. PATHMANABAN: No.

JUDGE FLAX: So when you plug them together, I'm looking at maybe figure 12 of the reference. It clearly shows that part that would go inside the other part. Does that matter if that -- would that not be the "at least a portion of" or does it have to be something else to satisfy that claim?

MR. PATHMANABAN: Well, it doesn't matter for two reasons. One is that it's -- that's the male connector. And the male connector does go into a female connector on the transmitter housing. However, there is zero evidence whatsoever that the sensor actually extends into that part. Okay, so that's one reason. The other reason is --

JUDGE FLAX: That whole part is not the sensor.

MR. PATHMANABAN: Correct.

JUDGE FLAX: Is that what you're saying?

JUDGE FREDMAN: You're reading the sensor is limited to just the actual sensor device, not the whole sort of unit that does the sensing.

MR. PATHMANABAN: Hundred percent, yes. And if you read their petition, that's the way they read the prior art as well.

And the other reason that I was going to say the sensor doesn't extend into the transmitter, but the other reason is even let's assume for argument's sake that it did, then that would have two separate housings, not a single housing in our view. And I can show this more clearly with slide 45.

JUDGE HARDMAN: So involving your -- I have a question.

MR. PATHMANABAN: Yes.

JUDGE HARDMAN: On the left figure there is a dotted line, some kind of cylinder or -- that goes from the sensor portion, the pink portion, into the yellow. Isn't that part of the sensor mechanism itself?

MR. PATHMANABAN: No, it's not at all clear that that's part of the sensor at all. The sensor is what both parties have labeled number 12. That's the sensor. That's a solid line. And then there's a cannula 16. And what that dashed line represents is not described anywhere in *Patel*. So we don't know what that is, but it is not the sensor. And even if it was, it doesn't show the sensor extending into the transmitter housing. So it's unclear.

JUDGE HARDMAN: If we don't know what it is, how do we exclude it as not part of the sensor?

MR. PATHMANABAN: Well, because it -- what they have labeled in their petition many, many times is the sensor -- as the sensor is this element number 12 and that's not labeled element number 12.

JUDGE FREDMAN: (Inaudible) essentially a needle going into the patient, right?

MR. PATHMANABAN: The sensor is part of the needle that goes into the patient.

JUDGE FREDMAN: Right.

MR. PATHMANABAN: So if I may, I'd like to show you slide 45 of our slides, Patent Owner's slides, 45. So this is *Patel-2009*'s disclosure. You can see the transmitter on the -- you know, colored in red there and you've got the sensor set in blue. They are completely separate pieces that are, of course, coupled together at a later point, but they're separate pieces with separate housings, not a single integrated housing.

And if I can go to slide 46, please, the disclosure of *Patel-2009,* this is Exhibit 1012 at paragraph 56, it talks about the transceiver "is coupled to the sensor set after the sensor set has been placed into the body of -- body 100 of the user." So here you put the sensor on and then you put the transmitter on, similar to the DexCom G6 device that I described earlier. Right? And again that shows that two things. One, there -- that it's a two-piece device. It's got two separate housings. And two, it wouldn't make any sense that the sense -- any part of that sensor extends into the transmitter housing because, if so, if you put the sensor on first, you'll have a portion of the sensor sticking out of the body. You can imagine it has health hazards and it'll be a very poor design. Right So the context of *Patel-2009* makes clear that it's a single -- it is not a single integrated housing.

And if we go to slide 47, this is just from the *Paradigm* documentation, which, of course, they have said effectively embodies *Patel-2009* and it's all from Medtronic prior art. You can see this is like a two-

piece device. You put the sensor set on first and then you put in the transmitter. And --

JUDGE FLAX: So as an analogy, let me see if I'm understanding this, I have a laptop computer here in front of me. I'm looking at the record on it. If I have a USB drive, thumb drive, and I stick it into a port, that does not become a single integrated housing. They remain to be separate even though they're electronically and communicatively coupled. Is that a good analogy?

MR. PATHMANABAN: In the context of this patent, yes, I would say that the USB and the laptop are separate -- have separate housings, so they're not a single integrated housing. In contrast to, for example, your flash drive on the laptop itself.

JUDGE FLAX: It's inside.

MR. PATHMANABAN: It's inside.

JUDGE FLAX: Yeah. Okay, I understand your point then. Thank you.

MR. PATHMANABAN: And I won't belabor *Mastrototaro* for ground 3 because Counsel didn't argue it, but basically it suffers from the same flaws. That's on slide 49 and both parties agree it's got the same figures.

Now, they also belatedly raised *Patel-2008* in their reply, which they never used before. Slide 50, please. They did not even refer to this in their petition for claim 21, but they belatedly raised this in their reply and they say, well, it's got a transmitter and sensor that is fused together. Even if it's fused together, you can see there the transmitter and sensor set, which is colored in red and blue, respectively, on slide 50, they have separate

housings. They may be fused with a wire or whatever, but that doesn't make it a single integrated housing.

And absent further questions, I'll move on to claim 1 Your Honors.

All right. Let's go to slide 5. And Judge Hardman, you asked a question of Petitioner that -- about contemporaneous CGM devices that were on the market and you're absolutely right. So the state of the art was that these devices showed data gaps. They did not backfill data for display on the receiver as required by our claim.

So the '056 patent, if we can go to slide 6, figures 7A and 7B, in 7A, it shows a data gap on the line graph. And in 7B, once the adverse condition that causes that data gap is corrected, it is going to backfill that data and it's going to backfill it in a specific way. So the claim is not just about backfilling, it's about backfilling using a line graph.

Now, let me use this as time to respond to something counsel said. He said that, well, their own demonstrative shows that you could color in something and show it differently as opposed to real-time data. Well, the problem is that like I think one of the judges pointed out, there's nothing in the *Paradigm* documentation that says you could color in backfill data separately. It, in fact, doesn't even say anywhere that you could display backfill data on the CGM display. And not only that, that's a black-and-white device, so obviously it didn't show anything in color this way. Okay?

JUDGE FREDMAN: So let me ask you a question. The claim doesn't require that, right? The claim only requires it to show the backfill data, not to highlight it in any way.

MR. PATHMANABAN: Well, the claim requires showing the backfill data as a line graph. And let me show you that.

JUDGE FREDMAN: No, I understand that. It has to be part of the line you're showing.

MR. PATHMANABAN: Correct.

JUDGE FREDMAN: If you simply threw the data into the line graph that was already there in the appropriate point, it would then meet that claim, right?

MR. PATHMANABAN: Yes.

JUDGE FREDMAN: So we're really talking just about does it do that and we're really not talking about anticipation, right? This is an obviousness case. So I'd rather have you focus not on what the references don't show, that exact embodiment they're requiring, but why it wouldn't have been obvious.

MR. PATHMANABAN: Well --

JUDGE FREDMAN: But you said that you made that argument already.

MR. PATHMANABAN: Well, thank you for asking that question. I did want to respond something that one of the Judges raised and Petitioner said something about it. For ground 1, let's be clear, they have not argued anywhere that -- let's go to slide 8, and I have the two contested limitations here, 1.K and 1.L. They have not argued anywhere that it would be common sense or obvious in view of the *Paradigm* disclosure to backfill data or display it as a line graph. That's not their argument. Their argument -- we are confined to the arguments they made in the petition. We should be. And their argument is that *Paradigm* actually discloses these limitations. Okay? So let's -- and 1.K is you have to backfill the data and 1.L is you have to backfill it as a line graph. Okay? And --

JUDGE FLAX: Okay. Counsel, why wouldn't it do that? I mean, what sense in the world would it make to have the data, to know that you need it for the purpose of the prior art device to be displaying data, the glucose readings, why in the world would you not display it? What sense does that make? I mean, to me, you seem to be making the argument that the person of ordinary skill in the art has ordinary stupidity rather than ordinary skill. So explain that to me.

MR. PATHMANABAN: Sure. And Judge Hardman raised the question and that is answered by Petitioner's own patents, Your Honors. If you can go to slide 19, for example, this is one of their patents. This is Exhibit 2023. And you can see the filing date on this is May 2016, years after the '056 patent was filed. And it is talking about why you would backfill data. And one of the reasons is backfilling may consume too much battery power. And remember this --

JUDGE FLAX: What exhibit is this here? I'm sorry.

MR. PATHMANABAN: I'm sorry?

JUDGE FLAX: What exhibit are you talking about?

MR. PATHMANABAN: Exhibit 2023.

JUDGE FLAX: Thank you.

JUDGE FREDMAN: Okay. So, you know, *Medichem* says you can weigh the balancing and to the extent that one reason supports it, one reason opposes it, we have balancing here. And there is some statement in the post data of the prior art that says that. But when you look at *Paradigm* and the fact sheet says that it's going to show you the effects of meals, exercise, insulin, and medication on your glucose control. That's what the *Paradigm* reference says.

And they thought, okay, exercise is probably not the one I should use, so we'll use a muffin. You eat a muffin at 9:15, right, and you lose contact because you walked away from your device. You know, I don't have diabetes, but if you did, your sugar gets elevated, the levels, and you need to take a shot and you -- or take some insulin and you didn't see that. Right? And now you come back and it's a little lower maybe, your body responds a little bit, but you have that missing data. You don't realize you've been elevated for 25 minutes. Why wouldn't it have been obvious to the person of ordinary skill, the physician who's telling the patient what to do, that you should -- when we develop this device we should add in this -- showing this graph so the patient will know he should have taken some insulin?

MR. PATHMANABAN: Well --

JUDGE FREDMAN: Or at least tested to see if he needs the insulin.

MR. PATHMANABAN: Of course. And let's go to the *Paradigm* disclosure and I'll explain that in the context. If you go to slide 11, please. We're not suggesting that all this backfill data is just ignored. Right? That's not our suggestion. The point is that the FAQs are very specific of what happens with the backfill data. Right? So if I can just walk through this and I will get to your question Your Honor, and I promise.

In yellow on slide 11, I've highlighted what happens when it's within range without an adverse condition. When it's within range, the CGM data will be displayed on the insulin pump screen. It says that. They are going to spell out when it's displayed on the insulin pump screen. And then in green, if the transmitter and pump are out of range for longer than 40 minutes, only the last 40 minutes will be repopulated. It doesn't say will be repopulated and displayed on the instant phone screen.

JUDGE FREDMAN: Okay. But how else would it be repopulated? That is, if I have the device and I'm a patient using it, how else am I going to see the data? I'm going to expect it. Well, you're on your hiking excursion in the jungle and I'm going to go to find a computer to plug it into and download it? I mean, that's not sensible. It's going to -- the ordinary artisan would recognize if you repopulate it in the screen, there's no other place to put it.

MR. PATHMANABAN: Well, respectfully, I would --

JUDGE FREDMAN: Where else would you put it?

MR. PATHMANABAN: Well, respectfully, I would disagree. It's repopulated in memory and then you can -- it says in blue when reviewing historical reports. And you can search this *Paradigm* documentation, I did a search, to search for reports. Okay? Nowhere does it describe reports in the context of data displayed on that small screen. It is always talking about reports in the context of CareLink reports for downloads. When reviewing historical reports --

JUDGE FREDMAN: Again, that's really an anticipation argument. You're failing to address the obviousness argument, which is not what the word means there, but whether the ordinary artisan will recognize it's obvious to put it on the screen for the patient's use. That's the question. Not the question of what -- whether historical could be downloaded onto CareLink later, right? The question is, would it have been obvious to the ordinary artisan at that time that it would be beneficial to put it on the screen?

MR. PATHMANABAN: Yeah, but --

JUDGE FREDMAN: That's the argument they're making and that's the argument I see you have on the screen.

MR. PATHMANABAN: Well, two responses. First, that is not the argument they're making. Yes, the ground 1 is obviousness as a whole. But they're not saying it would have been obvious to a person of skill in the art, in view of the *Paradigm* disclosure, to put the data on the screen. That is not at all what the argument is. They're saying this actually discloses putting the data on the screen. So we are bound by what's in the petition. So that's one. But even otherwise it would not be obvious for the reasons laid out in their own patents. Right? It says that you lose battery power. And remember, we're talking about devices, in this case 2007, battery power is highly constrained. Processing power is constrained.

And also, it says, let's go to slide 20, they have other patents, also Exhibit 2024, for example, where they talk about how the user may be confused if you backfill data because -- and remember this is an insulin pump. Right? So the whole *Paradigm* thing, *Paradigm* system is talking about CGM used in conjunction with an insulin pump. And the whole point is it's going to figure out when the user needs insulin and pump insulin. Correct? So if you have missed data and then it backfills, the user would be confused. Well, why didn't I see a spike? Why didn't I get an insulin dose at that point? That's part of the confusion here. Right? And that's why you wouldn't necessarily backfill and display the backfill data at the pump as required by the claim.

JUDGE HARDMAN: Counsel, I want to go back to something. I think you suggested that Petitioner's argument is solely based on the disclosure that *Paradigm* and the other documentation actually discloses

backfilling. But don't they also have in their paragraph 60, which I know Patent Owner has taken a lot of -- made a lot of arguments about whether we should consider paragraph 60 of Dr. Gross' declaration or not, but that paragraph, isn't he there articulating that regardless of what *Paradigm* says or doesn't say, he's saying it would have been obvious to a person of ordinary skill in the art to display the missing data in order to present as much accurate data as possible to the user?

MR. PATHMANABAN: Well, I believe the statements -- first of all, that paragraph 60, as, Judge Hardman, you pointed out, is extremely conclusory and we've made those arguments why it should carry no weight. But to answer your question --

JUDGE HARDMAN: Just to clarify, if you were suggesting that I said it's conclusory, that's not what I said. I -- my --

MR. PATHMANABAN: No, no, no, no.

JUDGE HARDMAN: Thank you. Go ahead.

MR. PATHMANABAN: We think it's conclusory, to be clear. But in any event, that paragraph 60 is in the context of establishing a motivation to combine the *Paradigm* documentation with *Patel-2009*. That's what the paragraph 60 is for. Why you would combine *Patel-2009* with *Paradigm*'s alleged disclosure of real-time data, including backfill data and the CGM display, according to Mr. Gross or Dr. Gross. That is not to say that he is opining that it would have been obvious, it would have been common sense to do this.

JUDGE FREDMAN: He is opining that exactly, actually.

MR. PATHMANABAN: Well, in any event, I've given you answers for the reasons why we think that it would not be obvious to do that, Your

Honor. That is, you know, the battery power, the processing power loss, the stale data, and the confusion that's caused by the users.

Let's go to slide 12. When reviewing -- these are other two FAQs that have been discussed in the papers, but I'll just briefly here. Again, it says, "when reviewing historical reports you would notice 'data gap' when information is missing during this period of time." Tellingly, it doesn't say you would notice data gap on the screen of the user.

And I want to just remind Your Honors that this *Paradigm* documentation, it's for users, right? It's for your teenagers, it's for 70-year-old grandmothers. And you would expect this type of documentation to spell out if the data is going to be backfilled, it would have said so specifically you will see this data as part of the data that you see on the screen. It doesn't say that, neither the *Paradigm* documentation that they relied on or the user guides that we've submitted, for example, Exhibit 2018. It doesn't say anything about backfilling whatsoever. And --

JUDGE HARDMAN: By the same token, Counsel, when it -- when *Paradigm* talks about the 3- and 24-hour graphs, it says we're going to show you the last 3 hours, we're going to show you the last 24 hours. And it doesn't say unless there was a -- unless you were out of range for more than 40 minutes or less than 40 minutes.

MR. PATHMANABAN: Well, actually let's go to their slide 2. Thank you for raising that. Let me -- it's interesting. This is Petitioner's slide 2 and you could see the missing data gap that they have highlighted in red at the top right there. There's a data gap that's not backfilled. Nowhere have they shown data gaps that are backfilled here. And, in fact, if you look at this, the current time there is 3:22 p.m., right? And the data that they're

1 looking for in historical data is 3:16 p.m., so that's six minutes and it's still
2 missing data. And nowhere does it show this data being backfilled. Well,
3 they tried to make a case that -- well, you know, they tried to juxtapose two
4 figures together and say this is showing the data gap and this is showing the
5 backfill data. And Your Honors rejected that, rightfully so, in the Institution
6 Decision because it was being taken from different chapters of the *Paradigm*
7 documentation in this.
8 JUDGE FREDMAN: They're not saying it anticipates. You keep
9 making an argument, an anticipation argument, and I don't think that that's a
10 good argument to be making in an obviousness case.
11 MR. PATHMANABAN: I understand, Your Honor. And for the
12 reasons I've explained --
13 JUDGE FREDMAN: I hear them. I'm just saying you keep making
14 the same argument and they don't show backfilling as anticipatory. Right?
15 MR. PATHMANABAN: But --
16 JUDGE FREDMAN: And I agree with that, that there's no
17 anticipation. That I think is true. Right? The problem here is that we have a
18 showing of an empty gap, right, right in that figure. And we have a teaching
19 that backfilling can be done. And we have a statement from Dr. Gross that
20 there's a reason to backfill. Right? Because the patient would see the data
21 and then after that six minutes, and six minutes is a pretty short time, the
22 patient's starting to feel a little faint and they looked at their device, they
23 realized they were exercising too long, they need some glucose, you know,
24 or whatever.
25 MR. PATHMANABAN: Well --

JUDGE FREDMAN: I mean, essentially that's a reason to do that. And that's something that Dr. Gross indicates the ordinary artisan would know. That's the question. It's obviousness. You keep arguing anticipation.

MR. PATHMANABAN: Well, let me address his point that you would want to know data. You would want to have the data as soon as possible. So that is actually contradicted by other opinions he's provided.

Let's go to their petition at page 54. And this is in the context of claim 19. Great. So this claim requires "configured to wait a predetermined period of time after the correction of the adverse condition before displaying the second line graph." Okay? And in the context of saying why this claim is obvious, Dr. Gross -- Mr. Gross, I think it is, says the opposite. Let's go to the next page.

Here they're citing Mr. Gross, the petition does. And they're arguing, alternatively, POSITAs would have found it obvious to wait a predetermined time, e.g., 10 minutes, 2 update cycles, before displaying repopulated data -- glucose data. So they're trying to have it both ways. They're saying, well, you want to show it right away, or it would have been obvious, just wait. Right? The point is that this is all hindsight. It's all hindsight for him.

JUDGE FLAX: One more question about that, sir. I feel like what they're arguing relates to the intermittent updating of that system and that the lag is the time between when that next one would happen. Is that not right? Am I misunderstanding?

MR. PATHMANABAN: They are pointing to the lag, but they are -- as you -- as explained in this statement, POSITAs would have found it obvious to wait a predetermined time. It could be 10 minutes.

JUDGE FLAX: Right. Is that not the predetermined time? So, for example, if I'm updating every minute or if I'm updating every five minutes and I have a -- immediately, I have a disconnect. It's going to be the adverse event, but I have a whole other 50 seconds before it's going to update, is that -- that doesn't count as the lag?

MR. PATHMANABAN: We're not disputing that that could be a predetermined time, just to be clear.

JUDGE FLAX: Okay.

MR. PATHMANABAN: But my point is that Mr. Gross, actually, in his declaration at paragraph 44, says it would be obvious to wait for as long as 18 minutes. Eighteen minutes. So, if so, why is it so critical to have backfilled data, which, according to him, it was critical and that's why you would display it on the screen.

JUDGE FLAX: What was his reasoning for 18 minutes as opposed to the next time it updated?

MR. PATHMANABAN: It is all conclusory, Your Honor. I mean --

JUDGE FLAX: So 18 was just kind of pulled out of the air?

MR. PATHMANABAN: Correct. It says, e.g., every 10 seconds, minute, or 5 minutes, 18 minutes, et cetera. So he's not even stopping at 18. He says it could be 40, according to him.

JUDGE FREDMAN: I don't think that's totally out of the air. In his declaration he stated a 2008 article by Breton could be the maximum sampling frequency, the Nyquist rate, for accurately determining blood glucose from interstitial glucose accounting for noise as longer than 5 minutes and optimally 18 minutes. And I'm pretty sure that comes out of nowhere. He's citing a reference to support that position.

MR. PATHMANABAN: Well, he also -- but, okay. So indeed that is inaccurate. Well, perhaps I overstated that. But let me just say it is contradictory to say, on the one hand, you would want this data immediately, it was critical for patient care, all that, and then say it could be you could wait 10 seconds, minute, 5 minutes, 18 minutes, et cetera. I just don't think that you can reconcile those statements and that speaks to the hindsight nature of his opinions.

And while I'm at it, let me just address one more point. Mr. Vandenberg made a big point about Dr. Ahmann and how he was the only doctor who prescribed CGMs to his patients. Dr. Ahmann was not even their expert who supported their petition. We pointed out in our Patent Owner's response the conclusory nature of Mr. Gross' opinions, especially because he was not a clinician, he was not a trained medical doctor and whatnot. And they came back with Dr. Ahmann's belated declaration, which almost wholesale adopted Mr. Gross' opinions. So it's all -- that speaks to the conclusory nature of Mr. Gross' opinions, in my view.

Let me just -- while we're talking about Dr. Ahmann, if I can point to slide 15, please, of Petitioner's slide. I apologize for jumping around. I've got four minutes. Let me just quickly do this. We asked Dr. Ahmann at his deposition, this is in the context of historical reports, the Petitioner disputes that that only refers to CareLink reports. Well, we asked him, "Can you point me to any evidence in your declaration where the document or authors use the word 'report' to refer to a graphical display on the user display?" Answer: "No, I can't."

He can't point to any evidence in the record to say a report means some something else other than these reports generated by CareLink or the like. He can't point to a graphical display.

Also, we can go to slide 27. We asked him "one way to inform the patient that there was no alarm because of a data gap would be to display backfill data differently. Correct?" Answer: he admits that there would be a benefit to doing so. Why is this important? Well, they have not in their petition -- I already talked to how they tried to juxtapose two portions of the *Paradigm* documentation. Your Honors are familiar and, rightfully so, rejected that argument.

In response, they say that -- let's go to slide 24. They try to meet the 1.L limitation, which, again, requires backfill data to be displayed as a line graph. They say, well, they've pointed to 1.H, 1.I and 1.K and, therefore, 1.L is met as well. Well, that's a new argument. It's belated and it's improper. But even otherwise it's wrong because if we go to slide 26, the limitations of 1.L are different from 1.H, 1.I, and 1.K. They're not the same. 1.K requires backfilling, but 1.L tells you how you backfill. It's the second line graph after the adverse condition is corrected. And they have not shown any evidence that that happens in *Paradigm*.

In my remaining two minutes, I do want to address the history portion that Mr. Vandenberg spent some time on. And that is -- oh, let's go to slide 16. I believe there was some suggestion that there's no evidence in the record that this *Paradigm* displays data values as opposed to a line graph. That is absolutely wrong. There is evidence. This is Exhibit 2018 at page 124. It discloses displaying the daily averages and, although not shown

here, it also discloses the high and low, for example as a data value, not as a line graph.

Let's go to slide 17. Okay. So Mr. Vandenberg spent some time about history and how, in his view, that is an example of a historical report. Well, tellingly absent there is any mention of the word "report." It just says "history." And there's no evidence that this history -- yes, you could scroll left and see history. There's no evidence that that disclosed -- that included backfill data.

Were there any other questions on this?

JUDGE FLAX: Your rationale for not providing data, wouldn't -- is it because it might use an extra battery? Is that right?

MR. PATHMANABAN: Battery, user confusion, among other reasons. Processing power.

JUDGE FLAX: Okay.

JUDGE HARDMAN: Counsel, is this 24-hour graph that you've shown here, is that the whole 24-hour graph or what -- it says you can scroll, but what are you scrolling to see?

MR. PATHMANABAN: So I -- this is -- I don't believe is the 24 -- the whole 24 hours. I think you can scroll left to see the remainder of the 24 hours.

JUDGE FLAX: I think that's 24 because the dark area is 12 hours --

MR. PATHMANABAN: Oh, I apologize.

JUDGE FLAX: -- and the other area is equal to the dark area. So that seems to be 24, you know, even with my math skills.

MR. PATHMANABAN: Twelve hours, yeah, that's right. I apologize. I apologize.

Okay. I'll reserve the rest of my time for rebuttal.

JUDGE HARDMAN: Thank you.

MR. VANDENBERG: My partner is my tech support, too. Apologize. I'm going to need about 30 seconds.

JUDGE HARDMAN: Sure, go ahead. Just let me know when you're ready.

MR. VANDENBERG: Thank you. Thank you. So I'd like to address claim 21. I think that the first point, Counsel said that there was zero evidence that the dotted line that is continued from 16 and 12 is the sensor. But Counsel did not address *Patel* paragraph 60 that I mentioned in my argument in which it said that the sensor interface could be permanently connected to the sensor set. So we submit that the transceiver in yellow has a sensor interface. That teaches that it's interfacing with the sensor and indeed it needs to interface with the sensor. That's how the transceiver gets the data from the sensor. So this thing doesn't work until you put them together, physically couple them together. And once you do, there's the circuitry in the transceiver that includes the sensor interface. That's part of the transceiver circuitry. You have a male-female connector that allows that interface and, therefore, the sensor by definition must extend. It's not like a wireless connection. It's a physical sensor interface connecting with the sensor and, therefore, that would --

JUDGE FREDMAN: Which takes us back to this earlier comment or argument or question. The USB that we're attaching to the computer, right, you wouldn't say that those were integrated even though they are electronically connected?

MR. VANDENBERG: So that analogy is distinguishable in that this product doesn't work until you physically connect them. The laptop works prior --

JUDGE FREDMAN: The USB doesn't work.

MR. VANDENBERG: Well --

JUDGE FREDMAN: The USB is one of the sensors.

MR. VANDENBERG: Right. The functionality of the overall product is not USB. The USB doesn't do me any good unless it is now -- unless the computer is functioning. I can't get data out of the USB unless I have a functioning computer.

JUDGE FREDMAN: Because it shorts, right? You can have it integrated as you have it, and the potential argument that they're arguing there's two pieces that are put together.

MR. VANDENBERG: Right. Well, again, in this context, what was the purpose of the sensor set and the transceiver? The purpose was, you know, for them to get in sensor measurements from the sensor into the transceiver, store it, process it, convert it to glucose data, send it off to a monitor. And that won't work until you put these together the same way that the specification of the '056 says you physically couple them together. So we submit that that's distinguishable from the interface. My computer is going to work fine with or without the USB port. The sensor is doing me no good until it's physically coupled into the single unit. The transceiver is doing me no good until they're physically coupled together and, again, they act as a unit. At that point they're on the body. The adhesive supports both of them.

The second point, Counsel argued that the sensor was attached to the body before the trip transceiver was inserted. We don't think the claim excludes that, but nevertheless, *Patel* paragraph 073 says that the sensor may be connected to the transceiver before the sensor is placed on the skin. So it has alternate embodiments in *Patel*.

Counsel is saying that you're ignoring the word "single." Our position is they're ignoring the word in "integrated." Again, the claim says that the portion of the glucose sensor and the transmitter unit are disposed within a single integrated housing. We submit it doesn't say within a single housing there. It says within a single integrated housing. So if they had a problem with our position on 8A, they needed to point on the single issue. They had to point to two integrated housings there, but they don't. We've identified one integrated housing and, therefore, the sensor is disposed within that one integrated housing.

Do Your Honors have any questions on claim 1 other -- I think I have responses to some of what Counsel said, but I'm happy to stop there and just limit it to claim 21.

JUDGE HARDMAN: Nothing for us.

MR. VANDENBERG: Okay. Thank you so much

JUDGE HARDMAN: Thank you.

MR. PATHMANABAN: Give me one second, Your Honor. Counsel talked about *Patel-2009*, paragraph 60 that says -- it says something about a permanent connection. First of all, it is not at all clear how this permanent connection is made. It doesn't say in *Patel-2009*. It could be as shown in *Patel-2008*, which I've highlighted in slide 50, where you have a wire that fuses the transmitter and the sensor set. So *Patel-2009*, it might say these

things can be permanently connected. It doesn't say how. It certainly doesn't say it has -- it's done so within one single integrated housing.

I didn't quite understand Counsel's point that we're trying to read out "integrated." Integrated helps us. Single -- it has to be single and it has got to be integrated. It's got to be both of those things. Simply adding the word "integrated" doesn't broaden the claim somehow and weed out "single" from the claim. It's got to be one housing that houses the transmitter and sensor set integrated together. That would be our position.

Just wanted to make clear I didn't misspeak. The sensor -- just I believe I made this pretty clear, but the sensor 12 is what they pointed to as the sensor. That is different from the sensor set. Okay. That's sometimes in the art, it's sometimes in the field. It's referred to as an OBU, on body unit. That is different from what is the glucose sensor that they have labeled for (inaudible).

JUDGE FREDMAN: And just to -- I don't think they point in the petition to an argument that it was an obvious (inaudible). Right? Is that true? In the petition, that would have included making -- for claim 21 it's just the one showing of the device.

MR. PATHMANABAN: Correct.

JUDGE FREDMAN: There's not really a -- even a citation of the MPEP 2144 talking about making these integrated, right?

MR. PATHMANABAN: Hundred percent, right. Yeah.

He talked about a physical connection between the sensor itself and the sensor interface. That's referring to figure 8A in *Patel-2009*. And if you go to that figure, it's a block diagram. Okay. And what is very clear is that the sensor interface is different, is separate from the sensor. It is not part of

the sensor. The sensor interface sits on the PCB board of the transmitter. Okay. And, of course, you have to have an electrical connection to the sensor. But that doesn't show in any way, shape, or form that the sensor extends into the transmitter housing.

Absent any further questions, that's all I have.

JUDGE FREDMAN: I'm kind of interested in one thing. I mean, you keep talking about the motivation for claim 1. And I was just looking at the Ahmann declaration, this is paragraph 49, he talks about it is "indisputable that having extra information with the CGM devices prior to 2009 (inaudible) therapy decisions based on indicators from the sensor values or trends." And he concludes the paragraph by saying, "Missing data could cause missed opportunities from glucose control for reduced hypoglycemia." And this was in the understood (phonetic) part in 2009.

And he points to a paper in Exhibit 1046 by Burge, *et al*. He tells the story of a person who was driving home and his glucose levels were going down. And even though it was still within the normal range, the CGM sensor clearly demonstrates that his blood glucose concentration was abruptly declining, most likely get in hyperglycemic range before you're out of town.

So that's sort of a story that suggests that there is a reason that Dr. Ahmann isn't just making this up. He's saying, well, the reason you want to fill in that data is to see that trend going down, so you know that. So you know you should be taking a snack then rather than later.

MR. PATHMANABAN: He hasn't pointed to any contemporaneous device that did that. This is all sort of hindsight.

JUDGE FREDMAN: (Inaudible) --

MR. PATHMANABAN: Yes, there -- was there --

JUDGE FREDMAN: I agree with you, it's not anticipatory. The question is, is it obvious?

MR. PATHMANABAN: Well, but my point is it shows the hindsight nature. If it weren't so obvious, why didn't anybody do it before? Why didn't anybody -- DexCom, you know, they tout themselves to be the leaders of CGM and they invented this space. And from 2003 onwards, they didn't have devices that backfilled. Why didn't they? It's all hindsight-based. Of course, sitting -- standing here today we can claim, yeah, we're obvious, everybody wants to do it, everybody wanted trend lines and wanted it as fast as possible so they could eat or they can make treatment decisions and what's on and so forth. They were constrained by technical issues at the time, processing power, battery power, as well as user confusion. These were real issues that they had to deal with. So that's, I submit, hindsight-based. Okay?

JUDGE FREDMAN: Okay.

MR. PATHMANABAN: Nothing else? Thank you very much.

JUDGE HARDMAN: Thank you, Counsel. Well, thank you to both parties for your presentation today. This case is submitted for preparation of the final decision in due course. And with that, we're adjourned, but I do ask that Counsel stick around in case Mr. Watson has any questions about spellings.

(Whereupon, the proceedings at 11:42 a.m. were concluded.)

PETITIONER:

John Vandenberg
Andrew Mason
Amy Haspel
Tucker Mottl
KLARQUIST SPARKMAN, LLP
john.vandenberg@klarquist.com
andrew.mason@klarquist.com
amy.haspel@klarquist.com
tucker.mottl@klarquist.com

PATENT OWNER

Peter McAndrews
Leland Hansen
David Petty
Michael Carrozza
McANDREWS, HELD & MALLOY LTD.
pmcandrews@mcandrews-ip.com
lhansen@mcandrews-ip.com
dpetty@mcandrews-ip.com
mcarrozza@mcandrews-ip.com

Giri Pathmanaban
giri.pathmanaban@lw.com