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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,
Petitioner

v.

MIRACOR MEDICAL SA,
Patent Owner.

IPR2025-00096 (Patent 11,351,356 B2)
IPR2025-00112 (Patent 11,351,357 B2)
IPR2025-00113 (Patent 11,376,415 B2)
IPR2025-00114 (Patent 11,572,879 B2)
IPR2025-00115 (Patent 11,674,517 B2)
IPR2025-00116 (Patent 11,754,077 B1)

Record of Oral Hearing
Held: March 5, 2026

Before ANNETTE R. REIMERS, JAMES A. TARTAL, and JOHN D. HAMANN, *Administrative Patent Judges*.

IPR2025-00096 (Patent 11,351,356 B2)
IPR2025-00112 (Patent 11,351,357 B2)
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IPR2025-00114 (Patent 11,572,879 B2)
IPR2025-00115 (Patent 11,674,517 B2)
IPR2025-00116 (Patent 11,754,077 B1)

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The above-entitled matter came on for hearing Thursday, March 5, 2026, commencing at 1:04 p.m. EST, at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P-R-O-C-E-E-D-I-N-G-S

1:04 p.m.

JUDGE TARTAL: Good afternoon. We are convened for oral arguments in six related inter partes review cases between Abbot Laboratories, Petitioner, and Miracor Medical SA, the Patent Owner.

The cases are IPR 2025-00096 concerning US Patent Number 11,351,356 B2, IPR 2025-00112 concerning US Patent Number 11,351,357 B2, IPR 2025-00113 concerning US Patent Number 11,376,415 B2, IPR 2025-00114 concerning US Patent Number 11,572,879 B2, IPR 2025-00115 concerning US Patent Number 11,674,517 B2, and IPR 2025-00116 concerning US Patent Number 11,754,077 B1.

I am Judge Tartal, and I am joined today by Judge Reimers and Judge Hamann who are appearing remotely. Let's begin with appearances for both parties for those who will be arguing today. If anyone else is attending in person or remotely with you today, but will not be speaking, please identify them as well.

And we will begin with appearances for Petitioner.

MR. BORDER: Good morning, or good afternoon Your Honor. I'm with Counsel for Abbot. I will not be presenting today however, Saranya Raghavan will be delivering the argument as will Nimalka Wickramasekera. And then our LEAP practitioner, Kevin Boyle will also be presenting argument today.

And with me also is Chuck Klein from my firm, Winston and Strong.

JUDGE TARTAL: Okay. Welcome. And for Patent Owner, if you could do appearances please.

MR. CAHILL: Good afternoon. I am Ron Cahill, Lead Counsel for Miracor Medical. I will be arguing today. With me are my partners, Derek Roller and Todd Vare.

JUDGE TARTAL: Okay, welcome Counsel.

Welcome to everyone to USPTO's Alexandria office. Today's hearing provides an opportunity for Counsel to orally advocate for your positions on patentability of the challenged claims as raised in the petitions. Recording of any PTAB hearing is prohibited.

Public access to this hearing has been provided to enable public attendance. It is our understanding that no confidential information is at issue today.

Is that correct, Patent Owner?

MR. CAHILL: Correct.

JUDGE TARTAL: Okay. And Petitioner?

MR. BORDER: Correct.

JUDGE TARTAL: The court reporter will provide a transcript of the hearing that will become part of the record. We have six related cases being argued together today, and a single transcript of this complete hearing will be entered into the record for each of the six cases.

We understand the arguments provided apply to all six cases. However, if you are addressing an issue particular to a specific case, it would be helpful to make that clear on the record.

We have the demonstratives as well as the briefs and evidence available to us on our computers. We are aware of Patent Owner's objection to one of Petitioner's demonstratives. We note demonstratives are not evidence and will not be relied upon for the final decision. Patent Owner may address its objection during its argument time, and it will be taken under advisement.

We ask that the parties not interrupt each other, and instead to hold the objections regarding the parties argument until it is your time at the podium. To ensure the transcript of this hearing is clear we ask that you speak directly into the microphone when talking, and to identify specific slide numbers and numbers for any figures when referring to any demonstratives.

We issued hearing orders in each of the cases at issue. Each party has been granted a total of 90 minutes to present their argument for all six cases. We received Petitioner's request for Kevin Boyle to participate in the oral hearing under Legal Experience and Advancement Program, or LEAP. Accordingly, Petitioner will have an additional 15 minutes of argument time during the oral hearing bringing their total argument time to 105 minutes.

Petitioner will open the argument and may reserve rebuttal time which may not exceed more than half of Petitioner's total argument time. Patent Owner may the respond to Petitioner's argument and may address any motion to exclude. Patent Owner may reserve sur rebuttal time, also not to exceed more than half of Patent Owner's total argument time.

We will maintain a clock, and we'll try to provide a warning as we approach the end of your time available for argument. You also have available a timer that includes a light that changes to yellow when you are nearing the end of your time, and to red when you have run out of time.

Petitioner, we'll begin with you. Do you wish to reserve any rebuttal time out of your 105 minutes?

MS. RAGHAVAN: Your Honor, we'll reserve 70 minutes for opening remarks and 20 minutes for the remaining, including the LEAP time for rebuttal.

JUDGE TARTAL: So, we'll begin with 70 minutes.

MS. RAGHAVAN: Yes, that's correct.

JUDGE TARTAL: Are there any questions from Patent Owner at this time?

MR. CAHILL: No, Your Honor.

JUDGE TARTAL: And any questions from Petitioner at this time?

MS. RAGHAVAN: None, Your Honor.

JUDGE TARTAL: Then Petitioner you may begin when you are ready. And sorry to interrupt. If we need to, we'll plan on taking a short break after Petitioner and Patent Owner have provided their initial arguments and before any rebuttal time to give the court reporter a chance to stop. Unless it appears unnecessary.

And you can begin when you are ready.

MS. RAGHAVAN: Thank you, Your Honor.

Good afternoon Your Honors. My name is Saranya Raghavan. I represent the Petitioner, Abbot Laboratories in these six IPRs.

To help orient us today, I am going to Slide 2 of our demonstratives which are Exhibit 1054 in the record. And this provides a chart of the six IPRs, the challenged claims, as well as our bases and grounds for challenging those challenged claims.

As Your Honors are aware, Petitioner presents four alternative grounds in each of the petitions. And if we turn to the next slide, this slide gives us -- Slide 3 gives us an overview of the various grounds. And what we understand to be the remaining disputed issues that we will be addressing today.

Per Your Honor's guidance at the pre-hearing teleconference we will be reserving our arguments for the disputed issues only. But if Your Honor has additional questions relating to other issues, we're happy to address those as well.

I will be starting with addressing Ground 2, which is the reference that -- which is the ground that covers Bourque as well as Bourque and the Wampler combination. And my colleague Ms. Wickramasekera will be addressing the remaining grounds, Grounds 1, 3, and 4.

So we'll start here with the axially aligned limitation as it pertains to Ground 2. And I will move on to Slide 6 of our demonstratives.

Here you can see how the axially aligned limitation is used in the '356 Patent and I will submit that it's used in a similar fashion in the other patents as shown in the limitations on the chart on the right. And so what this limitation pertains to, to give it context here, is that the magnetically driven motor is axially aligned with the inflow tube.

If we turn to Slide 7, in the petition, just as a reminder to set some, to set the stage here. Petitioner argued that the inflow subassembly of Bourque, which is shown in the green rectangle on the slide to the image to the left here from the institution decision. And we contended that the inflow sub-assembly is axially aligned with the element labeled the roto, which is in the pink box in the diagram to the left.

In the institution decision, at Page 32, the Board acknowledged that the Petitioner pointed to the portion of Bourque's inflow assembly that was after the 90 degree bend that connected into the impeller portion of the pump. But the Board finally held that -- the Board was not convinced on the record that it existed at that time, that that portion was enough to satisfy the axially aligned limitation of the patent.

The dispute has evolved a bit since the papers that were exchanged since the institution's decision. And that is the reason why Petitioner wants to revisit this argument at today's hearing.

The dispute, as it relates to the parties exchanges has now boiled down to whether the entirety of the inflow subassembly of the Bourque patent needs to be axially aligned in order to meet the claim limitations. Or whether it's enough for just a portion of the inflow subassembly to be axially aligned with the rotor to meet the claim limitation. Petitioner of course contends that the latter is enough. And Patent Owner disagrees.

So if we turn to Slide 8. We'll start with the position that Bourque is a centrifugal LVAD. As it says in the title of the Bourque prior art reference, so that's Exhibit 1007, and by definition a centrifugal LVAD provides a 90 degree redirection of the blood such that the inflow is axially aligned with the rotor as shown by the arrows in the diagram on the bottom right. So --

JUDGE TARTAL: Counsel, could I just interrupt you for a moment and address the claim language itself? Which, I think may be part of what is helpful to understand your position on. Because I believe shown on Slide 6, the language refers to a driven rotor that is axially aligned with the inflow tube. So is that referring to the inflow tube as a physical structure or to the fluid flowing in the inflow tube?

MS. RAGHAVAN: Happy to address that, Your Honor. It is referring to the structure of the inflow tube. And as the institution decision actually pointed out, the flow goes through the inflow tube of course. But we understand that the claims require that the structure be axially aligned.

JUDGE TARTAL: And so with your, with regard to your Slide 7, what is the structure in the green box?

MS. RAGHAVAN: The structure in the green box is a portion of the inflow subassembly that is connected to the magnetically driven rotor that is shown in pink here.

JUDGE TARTAL: Is it the inflow tube?

MS. RAGHAVAN: That is the inflow tube.

JUDGE TARTAL: And what is your argument as to how that is axially aligned as opposed to the flow within the tube?

MS. RAGHAVAN: Sure. So let me jump ahead a few slides to get to that point.

So what I was getting to earlier is that a centrifugal pump by definition has an inflow tube that is axially aligned with a rotor. And that is the type of pump that Bourque is. But in addition to that --

JUDGE TARTAL: Let me just stop you for a moment. Where is that definition? I thought you said the definition of a centrifugal pump is --

MS. RAGHAVAN: It's understood in the art that a centrifugal pump essentially means that there is a 90 degree redirection from the

direction of the blood coming in from the inflow tube, and then it exits out at a 90 degree angle.

JUDGE TARTAL: Is the definition in the record that you can refer to or cite actually, so that you're not just relying on attorney argument?

MS. RAGHAVAN: Yes. There's --

JUDGE TARTAL: And you can get that to me when you --

MS. RAGHAVAN: Okay Your Honor.

JUDGE TARTAL: With your other stuff.

MS. RAGHAVAN: We'll get back to you on that specific cite. And just to orient us again as to the structure of the inflow tube that we're referring to, the portion of the Bourque inflow subassembly that is at issue here is the portion that is show in green from Figure 1a of the Bourque reference.

So what Patent Owner seems to be contending is that everything from the suction end of the inflow cannula, followed by the flexible recovery section all the way into the portion that actually extends into the pump essentially needs to be axially aligned in order to meet the limitation.

And our understanding is that this claim term as well as any other claim term under Federal Circuit's guidance has to be interpreted in light of the specification, and in light of the embodiments that are disclosed within.

So if we look at the Federal Circuit's guidance in GP Lightning Solutions, this is a decision from the Federal Circuit. It's entitled *GP Lightning Solutions v. AgiLight Inc.* , and the decision from 2019. It essentially instructs us that claim terms must be interpreted in a way that would not exclude the specifications, only disclosed embodiment.

And so as a result of that it would be incorrect to construe claims here in a way that excludes the only disclosed embodiment of an inflow tube as it pertains to the asserted patents.

So let's take a look at that only embodiment that is provided in the challenged patents. So if we look at Figure 1, that is shown here on the left-hand side. It's an excerpt of Petitioner's reply from Pages 15 to 16.

The inflow tube that's disclosed in the patent is Element 9. It starts off near the triangular shaped element 6, which is the pump that is disclosed in the patent. And then if you follow that line down all the way down to 10, that's the suction end of the tube that's disclosed I the patent.

JUDGE TARTAL: You're on Slide 11?

MS. RAGHAVAN: Yes, that's correct. And if we draw, for just a matter of reference, if we draw a dotted green line through the pump's central -- what would be the pump's central access, we can see that the inflow tube line is actually curving away.

And again, this is the only embodiment of the inflow tube that's disclosed in the patent as Mr. Leschinsky, who is the Patent Owner's expert,

has agreed at paragraph 51 of his declaration. He says here, it's true that the '356 Patent discloses just one embodiment.

He also agreed in his deposition, which we have a cite here for Exhibit 1040, lines 135 -- column 135 from line 19 through column 136 to line 14. That he did, he agreed with us that the inflow tube is in fact curved.

JUDGE REIMERS: Counsel, I have a question for you. Going back to the claim language wherein the magnetically driven rotor's axially aligned with the inflow tube. Is it your position that it only has to be axially aligned with a portion of the inflow tube or with the entirety of the inflow tube?

MS. RAGHAVAN: Yes, Your Honor. Our contention is that it only needs to be aligned with a portion of the inflow tube. Because that is what is shown in the -- that is the interpretation that would be consistent with the patent. Doing so --

JUDGE REIMERS: Well I have a question for you then. So if we were to interpret this claim to mean that, what claim language do you, would you suggest that would then make it, that it would be with the entire inflow tube? I mean, upon reviewing this claim, how would you interpret it that the entirety of the inflow tube would be there? Would it have to say the entire inflow tube or some claim language similar to that?

MS. RAGHAVAN: Well Your Honor, I think that that's a good way of thinking of it in the sense that it doesn't specify whether it's a portion

or an entirety. And so it at least has to be construed in a way that doesn't exclude the only embodiment like the Federal Circuit has instructed.

So we get to Figure -- if we get to Figure 2, we can see the distinction between what would be an entirety and what would be a portion. And then we can better understand what is actually contemplated by the claims.

So if we look at Figure 1, that is the entirety of the inflow tube (9) that is shown in Figure 1. The same inflow tube, a partial aspect of it is shown in Figure 2 of the same patent. These are the same tube. And if we look at Figure 2, that is a cut out of what is represented in Figure 1.

And so it would be incorrect to interpret the term axially aligned with the inflow tube in a way that excludes the only embodiment which we contend, the only full embodiment disclosed on the inflow tube (9) is in Figure 1.

JUDGE REIMERS: Thank you for that clarification.

MS. RAGHAVAN: Of course.

So I'm now referring to Slide 13. So taking all of these together and looking at these side by side, it's either correct that Petitioner is -- it's either correct that Petitioner is correct, that Figures 1 and 2 show the same embodiment of inflow tube (9) which means that Patent Owner's interpretation that axially aligned is incorrect. Which means it was incorrect because it would exclude the only disclosed embodiment in the patent.

That would again run afoul of the case that we just looked at from GP Lightning. Which again would mean that it would include the curved inflow tube such as the one shown in Figure 1. And then we, Petitioner analogizes the curved inflow tube that's shown in Figure 1 of the patents to the curved or bent inflow tube that's shown in Bourque.

And so it's our contention that if Figure 1 can't be excluded from the limitation or the interpretation of axially aligned, and Bourque itself, it's inflow subassembly taken together should be enough to satisfy the claim as well.

The other option here is that Patent Owner is correct that Figure 2 shows axial alignment. That's what Patent Owner argued in its sur reply at page 13. And again, Figure 2 shows a cut out of inflow tube (9), and yet Patent Owner -- or Patent Owner says Figure 2 is enough to show axial alignment.

And so if Patent Owner is correct, that Figure 2 is a different embodiment and therefore we can look at Figure 2 alone to determine whether axial alignment is satisfied then it's analogous to the Bourque situation in which we too are pointing to a portion of the configuration that we highlighted here on the right side of the Bourque image in a red box that shows that a portion of the inflow subassembly of Bourque is in fact axially aligned with the rotor of Bourque.

JUDGE TARTAL: Just a reminder. It is very helpful if you say what slide you're referring to because when we look back on the record, you saying the red box it's hard to tell.

MS. RAGHAVAN: Sure Your Honor.

JUDGE TARTAL: So you're on Slide 14.

MS. RAGHAVAN: I appreciate the reminder. I will flag that going forward. We're on Slide 14.

And Your Honor, going back you had a question regarding where in the record we had support for a centrifugal pump by definition having an axial inflow tube. And we can find that in Exhibit 1008 which is the Wampler reference at Slide 76.

JUDGE TARTAL: Okay. Thank you.

MS. RAGHAVAN: I get to next cover our alternative ground under Ground 2 which is that Bourque in view of Wampler teaches the axially aligned term and renders the claim obvious in that way.

So now -- oh, sorry. Just to fix it for the record I said Slide 76, but I meant paragraph 76.

JUDGE TARTAL: Okay.

MS. RAGHAVAN: If we look at Slide 16 now. Here it's made clear from the initial determination that the Patent Owner does not dispute that the limitation is taught by Wampler and instead argues that the only remaining issue is that Wampler cannot be combined with Bourque. And so

that is the issue that we will be addressing today. It all comes down to motivation to combine.

Patent Owner points to the *Intelligent Biosystems* case in the Federal Circuit which confirms that all that is required for a POSA to have been motivated to combine the teachings from different prior art is to achieve -- is to be able to combine the teachings of the prior art to achieve the claimed invention. And that is going to be critical for us to understand here. And that a POSA would have had a reasonable expectation of success at arriving at that claimed invention. And we submit here that there is substantial evidence in the record to show that.

I'll now turn to Slide 17. Here we have excerpts of both the Bourque reference as well as the Wampler reference. And we see here that Bourque describes a pump design for what it calls the HeartMate III, Roman Numeral III. And it describes that there are bottom components from previously existing components, previously existing pumps made by the same company. So HeartMate I and, HeartMate II.

And the reason for this is because Kevin Bourque who wrote Exhibit 1007, the prior art reference, was focused on coming up with a new design for the pump. And he thought that it would be, for efficiency reasons, it would be easier to just take the peripheral components that were already in use and FDA approved and on the market in connection with HeartMate I and II, and then just use those inflow and outflow components. And that's how he arrived at the entirety of the system in Bourque 2001.

Why I point this out is because then the inflow tube becomes just a design choice. It is a design choice that Mr. Bourque made to use the inflow tube that was already in place or used with HeartMate I or II. It wasn't led by technical necessity.

Now if we turn to the Wampler reference on Slide 17. This is Exhibit 1008. Wampler discloses other options or design choices for an inflow tube for example. In fact, Wampler says in the first sentence that a centrifugal design pump allows a considerable amount of flexibility in implantation. So that leaves open the possibility that you could take a pump that is a centrifugal pump by nature, and you could do a lot of different things with it in terms of implantation.

Then more specifically in the same paragraph, 76 of Wampler, it says, owing to the axial inflow and radial outflow of the pump, a 90 degree redirection of the blood is affected without the necessity of the flow restrictive elbow fitting.

Again this is the paragraph that I was just referring to earlier with regard to the centrifugal pump. But this sentence that I just read necessarily says you can eliminate the elbow that's disclosed in Bourque and not only that, it calls it a flow restrictive elbow. And that's important because it now recognizes some drawbacks that are associated with the elbow in Bourque.

So now that we've seen the disclosures in both Bourque and Wampler, I'd like to turn to Slide 18. Here there's a lot of confusion and

mischaracterization from the Patent Owner in terms of what Petitioner contends is the motivation to combine.

So here I have an excerpt from the petition on pages 80 to 82 that says that a POSITA would have been motivated to apply the teachings of Wampler to Bourque. And specifically that says means to eliminate its elbow so that its inflow tube would also serve as the inflow cannula placed into the apex.

Again, just to clarify we are saying that the inflow cannula can be made straight. And having eliminated the elbow now that inflow cannula can go directly into the apex of the heart.

There is nothing in here in this motivation that says where the pump needs to go. This is specific to the inflow cannula only.

And to arrive at this motivation, we provided four different reasons. We said in our reply that Patent Owner fails to rebut all of our independent bases and really focuses in on the fourth reason.

And while we agree that they did a cursory treatment of the first three reasons, all of their treatment of the four reasons across the board are based on an incorrect assumption that our motivation to combine requires placement in the apex of the heart of the pump, not just the inflow tube, but the pump as well.

Before we get to the four reasons that I just articulated, I would like to address one additional argument that Patent Owner presents. Is that Bourque itself recognizes some benefits to the elbow.

So in order to do this they rely on a 2001 publication by Mr. Bourque, well Mr. Bourque is one of the authors and they cite that in their POR at page 28. And here it says in a highlighted sentence that one of the benefits of having a flexible recovery section or an elbow is to decouple the pump from cardiac motion and to provide a point for clamping and ligation for pump explant.

The issue with this argument, Your Honors is that the Axonics and Medtronic case from the Federal Circuit says a skilled artisan may be motivated to combine some particular features of different references and to secure some benefits at the expense of others.

So while we acknowledge that there may be some benefits acknowledged by Mr. Bourque to the elbow, there are other benefits that we've articulated as part of our motivation to combine to remove the elbow all together. And Your Honors actually found that in the institution decision that we have here on the right-hand side of page 36 to say that Patent Owner did not address then, and it certainly doesn't address now the benefits that -- whether those benefits that would have been lost in the asserted combination, or whether a POSA would have understood the benefits of the asserted combination that outweighed any detriments of having to remove the elbow.

So just quickly here, we can see here that there are some drawbacks to the elbow that are identified as well. So yes, Patent Owner

identifies some reasons to keep the elbow such as the, to provide a point for clamping or ligation for pump explant.

But here their expert himself acknowledges that an elbow creates swirling. For example, we cite Exhibit 2015 which is the Leschinsky declaration on Slide 20 from paragraphs 133 to 134.

Our expert says something similar. Our surgeon expert Dr. Wieselthaler as we have here on Exhibit 1041 at paragraph 49 says that Bourque's pump's elbow was flow restrictive and causes sheer forces. No only that, eliminating the elbow would cause -- would allow the realization of several other benefits. For example, maintaining blood integrity, minimizing thrombotic and hemorrhaging events, and ensuring safer, longer term circulatory support.

So now I'd like to turn Your Honor's attention to Slide 22 of our demonstratives. And here we'll start to address the expectation of success.

So Patent Owner argues that Petitioner's motivation to combine requires placement at the apex of the heart. And again, requires placement of the pump at the apex at the heart and that there is no reasonable expectation of success, or no expectation of success at all for placing the proposed combination at the apex of the heart. And Patent Owner provides two reasons for its position.

The first is that nobody had ever done that before. Nobody had ever put a pump or an LVAD specifically at the apex of the heart before the priority date of the patents.

And the second reason they provide is that proposed combination, which they think is the Bourque 2001 pump, is too big to fit at the apex. But as we'll walk through now, both of those arguments are legally and factually flawed.

I'll start with the legal reasonings. So first, as we see here in their POR and in their -- sorry on Slide 23 we see their excerpts from their POR and excerpts from their sur reply that our combination purportedly requires a pump to be placed at the apex and above the diaphragm.

And if we turn to Slide 24 we can see here that neither or the claims, nor the Petitioner's combination require the pump to be placed at the apex of the heart. I'd like to direct Your Honor's attention to Claim 1 of the '356 Patent. And I submit that the remainder of the challenged claims have similar language.

Here on the highlighted section of Claim 1 of the '356 Patent it says, delivering a heart assist pump device to the heart so that a suction end of an inflow tube of the heart assist pump device is inserted into the ventricle of the heart. So all it says is that the suction end of an inflow tube has to be inserted into the ventricle of the heart. There's no mention of the pump being inserted at the apex at all.

And then to revisit our motivation to combine, we have that here on Slide 24 as well on the right-hand side from the petition pages 80 to 82. Our motivation again is to eliminate the elbow of Bourque 2001 so that the inflow tube would be placed at the ventricle or the apex of the heart.

Why is Patent Owner's proposal of requiring the pump to be implanted at the apex of the heart legally flawed is because as I just showed, Claim 1 doesn't require any particular placement of the pump. It doesn't say anything. It's silent about it. The only thing it requires is for the suction end of the inflow tube to be inserted into the ventricle of the term.

And the *Axonics v. Medtronic* case that we see on Slide 25 says that the context of the claim matters. So in that claim the Federal Circuit, or in that case the Federal Circuit clarified that the proper inquiry is whether the relevant artisan would be motivated to make the combination to arrive at the claims actual limitations.

And there, the Federal Circuit found that a legal framework that required the motivation to combine to apply to what they call the trigeminal-nerve context was improper. Because the trigeminal-nerve context was nowhere to be found in the claims. And the same is true here where the apex of the heart and the pump being placed in the apex of the heart is absent from the claims.

Patent Owner seems to acknowledge this fact, that there's no placement or space restriction in the claims because it turns to the *Intelligent Biosystems* case. And there the Petitioner's motivation to combine dependent on the ability to meet what they called a quantitative deblocking requirement.

And that was the only reason the Petitioner there provided to combine the prior art references. And so the Federal Circuit said because

that motivation to combine and include this quantitative deblocking requirement was central to the question of motivation to combine, that was the reason to defeat the motivation to combine in this case.

Here we're not saying placement at the apex of the heart is central to the motivation to combine. All we're focused on is the inflow tube being a straight axially aligned inflow tube as we started Ground 2 with.

JUDGE TARTAL: Counsel, can I just ask between the two grounds, the one based on Bourque and the one based upon I believe Bourque and Wampler in combination. Are you arguing a difference in claim construction for axially aligned? And is that construction relevant to the motivation for the combination? So in other words, if Bourque teaches what is axially aligned under one proposed definition, which seems to only require some very minimal amount of axial alignment, how does that relate to the argument under Bourque and Wampler that a person of ordinary skill in the art would have had motivation to remove a 90 degree elbow to achieve axial alignment?

MS. RAGHAVAN: Sure. So our primary basis under Ground 2 is to find a correct interpretation of the term axially aligned. And we're saying the proper interpretation is met by Bourque because a portion of the inflow tube is axially aligned with the tube.

When we get to the Bourque and Wampler combination, that interpretation doesn't -- we still believe in that interpretation, we still think

that's the correct interpretation. But it's not required because Wampler explicitly discloses a straight inflow tube.

If I could point Your Honors to that, it's actually in Figure 5 of Wampler. And it's element 13 which is the elongated inlet tube. So if we go back to Slide 17.

I'm referring to the tube that's highlighted here in green. There's no bend. There's no curve to this tube. And Patent Owner doesn't dispute that.

And so our combination of Bourque and Wampler doesn't rely in any way on any interpretation of axially aligned. We believe that it's met just on its face.

JUDGE TARTAL: Thank you.

MS. RAGHAVAN: Okay. Turning next to Slide 26. So the next argument that the Patent Owner makes is that it would be impractically impossible to combine.

And what they're looking at here is if you strictly take the teachings of Bourque and Wampler and combine them, would it create a pump that is practically -- does it have a practical, physical way of being implanted.

Now Your Honors already found in the institution decision that a bodily incorporation argument is improper under the Axionics v. Medtronic case. And that's what we show here on Slide 27. And we continue to believe that is an improper argument because we think that it --

our position is that it's legally improper to require the physical placement of a device and the physical incorporation of a feature to fit in a particular location.

And as we'll show in the next few slides, we also have factual reasons as to why it was in fact possible to physically and practically implant that pump. And we have several different options that we've presented in our papers.

So with that I'll turn to Slide 29. So this goes to the reasons why Patent Owner is incorrect about their -- factually incorrect about their reasonable expectation to combine Bourque and Wampler as well. So as we see here, there are two different ways that the Bourque and Wampler reference, if combined, could have been implanted in a human. And in fact, were implanted in these ways before the priority date of the patents.

That was Patent Owner's first contention was that it was never -- an LVAD was never implanted at the apex of the heart. It couldn't have been implanted. But this slide clearly shows that it's false.

On the left-hand side we have option 1 which is the pump could have been put in a preperitoneal pocket. This is exactly what is already disclosed by Bourque. All we're saying is that we would take the teachings from Wampler, take the elbow out, replace it with a straight inflow tube, and implant it just like how the VentrAssist pump was implanted before the priority date of the patent successfully in several patients.

On the flip side, you could also implant the proposed combination at the apex of the heart. And that would be similar to what was done with the HeartWare HVAD which is an evolution of the Wampler design as we'll walk through in a little bit.

So I want to take a closer look at option 1 which is the VentrAssist device. Here we see on Slide 30, page 2 an image from Exhibit 2013 which talks about the VentrAssist device. And you can see here Your Honor, there's an excerpt from Exhibit 2013 as well that says, a cannula attached from the failing left ventricle delivers blood from the heart to the VentrAssist. And it also says that the blood pump that is implanted goes in a small pocket that is created on the left side of the body, below the diaphragm.

So again, this is exactly what is already disclosed by the Bourque 2001 patent, or Bourque 2001 reference in terms of where to put the actual pump.

And then if we turn back to the figure you see that we've highlighted the or annotated the white tube. That is a straight tube that goes directly from the rotor into the ventricle of the heart. There is no bend. There is no curve. It is an axially aligned inflow tube.

Option 2 for placement goes back to the Wampler device or the HeartWare HVAD. And this device as I mentioned earlier can fit at the apex of the heart. Patent Owner does not dispute that Figure 5 shows anatomical

placement of such a device at the apex of the heart. That's what they -- they agree that Figure 5 of Wampler shows that.

And then in addition to that we have introduced several pieces of evidence into the record as part of our petition and as part of our reply to confirm that that is in fact what was happening when the HeartWare HVAD was implanted.

So we see on Slide 31 we see an example of one such piece of evidence. It's Exhibit 1015. The underlying portion of that says that if this pump was appropriate for intrapericardial pump placement. So that basically means that there is pericardium around, a membrane around the heart, and that's where the apex is. So this pump would fit within the apex.

This Exhibit 1015 also says that the pump has a short integrated inflow cannula. And again we contend that that means that that is a straight axially aligned inflow tube.

So ultimately what this comes down to is that Patent Owner is factually wrong that no LVADs were placed at the apex. We see several excerpts from their expert's declaration. The testimony on Slide 32 of our demonstratives.

And they say that this purportedly didn't happen until at least five years after the priority date. And that, as we've seen from the HVAD evidence as well as the VentrAssist evidence which is clearly false.

And to make this even more clear we introduced Exhibit 1044 along with our reply. And excerpts of that are on page 33. This Exhibit

1044 is dated 2006. So a year before the priority date. And it said -- and it talks about the first clinical experience of the HVAD.

And if you note here on the very first line of the second excerpt. This is, these are statements made by Dr. Wieselthaler. He wrote -- he is our surgeon expert that put in a declaration about his experience about implanting the HeartWare HVAD well before the priority date of the patent, and what his understandings were about what that device looked like as well.

Now faced with this evidence Patent Owner contends that the HeartWare HVAD pump appears nowhere in the four grounds that we've presented in the petition. We submit that that's false.

So if we turn to Slide 35 we see here that we're not relying on the HeartWare HVAD as a cited prior art reference for any of our grounds. What we're relying on is evidence of HeartWare HVAD is to support our evidence of reasonable expectation of success.

And to be clear, we introduced this evidence because Patent Owner submitted that no one had ever implanted an LVAD at the apex of the heart prior to the priority date. And so to rebut that notion that is factually incorrect we submitted this evidence. It is not a part of our combination. That combination remains Bourque and Wampler.

Patent Owner next argues, as we see on Slide 36 that there were no documents evidencing the structure of HeartWare before the priority date. And our response to that is on Slide 37 and we made this point in our reply

papers as well, that there's no need for a structure or a picture of the HeartWare HVAD to be displayed in any of these pieces of evidence.

Because what is most important is what that pump implanted into the apex of the heart, and did it have a short integrated or straight inflow cannula. And both Exhibit 1015 that we have on Slide 37 and Exhibit 1044 which we also have on Slide 37 show that.

And so we see the highlighted portions here from 1015. It says the pump has a short integrated inflow cannula, and it is appropriate for intrapericardial pump placement. And then 1044 says something similar where it says the HVAD is implantable in the pericardial space above the diaphragm, and it has an integrated inflow cannula.

So if we go to Slide 39 we see here there's a case that we cite from the Federal Circuit. Homeland Housewares v. Whirlpool. It basically says that if we have evidence that is clearly contradicted by the record that was submitted by the other party's expert, then that other party's expert's testimony should be ignored on that point. And that is what we submit is the correct result here as to HeartWare HVAD.

And finally Your Honor, with regard to the combination of Bourque and Wampler, we think it is a good way to sum up that Mr. Bourque himself in a 2021 interview, referring to his mindset as of 2006, he himself recognized that he could have made the Bourque 2001 pump smaller.

So he says, between 2001 and 2006 when he was referring to what he was thinking of at the time, chips had shrunk. There were advancements in technology that would have inherently allowed anyone a POSA, including Mr. Bourque to make that Bourque 2001 pump smaller.

It would have been then optimal to fit in a pocket as it was disclosed to be in the Bourque 2001 reference. But perhaps it could have been placed in the apex of the heart as well.

He also says here that when the pump itself is made smaller and you have a little bit more flexibility about where it goes, then he could have perhaps come up with a short integrated cannula like the ones that we've seen used with the HeartWare HVAD pump and the VentrAssist pump.

I'm going to turn briefly Your Honors to dependent claims 5 and 7. And I'm happy to readdress some points if there are questions about these claim limitations on rebuttal as well. But I just want to save time for the remainder of the grounds as well.

Dependent Claim 5 says that the external control unit controls the second magnetic device in response to measurement values indicative of cardiac output of the heart. And if we turn to Slide 43, no 33. We see here that Bourque's external controller controls the pump based on the pump speed.

And first of all Your Honor, I would like to note for the record that there is no dispute among the parties that Bourque discloses an external controller. So the dispute for dependent claim 5 comes down to whether

there are in fact measurement values disclosed that are indicative of cardiac output.

And here we see that Bourque discloses on the left-hand side on page 3, electronics for power and control of the LVAD. So that -- and that resides on a shelf. So that's the external controller. And on the right-hand side also on page 3 we see speed and motor parameters were set and controlled using software. And we submit that the speed is in direct proxy of cardiac output. So therefore it is a measurement value that is indicative of cardiac output.

I'll also say that procedurally Petitioner made certain arguments, Petitioner made these arguments as to speed being indicative of cardiac output in its reply on page 27 in response to concerns and purported deficiencies that were raised by Patent Owner in its POR.

And Patent Owner did not rebut these positions in its sur reply. So it's our understanding that our expert's opinions and our positions regarding the pump speed being indicative of cardiac output are undisputed at this point.

I'll turn now to dependent claim 7. So on Slide 46, dependent claim 7 shows providing feedback signals to the external control unit for one or more sensors.

Again, the fact that Bourque has an external control unit is not disputed. So really the only disputed point is whether the feedback signals are provided from one or more sensors. And we see here that there are

several examples on Slide 47 as to how Bourque discloses such sensors and sensor providing feedback signals.

So on the right-hand side we see Exhibit 1007 at page 3. It says speed and motor parameters. And then we have our expert, Mr. Crosby who opined in his declaration at paragraph 439 that a POSITA would have understood based on the disclosure of the setup, so the calculation is setting the speed and rotor parameters, that those parameters were monitored by a sensor and then provided to the system. So in this case the external controller of Bourque.

And if that's not enough, there's also additional disclosure of further sensors in Bourque. And that is on Slide 48. Again at page 3. Bourque refers to flow measurements that were made with an ultrasonic flow probe and also pressure measurements that were made with a solid state catheter type pressure transducers.

Again, we may -- we introduce these arguments in response to some concerns raised by Patent Owner in their POR. We introduced these in our reply at page 27 and Patent Owner did not rebut them. So we understand that these points are not disputed.

We would also note for dependent claims 5 and 7 that Patent Owner appears to demand more than what the specification itself describes in so far as measurement values that are indicative of cardiac input. But also the sensors that provide such feedback.

For example the only disclosure of measurement now used that provide a cardiac output purportedly would be in column 4 of the '356 Patent at lines 36 through 40 which describe that the control unit 5 in the system can be provided fixed values. Now that is exactly what our position is for dependent claim 5.

And then as for sensors, it's even -- the patent is even weaker. Because at column 1, line 65 through column 2 line 19 the only disclosure of sensors that is meaningfully detailed appears with regard to a known device. So the patent is describing a device that was known in the prior art.

And as for any other sensors it just says, sensors element 4 as it pertains to Figure 4. So we -- it's our position that not only are these issues uncontested as to dependent claims 5 ad 7, Patent Owner's position is also incorrect because they demand more disclosure of the prior art than is actually present in their own specification.

JUDGE TARTAL: I'll just say Counsel, I don't think we would share your view that it's uncontested if they don't address it in their sur-reply. I think the fact that it's raised in the Patent Owner Response and that you provide a reply means we'll take into consideration your reply.

If your reply is insufficient to overcome what our review is, within our review of the Response, they didn't waive the argument or say it is uncontested just because it's not directly addressed in the sur-reply.

MS. RAGHAVAN: Fair enough, Your Honor.

JUDGE TARTAL: I understand your point you're making as to whether or not any additional evidence or argument was provided in the surreply.

MS. RAGHAVAN: Understood. And with that I will turn it over to my colleague, Ms. Wickramasekera to address the remaining grounds. And I'm happy to address any other questions as to Ground 2.

MS. WICKRAMASEKERA: Good afternoon, Your Honors. Nimalka Wickramasekera for Abbot, the Petitioner.

I'm going to start with Slide 49. And I'll be covering the remaining grounds, Grounds 1 through 4. I'm going to start with Grounds 1 and 3 with respect to the Wampler and the Akamatsu references.

And I'm specifically going to start with the axially adjacent and the axially closer limitations. I'm going to address them together and then address the differences between them.

The issue between these two grounds, Grounds 1 and 3, is largely the same. The issue is the plain and ordinary meaning of these terms. Now the Petitioner has put in our petition at page 27 our understanding and application of the plain and ordinary meaning.

To be clear, we did not construe or propose a construction for these terms because we didn't actually understand there to be any dispute regarding the meaning of these terms based on our understanding of Patent Owner's accusation in the district court. And I'll go through that in a little bit more detail.

But in our petition we were clear at page 27 that we understood axially adjacent to mean situated next to each other on the same axis. Essentially no gaps between them on the same axis. That was the understanding that we applied.

If we could look at Slide 50 we see the claim language here. The '356 Patent has the axially adjacent language. And then the '357 Patent has the axially closer language. There is combinations of these terms are at issue in all of the patents at issue in these petitions.

Now I'd first like to look at what the Board said in the institution decision on the two terms. So for axially adjacent the Board considered Patent Owner's argument that axially adjacent requires that they be adjacent to one another as measured along a central access. And the Board has essentially adopted the Patent Owner's position.

I want to be clear here, nothing, none of the claimed components actually sit on the central axis. And so our interpretation in the claim language if you look back at it does not actually say that it needs to be -- these components need to be positioned on the central axis. It doesn't reference the central axis when it says axially adjacent.

But we do agree that the understanding within the context of the claims means essentially it needs to be positioned adjacent to one another along a longitudinal access that is parallel to the central axis. Because none of the components actually sit on the central axis.

So we understood the institution decision's definition when Your Honor's stated that it should be positioned adjacent to one another as measured along the central axis. We understood that to mean along an axis consistent with the claim language, that these components are situated next to one another or adjacent. And then you would map that to the central access and find their locations. Because physically it's impossible for two physical objects to occupy the same position on an axis.

So the issue here is whether Wampler and Akamatsu disclose these limitations under the Patent Owner's of the District Court. We'll also address whether Wampler and Akamatsu disclosed these limitations under the Patent Owner's IPR interpretation.

We would like to make clear to Your Honors that they are directly contradicting their positions before the District Court in order to make their invalidity arguments.

So here Your Honors, on Slide 53 we have shown you exactly what the Patent Owner has accused of infringements and what the prior art looks like.

The prior art closely resembles the accused device in structure and in orientation. All three shown here are having magnets inside a rotor. The HeartMate III which is on the left, the Patent Owner has accused this permanent magnet in a rotor in three separate District Court complaints, and over a dozen infringement contentions.

Wampler, which you see in the middle of Slide 53, Patent Owner admits that this is also a magnet housed within the rotor. And for Akamatsu the Patent Owner admits that this is a magnet imbedded in the impeller.

So the issue here Your Honors is other axially adjacent includes the overlap that you see here for all three of these devices, or it has to exclude Patent Owner's District Court interpretation. This is a situation where they're taking directly contradictory positions before two different boards.

And the Federal Circuit has said this is not appropriate. And this, and the precedential decision in Revvo reiterates this. The directive has just reiterated the point, that a party cannot take inconsistent claim construction positions between two forums. And that's what's happening.

Now I want to go into a little bit of detail as to how they have alleged infringement in this case. So to allege infringement, the Patent Owner has asserted that axially adjacent includes components that overlap or occupy the same portion of an axis, the central -- map to the central axis.

The accused device as you can see, this closely resembles other prior art LVADs that we've been talking about, that my colleague has explained. It's a third generation centrifugal LVAD with a rotor.

Now it rotates, this pink box, the magnetically driven rotor, this rotates together. The entire structure rotates to achieve the purpose of a rotor which is to pump the blood.

The accused device closely resembles these other prior art LVADs that we've been talking about and again, the entire rotor here rotates to pump the blood.

To allege infringement the Patent Owner has asserted that these components which overlap are axially adjacent. Here is the description of the accused device. The accused device indicates that it has a permanent magnet in the rotor. It's expressed. What has been accused of infringement is a magnet inside the rotor.

JUDGE TARTAL: Counsel, if I could just ask you to pause for a moment.

MS. WICKRAMASEKERA: Yes.

JUDGE TARTAL: Because I think for the panel it's not under consideration or our determination as to what infringes or doesn't infringe. And we're not making rulings for the District Court and we're not basing your challenges on any kind of evaluation of your own product for infringement purposes.

So I understand you're perhaps highlighting this to show what Patent Owner might have construed something to mean in District Court, but you seem to be going a bit far afield of what's actually at issue before us, which is your construction, your prior art, how to use it, what the proper interpretation of the claim is. Not whether Patent Owner has made a good accusation or a crazy accusation in District Court.

So I guess I would just suggest focusing on what we need to resolve, not just on the context of all of your disputes with the Patent Owner.

MS. WICKRAMASEKERA: Thank you Your Honor. The issue here though is this raises a *Revvo* issue. Because there is, they are advancing two different interpretations. But I do want to show how under the interpretation the prior art meets it.

JUDGE TARTAL: Is there some interpretation of *Revvo* that Patent Owner loses because of the *Revvo* decision and the positions they've taken? I mean, it's not as though we're going to find in favor of Petitioner because of *Revvo*.

MS. WICKRAMASEKERA: So Patent Owner's interpretation in the District Court, and this is part of the reason why we Your Honors, when we saw the Patent Owner' preliminary response we were surprised by it and we requested additional briefing on this particular issue.

Because our understanding of the interpretation with respect to axially adjacent was that it could be met by components that, where the magnet is inside the rotor. Because that's what they had accused. That's their interpretation.

JUDGE TARTAL: But what is the meaning of the term? You're referring us back again to what they accused in District Court. And that just --

MS. WICKRAMASEKERA: Sure.

JUDGE TARTAL: -- is unlikely to be the basis for how I construe a claim term. I'm not going to say it means a rotor within a magnet or a magnet within a rotor because that's what Patent Owner said in District Court – allegedly said in one filing.

MS. WICKRAMASEKERA: Sure.

JUDGE TARTAL: So it's just not the evidence that we're looking at that's going to be the basis of our decision by in large.

MS. WICKRAMASEKERA: So I can point you to the prior art and explain how this interpretation maps on the prior art.

JUDGE TARTAL: I understand how it maps on the prior art. The question is how is it that that's what that claim language means. It has to be more than an accusation that Petitioner -- excuse me, Patent Owner alleged something in District Court. That cannot be the basis of our claim construction and that alone.

MS. WICKRAMASEKERA: So our interpretation is set forth in our petition. In our petition at page 27, we have indicated that axially adjacent means situated next to each other on the same axis. And I'll show you how this plain and ordinary meaning is met by these two prior art references.

So we're looking at Slide 58. Okay. As I mentioned, the Board's interpretation included as measured along the central axis.

Now as I mentioned, none of these devices have anything actually sitting on the central axis. That's the axis of rotation. The claim

language doesn't specify that axially adjacent needs to be along or in reference to the central axis.

But we do agree that a logical reading of the claim requires that it be at an axis, longitudinal axis parallel to the central axis. If you take an axis parallel to the central axis. A longitudinal axis parallel to the central axis and you run it through Wampler, you will necessarily have a position where you have an impeller, the magnet, and then the impeller again with no gaps and no spaces between them.

So there are axis' that pass through where those components are adjacent. And if you map those to the central axis, they are adjacent, there are no other components next to one another.

There is no reference to them actually being on the central axis and none of these devices have anything at the central axis. That's the axis of rotation.

But the longitudinal axis, so it requires axially adjacent. It doesn't reference which axis specifically in the claim language. It says axially adjacent. The only other axis that's referenced is the central axis.

If you run an axis through this device that passes through both the impeller and the magnet, they are adjacent. They are situated next to one another. That was our understanding frankly when we read their contentions, which is why we did not propose a construction. Because that's consistent with what they were accusing at the District Court.

That was the plain and ordinary meaning that we applied, was that if they're situated next to one another along an axis, that meets the axially adjacent limitation.

So we applied that to Wampler and Akamatsu. And the same is true. If you pass the longitudinal axis through these devices, these components, you will have an impeller and then the magnet. And there is nothing between them on that axis. And that is the way we applied the plain and ordinary meaning.

Does Your Honor have a question?

JUDGE TARTAL: No. Thank you for your explanation.

MS. WICKRAMASEKERA: Okay. So Your Honor it is not simply that we're saying that the Patent Owner is wrong. What we're saying is, we applied what we understood to be the plain and ordinary meaning. It's consistent with the way they read it at the District Court.

But now there's an argument that it can't be adjacent if the magnet is inside the rotor. But that can't be the correct construction because nothing is sitting on a central axis. You have to look at an axis that passes through these components and see, are they situated next to one another along that axis.

That is the correct construction. It is consistent with their position at the District Court, and it is expressly what is taught in these prior art references.

JUDGE HAMANN: Counsel?

MS. WICKRAMASEKERA: Yes.

JUDGE HAMANN: This is Judge Hamann. It needs to be reiterated the point that's already been raised. I think when you mean construction, I understand pointing to what Patent Owner said before may you know, allow us to put some weight as to how credible one of the argument's Patent Owner's making are, and to be specific contradictory.

But again, you know claim construction has been something that's sort of first principles to go to the intrinsic record more than anything else obviously. So I think that's what the focus is. So we're trying to you know, go back to that focus.

And I recognize that you've talked about some of that. But there's also, I think an awful lot put on things that are beyond intrinsic evidence.

MS. WICKRAMASEKERA: Thank you Your Honor. We were following I think the guidance from the recent decision in *Revvo* regarding taking two different claim construction positions in different forms.

As I mentioned, our view of the plain and ordinary meaning is that axially adjacent requires the components be situated next to one another on an axis. And that was our understanding consistent with the positions that the Patent Owner was taking as well as with our understanding of the prior art. And that was the understanding that we applied in our petition at page 27.

And so we --

JUDGE HAMANN: And --

MS. WICKRAMASEKERA: Yes, sir.

JUDGE HAMANN: This is Judge Hamann. And I assume also consistent with the specification in the other intrinsic record.

MS. WICKRAMASEKERA: Yes, sir. That's right.

JUDGE HAMANN: I mean, that's obviously I think the focus and to be consistent with *Revvo* as applicabile. You know, it's still, we still need to look at obviously how to construe something in you know, in view of the canons of construction.

Which again, intrinsic record is you know, first most in that.

MS. WICKRAMASEKERA: Yes. Absolutely Your Honor. And that is the reason why I wanted to focus on the claim language itself. Axially adjacent within the context of that claim.

It requires that the components be situated next to one another along an axis. And that's the way we applied the construction. And what we were addressing was Patent Owner's argument that that can't be met when you have a magnet inside a rotor.

But that absolutely can be met when you have a magnet inside a rotor. It's consistent with what they'd done at the District Court. It's consistent with the claim language, and it's consistent with the prior art.

The prior art describes structures where you have the magnet and the impeller adjacent one another along an axis which is what axially adjacent requires.

So looking at Slide 59 now, and axially closer presents a similar issue. In comparing this to our understanding of the application of the plain and ordinary meaning that the Patent Owner has advanced at the District Court is consistent with our understanding as well.

So their argument here is that you can't have axially closer where the magnet is within the rotor. It's the same argument that they're making with axially closer and axially adjacent.

And our understanding is that you can look at a portion of it. Now in the institution decision, and I think I'll move forward. In the institution decision Your Honors noted that one question -- sorry, I'll jump back to the right slide.

In the institution decision Your Honors noted that you would like further development of whether it's a portion or whether it needs to be the entire structure. And I think here they were, the Patent Owner is clear as well. Both sides agreed it can be a portion. And so we'll adjust what portion it is.

I think this is a question that was asked as well of my colleague with respect to another component earlier in the claims. But both sides agree that it's a portion that you look at.

And then the next thing I want to address is -- that's slide, let me jump back to the slides. Here we go.

So just to jump back to the axially adjacent. To the extent that I didn't explain this already. The Patent Owner has agreed that touching or sharing a common side, this is Slide 61. That touching or sharing a common side would meet the limitations of axially adjacent.

If you look at the central axis, if you take Slide 61, if you look at the image where the central axis is. If you take an axis that's parallel to that axis, a longitudinal axis that's parallel to that axis that actually passes through the components you will see that along that axis the impeller and the permanent magnet are adjacent one another. There are no gaps. They are situated next to one another.

That's what the claim language requires. And that claim language is met with Wampler.

JUDGE TARTAL: Counsel?

MS. WICKRAMASEKERA: Yes.

JUDGE TARTAL: Just one thing I was sort of thinking back to and wanted to ask.

MS. WICKRAMASEKERA: Sure.

JUDGE TARTAL: And this was raised in these petitions I believe. There's a reference in the petition to Patent Owner's "apparent claim constructions" offered in the parallel proceeding that differ from the plain and ordinary meanings in the context of the '356 Patent. This was in

the IPR 2025-00096. Do you know what claim constructions you were referring to there?

What terms were you asserting in the petition that were apparent constructions by Patent Owner that are different from the plain and ordinary meaning?

MS. WICKRAMASEKERA: I think our position is that the Patent Owner's response differs from the plain and ordinary meaning.

JUDGE TARTAL: Well this was before Patent Owner's response because it would have been in the institution decision where it was raised.

MS. WICKRAMASEKERA: In which petition? In the --

JUDGE TARTAL: In the IPR 2025-00096.

MS. WICKRAMASEKERA: I won't --

JUDGE TARTAL: I guess my question, to be more particular about it. It wasn't sort of esoteric, but were there assertions in the petition that Patent Owner's construction of axially adjacent was not the plain and ordinary meaning?

And let me rephrase that. Patent Owner's "apparent construction" of axially adjacent in the parallel proceeding differed from the plain and ordinary meaning.

MS. WICKRAMASEKERA: In the parallel proceeding? I don't believe so. I'd have to confirm the portion that you're looking at. But I believe that the -- we believe that the current construction is as we stated.

Situated next to one another along an axis. To the extent that Patent Owner is interpreting -- for example, the Patent Owner has said that they are only pointing to a bottom portion of the rotor.

To the extent that they are trying to -- Your Honor, I would have to come back to you on that one.

JUDGE TARTAL: Sure.

MS. WICKRAMASEKERA: I don't remember exactly which point we were making, or if that was a misstatement in the statement at that point.

JUDGE TARTAL: So if you can, definitely respond later as well as in reply. But I believe that's what you said in each of the petitions, and in IPR 2025-00096 under claim construction. And it says broadly, Patent Owner's apparent parallel litigation construction's differ from the plain and ordinary meanings in the context of the '356 Patent.

MS. WICKRAMASEKERA: Yes, Your Honor.

JUDGE TARTAL: But you don't say what constructions you're referring to.

MS. WICKRAMASEKERA: No. Yes, Your Honor. Actually that does not relate to the axially adjacent. That's why Your Honor I was confused. That refers to two other terms, the magneto coupling and the, by the blood flowing.

JUDGE TARTAL: Okay.

MS. WICKRAMASEKERA: So those were -- those we addressed specifically in the claim construction. I apologize, Your Honor. I got confused as to which terms.

We specifically didn't raise that as to axially adjacent because we didn't know there was a dispute regarding the understanding of axially adjacent.

JUDGE TARTAL: Understood.

MS. WICKRAMASEKERA: Yes. I apologize, Your Honor.

JUDGE TARTAL: Thank you.

MS. WICKRAMASEKERA: So Your Honor, just to, now to move to axially closer for the Wampler reference at Slide 62.

Again I apologize, Your Honor. I got a little bit confused there. I need to remind myself.

Okay. So we addressed the axially adjacent limitation for the Wampler reference. I'm now going to address the axially closer limitation for the Wampler reference.

This is met under any construction, but the Patent Owner statements in the POR confirm that our interpretation is correct. So first, one of the things Your Honor said you would like further development of in the institution decision was whether axially closer refers to the entire component or can be a portion of the component.

Now we both agree that it can be a portion of the component. However what we have done is look at the component as a whole in light of its claim language.

So the claim language requires, pardon me. The claim language requires, at Slide 50 -- the claim language requires at Slide 50 that the second magnetic device must be positioned axially closer to the first magnetic device onto the magnetically driven rotor as to provide a magneto coupling with the first magnetic device to drive rotation of the magnetically driven rotor.

So it says that it needs to be positioned axially closer to achieve a purpose. What we did was look at the claim language as a whole. We understand that it's a portion. We agree with the Patent Owner that a portion, it only needs to be a portion.

But what we have done is, if we jump back to Slide 62 please. What we look at is the rotor component as a whole. Patent Owner looks at a very small portion of the rotor to determine whether it is axially closer to the second magnet which is the motor in blue on Slide 62. The first magnetic device is the purple part 88 at the top.

So what we do is we look at the impeller as a whole, the rotor as a whole. The vast majority of that rotor. So we both agree it can be a portion. But we look at the vast majority of that rotor as spaced apart to a greater distance from the motor that is the first magnetic device. And we think that's consistent with the content of the claim language.

And so then to move to axially adjacent for the Akamatsu reference which is Ground 3. As I've already explained, when you take a longitudinal axis that's parallel to the central axis, and you pass it through both the rotor and the permanent magnet you will find that they are situated next to each other along that axis.

As you can see in Figure 2 of Akamatsu on Slide 63, obviously nothing is sitting on the central axis. You need to pass an axis through. That's all axially aligned requires. You pass the axis through that's parallel to the central axis, and you have rotor and then magnet. No gaps, no space. They are next to one another. Because two objects, two physical objects cannot occupy the same space along the same axis.

And this is consistent with Patent Owner's expert's admission that they are touching. And it's consistent with Patent Owner's response.

And now I'm going to cover -- well, I don't have much time to cover the remaining limitations. I will, unless Your Honors have any questions. The only thing that I would like to say regarding the remaining limitations is as to Ground 3 Akamatsu, the primary dispute is whether it's inserted into the ventricle of the heart.

Patent Owner argues that it's, it needs to be in a human. The claims don't require that. The claims -- the insertion of the suction end of the inflow tube into the ventricle of a sheep satisfies the limitations of the claims.

Arguing that it needs to be in a human body is outside the scope of the claims. There's nothing in the claims that says patent or human.

As to Wampler, we are not -- Ground 1 -- we are not mixing embodiments. Wampler expressly teaches that the features of Figures 1 through 8 can be incorporated into the features of Figures 11 through I believe it's 18.

We rely on the second embodiment in Wampler, and we rely only on the teachings, the general teachings of the external controller and insertion of the suction end of the inflow tube into the ventricle of the heart which is depicted in Figure 5. But Wampler itself expressly states that you can use these features interchangeably.

And then as to Ground 4, the disputes are very limited, but as to Ground 4 I just want to point out that this one is under the narrower constructions that were proposed for magneto coupling and for by the blood flowing.

And so if you adopt the constructions that were adopted in the institution decision, the patents are invalid under all grounds, if you were to adopt the narrower constructions for magneto coupling and by the blood flowing that we proposed in the petition, they are invalid under Ground 4.

JUDGE TARTAL: And then Counsel, I notice that Mr. Boyle has been identified as providing argument.

MS. WICKRAMASEKERA: Yes, sir.

JUDGE TARTAL: Correct?

MS. WICKRAMASEKERA: We were going to save that for the rebuttal period.

JUDGE TARTAL: Okay. So then I think you went over by a minute or so of your 70 minutes. So that will provide something on the order of 35 minutes for rebuttal.

MS. WICKRAMASEKERA: Yes. Thank you.

MR. CAHILL: Yes, Your Honor. Ron Cahill for the Patent Owner, and I would like to reserve 15 minutes.

JUDGE TARTAL: Okay. So you'll begin with 75 minutes of primary argument time, and you'll see the indicator on the clock when you are approaching the 75-minute mark. And you're welcome to begin when you're ready.

MR. CAHILL: Thank you, Your Honors, and thank you for hearing from us today. We're going to take the rounds in order. We'll start with ground 1 and Wampler. And so could we go to slide 5? Let's jump right into the merits. So axially adjacent and axially closer. We want to talk for a minute about why this matters. And we have up the petitioner's markup of Wampler. And they've described the red or pink portion that that is the magnetically-driven rotor.

Now, Wampler says that his rotor is the impeller portion plus the spindle that extends out from it. But Petitioner has been quite clear that the magnetically-driven rotor of the claims corresponds to that impeller portion. And the impeller is driven by two stators, one above and one below, below

being more to the right away from us. And you can see that there are stators there labeled number 91. And we think that axially adjacent and axially closer have to do with that relationship. The second magnetic device -- the first magnetic device, which here is uncolored, it's white, and the rotor.

And the magnets here are embedded inside the magnetically-driven rotor, and they're flush with the ends. And so if the proper claim construction is adjacent or next to each other in the axial direction, then there's no way that this can meet that limitation. Because they're not next to each other in the axial direction. A lot of what I thought I heard Petitioner saying was, well, they're next to each other in the lateral direction. They share a common line. If you move an axis someplace else, they can be next to each other. But they're laterally adjacent. They're not axially adjacent.

And the Board got this right in the institution decision. So here is, for the purposes of this decision, at a position axially adjacent. And it's the magnetically-driven rotor and the first magnetic device that need to be axially adjacent. They're adjacent to one another as measured along a central axis. That's sensible. It's plain and ordinary.

Can we go to slide 7. So in the institution decision, the Board also looked at the plain and ordinary meaning, looked at the intrinsic evidence, and disputed the petitioner's claims that we had taken a different claim construction position in the District Court. Now, mind you, there hasn't been a claim construction in the District Court yet. We have provided contentions. They are in the charts. We're going to get to those. But there

hasn't been a claim construction yet. We haven't exchanged claim construction positions. But, here, this is the intrinsic evidence for what axially adjacent means.

In this figure, number 18 is the rotor, and number 16 is the first magnetic device. And they're next to each other in the axial direction. Exactly what you think axially adjacent means. Now, there doesn't seem to be any doubt what the plain and ordinary meaning is and what the intrinsic evidence shows. So we think there's no reason to depart from the claim construction that's in the institution decision.

Can we go to slide 8 and look at axially closer. So the second magnetic device, and that's the stator that we looked at before. According to the claims, it has to be axially closer to the first magnetic device than the magnetically-driven rotor. So the stator has to be closer to the first magnet than to the rotor. But, in Wampler, they're coincidental. We looked at it earlier. When you look -- can you pull up there slide 62?

Right. So the petitioners use this slide. And you can see the stator is number 91, and so it's all the way at the right-hand side, the bottom of the pump, if you will. And the first magnetic device is in purple. And the rotor is partially colored pink or red. There's a portion of it above the magnet, but it's not cross-sectioned, so it's not colored here. There's actually a blade there. But the bottom of the rotor and the bottom of the magnet, they're coincidental. They're the same. So, the stator, the second magnetic device, isn't axially closer to one than another. They're the same distance.

Now, you know, they say, well, it curves, and it's off the axis. Closeness is generally measured by the closest point. If I were to ask how close am I to the left wall, I'd look straight to the left wall, and that's how close I am. I wouldn't pick a spot up in the corner and say, that's how close I am. Both the magnet and the rotor pass over that stator coil, the second magnetic device. And one of them is not closer than the other. The claims require that the first magnetic device be closer.

So can we go back to Figure 2 of the Miracor patent. There we go. So here, the second magnetic device is number 19. And it is closer to the first magnetic device number 16 than it is to the magnetically-driven rotor number 18 in the axial direction. The two magnetic devices are close to each other, the rotors are farther away. That's exactly what the claim language means.

Now, I do feel like I need to spend a little time talking about the District Court positions, and how they're not inconsistent with this. Can we go to slide 9. So in the petition, the petitioner did rely on our infringement charts when determining the meaning of this claim. But what it looked at was a figure that looks like this. And we can pull it up if we need to. It's Exhibit 1019 on page 7, but it's this chart. And what it shows, and in that chart we are discussing the axially adjacent claim language, and this is how we're saying that it's met.

And the first magnetic device points to a magnet and the second magnetic -- I'm sorry, the magnetically-driven rotor points to the blades, the

impeller, that drive the blood. So the magnetically-driven rotor, the blades that drive the blood, just like the petitioners argue, Wampler does. That the magnetically-driven rotor is the impeller portion that drives the blood. That's on the bottom, and then the magnet is attached above it.

And yes, the whole thing rotates together. The first magnetic device is attached, it's fixed to the magnetically-driven rotor. Of course it all spins. That's how it works. But we picked out these things and pointed out that they are axially adjacent. They're next to each other in the axial direction. And that's what they pointed to in their petition. So what changed? So they showed you a figure from -- let's pull it up, their slide 55.

Okay. So this is in fact a figure, it's one half of a figure, from one page in an infringement chart, page 20, from a different infringement chart than the one they cited in the petition. And I apologize. I posit to you that that arrow is an error. And here's how I know that. So can we pull up Exhibit 1036? Okay. Could you go to page 5?

Okay. So this is that same infringement chart. And this is page 5. And this is the portion, and this is all referred to in our surreply responding the petitioner is making this argument for the first time in their reply. This is the language that says the magnetically-driven rotor rigidly coupled and axially adjacent to a first magnetic device. And lo and behold, there they are. The first magnetic-device points to the magnet, and the magnetically-driven rotor points to the impeller section with the blades that drive the

blood below it, completely consistent with everything we have said in this proceeding.

And so this is the exhibit that they cite, saying we get it wrong, we do it differently. And it's exactly the same. And it's exactly the same a lot. Could we look at page 6 of this exhibit? So there's page 6. And there it is again, the first magnetic device in the magnetically-driven rotor, axially adjacent. Could we go to page 7? There we have it again, the first magnetic device and the magnetically-driven rotor. And in fact, you can see how the first magnetic device is axially closer to the second magnetic device than the magnetically-driven rotor is in this case. Let's look at page 8.

JUDGE TARTAL: And you're still on what exhibit?

MR. CAHILL: This is Exhibit Number 1036 in the '096 IPR.

JUDGE TARTAL: Thank you.

MR. CAHILL: And this is cited by the petitioners as proof that we are inconsistent. Let's look at page 9. So here it is again with a different picture. But again, the first magnetic device is where the magnet is, and the magnetically-driven rotor is the bottom where the impeller blades are.

Let's look at page 10. Here it is again. The magnetically-driven rotor is where the impeller blades are on the bottom. We could do this all day. We have dozens of these charts and they all look like this. So they managed to find one that had the arrow in the wrong place and they made an entire argument about it. That one with the arrow in the wrong place, that's not a

claim construction conclusion. That one just has the arrow in the wrong place.

So the punchline is -- can we go to slide 11. So Wampler does not teach or suggest the claim language. It does not teach or suggest a first magnetic device, the magnets, which are white here, that is axially adjacent. It's adjacent in the axial direction to the rotor, which here, the magnetically-driven rotor is the impeller portion of Wampler.

So our position is the Board got this exactly right in the institution decision, and none of the things that have happened since have really changed it. The plain and ordinary meaning, the intrinsic evidence, informs the construction, and Wampler doesn't meet it.

Can we go to slide 12? So again, for axially closer, it's the second magnetic device, which is the stators marked at 91. To meet the claims, the first magnetic device, which is white here, the numbers 88, needs to be axially closer to the stators than the magnetically-driven rotor, which is pink here. And it's not. They're coincidental. They are the exact same closeness. One is not closer than the other. So this is a different configuration than what the claims ask for.

And again, our position is the Board got this exactly right in the institution decisions. So axially closer appears in different IPRs than the '096, and we've cited some of them here.

So let's continue with Wampler. In particular, can we go to slide 13. So the teachings of Wampler, because this is -- they can prevaricate all they

want. This is the basis of the motivation to combine. So Wampler has two distinct embodiments. The first embodiment, shown in Figure 3 -- and the Board in the institution decision puts these two figures next to each other to identify the first and second embodiments of Wampler.

The first embodiment, shown in Figure 3 here, Wampler says that it has good anatomic capability since the pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm. So I mean, we'll talk about this a little more, but they refer to this language 20 times in their opening papers, 20. It's hard for them to say today that this isn't central to the motivation to combine. They refer to it 20 times in their opening papers.

And the Board quoted it three times when discussing motivation to combine in the '096 institution decision, pages 34 and 35. This language is quoted three times for the motivation. It's about fitting that compact disc between the apex of the heart and the adjacent diaphragm. That's how you solve a lot of problems in this field, is by getting the pump there.

Now, our position is they're mixing and matching from the different embodiments. They say, oh, no, no, no, we're not. They're only relying on the second embodiment. Well, that teaching is for the first embodiment. If you look at the second embodiment in Figure 13, it's a different shape. It's much thicker. We don't have that compact disc shape now. We have a longer cylinder.

And Wampler actually says that that difference is important. So in paragraph 78, Wampler talks about the thickness in the axial direction, and that by increasing the thickness of the blade sectors and narrowing the blood passageway, the ratio between the working areas -- the area of the working surface of the blades and the volume of the passageway is increased, which it says increases the efficiency of this very small pump. So in the second embodiment, it's important that that disc be thicker. Wampler says so.

So I don't know how you get to where you can mix and match every teaching. These two teachings seem to be at loggerheads. The second embodiment says you want it to be thicker because you make the pump more efficient, whereas the first one says you want it to be thinner, you want it to be compact and disc-shaped so it'll fit at the apex of the heart.

Now, they then take this from the first embodiment, which they say they're not relying on, and they apply that to Bourque. We think they're mixing and matching from the embodiments without a rationale. To us, it's classic. If you have two different embodiments and you pick and choose features from the two different embodiments, especially here where the teachings are different, you've got to provide a rationale, and they don't. The rationale is, well, no, Wampler says it's all the same, so you can use anything.

So can we go to slide 14. So another way in which this difference between the embodiments matters is Wampler seems to have an external controller in the first embodiment. There's no controller discussed in any

way, shape, or form in the second embodiment. And while it's true that pumps need some kind of control, there's no requirement, like the claims, that it be external to the body.

What the claims say is, when the suction end is inserted into the ventricle, the external controller is outside the body. Well, you could control from inside the pump, you could control from an implantable controller, or you could control from outside the body. The second embodiment doesn't tell you anything about it, and it's a different pump than the first embodiment.

One of the ways that Wampler achieves this compact disc is he uses thrust bearings in this embodiment. The rotor isn't suspended, it bounces back and forth off the bearings. And so they can't use the first embodiment for a lot of the claim elements, because it requires a gap around the rotor, a gap between the housing and the rotor that's filled with blood. And that doesn't happen if you have a thrust bearing, if it's actually contacting the bearing. So they can't rely on the first embodiment for that reason.

But once they can't, now they've got to provide reasoning for why you would take the controller from the first embodiment of Wampler and add it to the second. They don't do it. We agree that there has to be some kind of control, but there's no reason why it has to be an external controller.

So if I could, I'd like to move on and talk about the Bourque reference. Thank you. We're on slide 15 now. So actually, this is just to make a quick point before getting on to the Bourque reference. So obviously, this

reference has a very different footprint. It's shaped very differently. It is implanted in the body -- proposed to be implanted in the body very differently, and it's an extraordinarily different size.

So we pulled up a Wampler paper in which he manufactured a prototype of his first embodiment. And he said that blue disk, the compact part, was 28 cubic inches -- I'm sorry, 28 cubic centimeters, 28 cc's. And it weighed 195 grams. The Bourque pump, we know, was 168 cc's. So it was six times the size. So when you talk about a compact disk, this isn't it.

So let's finish up with Wampler. Number 16, slide 16. Essentially, I think I've made this point. We can't just willy-nilly take different features of different embodiments of Wampler and apply them to a teaching for the combination of the second embodiment in Bourque. It's got to be -- they've got to give us a reason why we're going back to the first embodiment to grab something and apply it to the second embodiment, add it to Bourque. And we don't have it. They just don't say it.

Now, we also heard, and we see in their slides. They say that, oh, well, yeah, the second embodiment of Wampler, well, it kind of was implanted at the apex of the heart because that's what the HeartWare LVAD was. And it wasn't. This is one of the reasons why we moved to exclude the evidence of products that were not described in the publications. At the time of the priority date, it's clear. We know that the HeartWare device was implanted because there was an abstract in a press release that said so, but we don't know what it was.

And so, for example, Dr. Wieselthaler says, he's Dr. Wieselthaler, says all kinds of things about it, but he says all kinds of things that don't appear in the printed publications. And, you know, one of the things that's in their reply papers, in the reply itself, and in the language from their experts, Dr. Wieselthaler and Mr. Crosby, are that, well -- essentially, Crosby says it pretty clearly. He says they were mostly identical. But the fact is they weren't. The HVAD was a very different pump from Wampler's second embodiment.

And their experts, on cross-examination, Mr. Crosby admitted that he had no idea what the HVAD looked like at the relevant time. And Dr. Wieselthaler admitted both that the HVAD was different from the second embodiment of Wampler and that the second embodiment of Wampler was never built. Nobody ever built it. So you can't say that the second embodiment of Wampler was axially implanted at the apex of the heart. A, it wasn't. But we object to this line of evidence entirely because we're talking about products that we can't see. It's product prior art. It's not printed publications.

JUDGE TARTAL: Counsel, is there some premise that you were operating under that an expert in an inter partes review can only base his opinion on printed publications and patents? Because I think that's the fundamental problem we have with perhaps what you're arguing, which is I'm not aware of that.

MR. CAHILL: So I agree with your point. So the grounds cannot include products. I think we can agree on that. They have to be printed publications in the grounds. Can an expert refer to a product? I think an expert could refer to a product. I think the expert here goes too far. The expert here is dragging this product into trying to attach it to Wampler and trying to explain how this product was just like Wampler and it was implanted in this way.

Well, we can't challenge that for at least two reasons. One, we can't see it. It isn't in a printed publication. And two, they do this on reply so our experts can't say anything about it. We feel sort of doubly having our hands tied behind our back when it comes to this information about HVAD and other information about products that we can't see.

JUDGE TARTAL: Is Petitioner relying on products to demonstrate how prior art discloses limitations? Or are they using it in the context of replying to arguments Patent Owner raises concerning motivations to combine?

MR. CAHILL: Well, we heard it today that the HVAD had a short, axially aligned input to it.

JUDGE TARTAL: But that's not what they're relying on in the grounds, correct? They're not relying on what's disclosed in a product in the grounds because it may very well be the printed publication they're relying on shows that element. So the fact that it shows the element as well as they assert a product does is not a deficiency in their ground. It's just their

opinion on what is shown in or what would be known by a person of ordinary skill in the art.

MR. CAHILL: So in fairness to us, it wouldn't be known by a person of ordinary skill in the art because they couldn't see it. And we objected to their slide 38. That was the one we objected to. And counsel skipped over it today. But if you're reading those, it's Dr. Dr. Wieselthaler in his reply cross-examination being redirected, talking about how everybody knew what was in the HVAD device. Everybody knew it. They do go further than just simply saying, oh, there was something out there that repots your testimony.

And by the way, I kept hearing that we say all of this was impossible. No, we were pretty specific. So the HVAD was not FDA cleared until 2012. So a person of ordinary skill in the art couldn't just get one. Somebody on the inside, like Dr. Wieselthaler, may have known, but other people didn't know. The structure of it hadn't been published. And we'll get to this. We have a couple of slides to talking about what was actually disclosed about it.

But unless you were on the inside, you didn't know what it was. A person of ordinary skill in the art wouldn't know what it was. Our experts didn't know what it was because they didn't have access to it. Our surgeon couldn't get one until after it was FDA cleared. That's what we meant. And when it comes to practical impossibility, we're specifically referring to large pumps, like Bourque 2001 and Akamatsu.

Our experts say those pumps are so big that it's a practical impossibility to implant them at the apex of the heart, between the apex and

the diaphragm, as Wampler supposedly teaches. That it's practically impossible to do that.

JUDGE TARTAL: And then just to follow up, you, I thought, indicated that because arguments were put forward in the reply, you had no opportunity to respond. What were you referring to? Your reply or surreply?

MR. CAHILL: Well, our experts couldn't. We could not put in new expert declarations to address.

JUDGE TARTAL: Did you make any kind of request to the Board for leave to submit additional declaration testimony from your experts in response to the reply?

MR. CAHILL: We did not. And if I'm being honest, we didn't because I've never had one granted. But we did not.

JUDGE TARTAL: Thank you.

MR. CAHILL: So let's go to slide 18. So just to beat this dead horse completely, so we have some post-priority date publications that tell us what the HeartWare HVAD looked like. And it's very different from Wampler's second embodiment. If you just look at the rotor, instead of having a spindle that sticks up through the inflow tube, it's got a hole. It's just, it's a different configuration. So we eventually found out what was in it, and it wasn't Wampler's second embodiment. There's no basis for believing the second embodiment of Wampler was in it.

So now let's turn to Bourque, slide 19. So axially aligned. So our position has been talked about a lot. And we did not ever take the position that to the bitter end, every bit of the inflow tube has to be axially aligned with mathematical precision. What we pointed out, and it was clear in the slide that Petitioner's put up, what we pointed out is the inflow tube ends with a suction hole or a suction opening.

And so that figure where the entirety of the inflow cannula is outlined in green, that comes from Petitioner's expert. He seems to agree with us that that whole thing is the inflow tube. So our position is that entire thing has to be the inflow tube. So once you define what the inflow tube is, and you know what the axis of rotation of the lure is, now you look at those two things and ask yourself, are they axially aligned? And it seems to us that Bourque is not. That tube is perpendicular to the rotational axis. It's the opposite of axially aligned.

JUDGE TARTAL: What is your argument in response to Petitioner's contention that the only embodiment disclosed dictates how the term should be construed? And under that sort of construction, it must be interpreted to mean that only some small portion is axially aligned of the inflow tube, not the entirety of the inflow tube?

MR. CAHILL: So some small portion seems completely incongruent with the evidence. So let's go to slide 21. So this is Figure 2 of the Miracor patent, the '356 patent, the '096 IPR. Slide 21. The magnetically-driven rotor 18 spins and has an axis that goes straight up and down. The inflow

tube 9 goes straight up and down. They are axially aligned. There's no doubt that they're axially aligned.

In fact, we asked Mr. Crosby, the petitioner's expert, is the axis straight up and down? Yes. Is the tube straight up and down? Yes. Are they axially aligned? He said, I don't know. I've never taken a position on what axially aligned means. Which makes it hard for us to understand how they can make any of these arguments. But this is clearly axially aligned. Now, this is a partial view of the inflow tube. No. Is it possible that it curls slightly at the end? Sure. The ordinary meaning of axially aligned doesn't seem to require mathematical procedure.

Would a person of ordinary skill in the art look at the rotor, understand where the axis is, look at the inflow tube, and say, yeah, those things are axially aligned? I think the answer is yes, even if there's a slight curl at the end.

JUDGE TARTAL: Do you agree that there's only one embodiment shown in the '356 patent?

MR. CAHILL: Well, I agree that there's one embodiment, but it's illustrated differently. The inflow tube 9 is the inflow tube 9. The line drawing of Figure 1 doesn't look like it's intended to be hyper-accurate, and we should look at the geometries and the dimensions and figure out what portion is and what portion is axially aligned or not. It just doesn't seem to be that. It's a line drawing. It's a diagram. This one is much more specific, and it clearly shows axial alignment.

The problem I have with the portion argument is that's a pretty small portion. In fact, it looks like the inflow tube is 100 percent at a 90-degree angle to the axis. It's got a hole in the side for the blood to come through. And the petitioner's try to make a big deal out of the flow going down. The flow is more complex than that, and the Board recognized that in the institution decision.

Mr. Bourque did a computer fluid-dynamic model and showed that it was more complex than that. But it's not the flow that's claimed. It's the tube, and the tube is perpendicular. All the way from the beginning to the end, it's perpendicular. How can that be axially aligned? It's the opposite of axially aligned.

Okay. Let's move to slide 23. So we think that a person of ordinary skill in the art would not believe the motivation that has been proposed by the petitioner, that the evidence simply doesn't support it. And we're starting here with -- this is an abstract of a paper by Richard Wampler. It's around the same time as this patent application, and it shows the first embodiment pump. It's where he built his prototype of it.

And he's pretty clear. He's talking about, in this paragraph, he's talking about magnetically suspended rotors, like the Bourque 2001 reference. Magnetic suspension rotors. And he says, the electromagnets used for active magnetic bearings add significant volume and weight, making these pumps large and heavy when compared to other rotary pump concepts. So we think Richard Wampler got this exactly right. So because

of the size of the magnets required by the Bourque 2001 pump, it's too big and heavy. And Wampler recognized it. Mr. Bourque recognized it too.

So let's go to slide 24. So here are some pieces. In the petition, we quoted this one sentence. A POSITA would have adhered to express teachings of Wampler, which focused good anatomic capability so that the device fits well between the apex of the heart and the adjacent diaphragm, eliminating the need for peritoneal pocket dissection associated with increased rates of infection.

So, the petition, this is one example. We submitted an exhibit that listed 20 of these between the petition and the initial Crosby declaration, explaining that a person of ordinary skill in the art would have made this change, would have added the inflow tube from Wampler to the Bourque pump in order to fit it between the apex of the heart and the diaphragm.

And like I said, the Board quoted this language three times in the discussion of motivation. It just seems incredible that this isn't the basis of the motivation. It is. The petitioner has the burden to prove motivation to combine. And this is what they say the motivation to combine is. And we say the evidence clearly cuts the other way. If we're right, if the Board evaluates the evidence and says, no, this really doesn't make sense, a person of ordinary skill in the heart wouldn't believe this, wouldn't do it, then they're left without motivation. And without motivation, they can't make the combination.

Let's go to slide 25. So here's one chart that our experts put together to talk about the size of the pumps. And we'll get to the issue of whether size needs to be in the claims a little bit later. But these sizes are telling. So the Bourque 2001 pump is gigantic. So looking at the HeartWare HVAC device, which ultimately is a device that we knew was implanted at the apex of the heart, and Bourque 2001 pump is three times bigger than that. It's three times bigger.

You look at the Wampler blue disk. Volumetrically, Bourque 2001 is six times bigger. This pump is large by any standards, and a person of ordinary skill in the art would know. Because other pumps that are large don't go to the apex of the heart, this one can't go to the apex of the heart.

So let's go to slide 26. So Petitioner never says, oh, that's not true. Bourque 2001 is small enough to fit -- to have that good anatomic capability and fit between the apex of the heart and the adjacent diaphragm. They never say that. They say all kinds of other things. They say, oh, you could make it smaller. You don't have to implant it there. We're wrong to say you have to implant it there. They say you have to implant it there. It's in their motivation.

So let's look at what Mr. Bourque said about that. Slide 27. So we saw some of this from the petitioner, that in a 2021 interview, Mr. Bourque said, looking back at 2006, we decided we had to go back to the drawing board and redesign the pump. We made it smaller. And then because we

made it smaller, we could move it to the apex of the heart. That's what he said. Can we pull up that exhibit? Exhibit 2007.

Okay. So go to the bottom of page 5. So he's talking about the history of heartware. And he gets to the very bottom, and he says, so in 2006, we said, let's stop. Let's do exactly this, but let's make it -- next page -- a mini one of those. So how did they do it? All the work in a smaller package. So again, the bottom paragraph, they needed something significantly smaller. So that's what they designed. And that's a good thing. But that doesn't mean it delivered half the performance.

So the bottom paragraph, again he explains what he did to make it smaller. A couple of things. One, by flipping the rotor upside down -- flipping the rotor upside down, we're able to gain a little bit of the real heart. The electronics themselves, the chips are smaller, so we shrunk for that. But then, when we got this small, we said, wait a minute. Now we don't need to implant it down there in the abdomen. We can go right in the chest.

So ultimately, he did, and he says, we took away this whole business about creating a pocket for the pump and then requiring a conduit. So all the things that they said, yeah, Mr. Bourque figured those out. So he did that, though, later than the priority date. And the changes, the flipping the rotor upside down, that's patented.

So this isn't something a person of ordinary skill in the art would think to do at the priority date. Mr. Bourque, whose pump it was -- I think his provisional was filed in 2010. We didn't actually see the structure of the

redesigned pump until a 2016 paper. That's how long it took to redesign the pump, to get it small enough to go to the apex of the heart.

Could we pull Mr. Leschinsky, Exhibit 2015? Yeah, page 102. I'm sorry, page 89. Okay. So this is where Dr. Leschinsky -- I'm sorry, Mr. Leschinsky, our biomedical engineering expert, he analyzes the Bourque patent. And what you'll see here is the Bourque 2001 pump is on one side and the redesign is on the other side. And the rotor is flipped over. Now the rotor is at the bottom, and the blood flow goes through the stator and into the rotor.

And Mr. Leschinsky explains all that, and he ties it to the claims of the patent. This was a patentable redesign that got this pump small enough to be ultimately the clinical HeartMate III implanted at the apex of the heart. And it's two and a half times smaller than the original pump. That's what it took to make it smaller. So when they say, oh, you could just make it smaller. No, a person of ordinary skill in the art, at the priority date, could not make it smaller. So let's --

JUDGE REIMERS: Counsel, I have a quick question for you. I know you're mostly referring to the '096 patent.

MR. CAHILL: Yes.

JUDGE REIMERS: And I know we have several patents here. And I'm receiving all of your points here regarding the combination. But where is this found in the claims where the implantation has to be at the apex of the

heart? Is that located in any of the independent or dependent claims from any of the patents that are cited here?

MR. CAHILL: It's not. So could we go to slide 20? So, Judge Reimers, it is not our position that it's required by the claims. Our position is this is their motivation. They have said a person of ordinary skill in the art would be motivated to take the inflow tube from Wampler and add it to the Bourque pump in order to place Bourque at the apex of the heart.

And our position is the evidence for that fails because a person of ordinary skill in the art would know that the pump was too big and wouldn't be able to do that. This is a failure of evidence to support motivation. It's not an argument that says they're failing to make the teachings of the claim.

JUDGE REIMERS: Thank you for that clarification.

MR. CAHILL: And here's some of the case law. So in particular, and this is about the case we cite, Intelligent Bio-Systems. Interesting case. So the Federal Circuit actually disagreed with the patent owner on reasonable expectation of success, but agreed on evidence as to the motivation. And the key to the evidence on motivation was this quantitative deblocking requirement.

So the motivation to change the primary reference involved making it more efficient, more reliable with the process. And in order to do that, in order to do it, you had to provide quantitative deblocking. And the thing they added didn't do quantitative deblocking.

And so the Federal Circuit said that's a failure of evidence for motivation. A person of ordinary skill in the art would know you needed this thing in order to make it work for the motivation. And the evidence says it's not there. But that's a failure of evidence for the motivation. And when the motivation collapses, you've got no reason to combine.

Now they've said, oh, but there there's only that one motivation. They have a bunch of motivations. They have one motivation to which they also add the elbow. We'll talk about the elbow more. But the motivation is if you move the pump to the apex of the heart, you can remove the elbow. You can get rid of the peripheral hardware. You don't need to create the preperitoneal pocket.

All things that are good come from moving to the apex of the heart. But if the pump's too big, you can't do it. And if a person of ordinary skill in the art would look at it and say, yeah, that pump's too big, you wouldn't do it, then there's a failure of evidence for the motivation.

Now, we raise this in our preliminary response. And in the institution decision, the Board said, huh, this is interesting. But it's turned the argument. You didn't put in any expert declarations. Well, now there's a lot of expert declarations.

We put in Mr. Leschinsky who's our biomedical engineering expert, Dr. Gallegos who has a very busy surgical practice implanting health ads, who talk about all the reasons why a person of ordinary skill in the art would recognize the Bourque 2001 pump is distinguished from some of the other

pumps. The Bourque 2001 pump was just too big. It would never go there. And we look at some -- there's so much data on that.

Now, the Axonics, the Medtronic case the petitioner sites, it's a different context. So in that case, the -- it had to do with medical electrodes. And one of the pieces of the prior art involved the activation of trigeminal nerves. And in that case, the Board decided to limit the motivation to the trigeminal nerve context based on the prior art.

And the Federal Circuit said, no, no, no, you don't get to do that. That the context is the claims, and the motivation is what's stated in the petition. And you don't get to change the motivation and make it narrower because a particular piece of prior art says -- essentially, it teaches what it teaches. And if it can be used in other contexts, it can be used in other contexts.

That's very different from here. So here, nobody's changing the motivation. Petitioner said, if all these benefits from moving it to the apex of the heart, the way to move it to the apex of the heart is to combine it with Wampler. Our position is, the evidence says that doesn't work. You can't do that. A person of ordinary skill in the art would know better than that. And that, we think, makes us exactly like Intelligent Bio-Systems. So the size requirement, placing the pump at the apex of the heart, those don't have to be in the claims.

And I urge you in the strongest terms to read the motivation section of the Intelligent Bio-Systems case because the Federal Circuit's really clear. The motivation doesn't have to be in the claims. If the evidence for the

motivation fails, then the motivation fails. And if the motivation fails, you've got no reason to combine. That's what our argument is.

Okay. So I'd like to talk a little bit about VentrAssist. So the petitioner's put up this slide. And they didn't make this argument in the petition and they didn't cite to this reference in the petition. But they cite to it now for the proposition that, well, to combine Wampler with Bourque, you don't have to position it at the apex of the heart. You could do this instead. And they talked about this a lot in their presentation. And we think a number of things about this.

So it's not in the petition or the opening reports. But it doesn't have the inflow tube from Wampler. It has something very different. And there's no evidence that the Bourque pump could be implanted this way. So the Bourque pump is actually much bigger than the VentrAssist pump. And Mr. Bourque is very specific about how his pump is implanted. The Board looks like it has a question.

JUDGE TARTAL: Wasn't the -- yes, thank you. Wasn't the -- I'll paraphrase the issue, correct me if I'm wrong, but wasn't there a dispute over the fact that Patent Owner's position seemed to be that no one had ever placed a pump at that particular location? And they were pointing to some other disclosures that indicated pumps had been placed at that location at the time relevant for priority. So it was rebutting not so much the details of what was placed there, but that it was rebutting a factual assertion made by Patent Owner that it had never been done. Is that wrong or --

MR. CAHILL: Yes. And what we've said is more subtle than that. But this doesn't show implanting. The thing that we supposedly said is no one had ever implanted at the apex of the heart.

JUDGE TARTAL: Well, did you say that or did you supposedly say that?

MR. CAHILL: So I would have to think about that. So certainly, we were very clear that it was impossible for someone to implant Bourque or Akamatsu at the apex of the heart. We also said that in the sort of public domain, there was no evidence of someone implanting at the apex of the heart, that the descriptions of HVAD came later. It was FDA cleared in 2012 after the priority date.

So sure, there were people behind the clinical trials who knew what it was, but a person of ordinary skill in the art looking at the public literature wouldn't. So that's what our position was. So this doesn't suggest implantation at the apex of the heart. So they suggest that what this shows is, well, you could use an axially aligned inflow tube and implant in a preperitoneal pocket someplace else in the body, because that's what VentrAssist did.

And we don't think that this is what VentrAssist did. We think it's really clear from this picture that that's not an axially aligned tube. It's not straight. And the reason I say that is one can use one's own eyes. This is a perspective. You're looking down a little bit at the patient. And that pump is implanted horizontally, and you can see the top of the pump. But then you

can also see the bottom of the cuff at the apex of the heart. So the heart -- in a person who's standing straight up, the apex of the heart doesn't point straight down. There's lots of figures in here that show that.

So the fact that you can see both the top of the pump and the bottom of the cuff tells you that that curves or angles or bends. It just does it in the plane that you're looking at. So you can't see it clearly. But logically, it has to curve, because the pump is facing straight up, but the heart's not facing straight down. And that's why you can see the top of the pump and the bottom of the cuff.

Now, the person who talked about this, Mr. Crosby, he was actually the CEO of VentrAssist. He didn't provide any more information. He just used the reference that we cited. Didn't provide instructions for use or surgical guide or catalogs or inflow tubes. Didn't provide any of that. All we have is this one figure. And we don't think it shows, but they say it shows. You can stop.

I think we've talked enough about each one of them. So let's go to slide 31, Patent Owner's slide 31. So again, I mean, even looking at this chart, comparing VentrAssist to Bourque 2001, VentrAssist weighed 50 percent less. Significantly smaller pump. There's no reason to believe, and there's no one who says you could take the Bourque 2001 pump and implant it the way we saw in that figure. Bourque is much larger than anything that gets implanted at the apex of the heart.

Now let's talk about some of the other motivations to combine that have been raised. Yeah, slide 32. So this is the so-called flow-restricted elbow. And so the petitioner says that Bourque did that because he just wanted to use the old tubes, or tubes lying around for previous pumps, and he wanted to use those. We don't think that's the case at all. We think that the elbow is there specifically to make it anatomically compatible. That's how he fits this big pump in the human body.

Could we go to the Bourque 2001 reference? Down one. Okay. So the bottom of the first column. The flow path is a circular cross-section through the inflow and outflow sections. The shape was gradually flattened near the pump in both the inflow and outflow to reduce the effect of pump height.

To orient the pump in the least intrusive position, i.e. in the human configuration, as in Figure 3, it was decided that the rotational axis of the pump's rotor should be perpendicular to the body's long axis. That resulted in a sharp bend in the flow before it enters the impeller. To minimize losses in this transition, the flow is slightly accelerated through this elbow.

So Mr. Bourque knew what the elbow was, and he put it in there so that he could place it inside the body. This is a big pump. It has to go up and down. He's clear about that. And to get it to do that, you have to put the elbow on. So this isn't a question of just using old tubes. He is specifically designing it this way, to fit inside the body.

Now separately -- moving back to slide 32 -- separately, Mr. Bourque did his own CFD analysis, a computerized fluid dynamics analysis, and found benefits to the elbow. He liked the elbow. It caused a swirl. We heard the swirl was a problem. Their experts said the swirl was a problem. Mr. Bourque said the swirl was great. That because of the swirl, there was no stagnation in the flow and no thrombus buildup. When they looked at the pumps from the animal studies, there was no thrombus, in part because there was this swirl that cleared it out. So no thrombus means no strokes for the patient. This is a big deal.

We don't think that you can remove the elbow. You certainly can't fit it at the apex of the heart. Everyone agrees with that. Our experts also say if you put an axially aligned flow tube on the top of the Bourque reference, you're not going to be able to fit it in the body. A person of ordinary skill in the art would know that. A person of ordinary skill in the art reading Bourque and reading Wampler would know that you can't just put a straight tube on it and implant it in the body. There's no place to put it in that orientation.

Mr. Bourque says it needs to be up and down. The flow -- the rotational axis needs to be perpendicular to the body's long axis, and that's why he puts it there. You can think of it almost like if I wanted to implant a dental plate, you can imagine I might be able to tuck it behind the muscles, but if I tried to put it in horizontally, that could be a disaster. So he implants

it in that configuration where it's straight up and down. And for that, he needs the elbow. You can't just take it away.

So another so-called motivation to combine -- they identified four in the petition, we've talked about two of them. Another one is the removal of peripheral hardware. So this is the tubing. But you can only take out the tubing if you move the heart above the diaphragm and connect it right at the apex.

If you don't do that, even the VentrAssist example, that's got screw threads on the top, and you've got to screw on flow tubes that then cross the diaphragm and attach to the heart. So you only get this benefit of removing the peripheral hardware if you implant at the apex of the heart.

The last motivation is they're analogous. Well, we agree that both Wampler and Bourque are directed to hollow ends. But a person of ordinary skill in the art, looking at them, would understand you could never do what their motivation says, looking at the size of the pump.

They're not analogous from the terms of the teaching in Wampler that says, you have this compact disk that fits between the apex of the heart and the diaphragm. They're right next to each other. Bourque shows that. They're right next to each other. So you need something small. Bourque isn't that. They're not analogous from that perspective. A person of ordinary skill in the art would know that you can't replace that blue disk of Wampler with the much larger pump of Bourque.

So I only have a few minutes left to move on to Akamatsu. So Akamatsu does not teach an axially adjacent magnetic device and motor. This is Petitioner's mockup of it, and I don't think it does it justice. Could we go to the original? This is Exhibit 1006, page 2. So can you blow it up?

Yeah. So you can see those circular arrows, they surround parts of the impeller, and the magnet is embedded in the impeller. The surfaces are coincidental. So it isn't the case that there's one, and then there's another next to it. It's embedded inside of it, as it is in Wampler. It's a different configuration, but it's the same issue. So it's not axially adjacent. They're not next to each other in the axial direction. One's inside the other.

Similarly, for axially closer, which one is axially closer to the second magnetic device. So the second magnetic device is to the left, the other side of the wall. There's a platform there. It's not cross-hatched, and it's got the black magnet on it. So that's the second magnetic device. It's not closer to the first magnetic device than it is to the other. At best, they're coincidental. So it's not axially closer. So we think Akamatsu doesn't teach these limitations, and so it can't be used on its own.

Can we go to slide 37? So a person of ordinary skill in the art would not do what Petitioner suggests, which is they say, well, what you do is you take the pump of Schima, and you would implant it in the manner of Akamatsu, right? Because they're analogous, you do it the same way. So first of all, we don't think Akamatsu is implanted at the base of the heart.

Can you go back to Akamatsu? Show that page. And go up. So Petitioner presents this with all kinds of drawings on top of it. And sure, it looks great when they draw in all the features. But we asked their expert, Mr. Crosby, how is this pump attached to the heart? And he said, I don't really know. This kind of looks like a bad copy.

JUDGE TARTAL: Could you repeat that?

MR. CAHILL: He said, I don't know how it's attached to the heart. This looks like a bad copy. I don't know how to figure it out from this picture. That's what he said.

JUDGE TARTAL: Okay.

MR. CAHILL: Now, our experts also asked Mr. Crosby, is this pump implanted above the diaphragm? He said, I don't know. Can we look at what Mr. Leschinsky said about this? Exhibit 2015, page 102. So he explains this in his declaration. But on the left, we have Petitioner's mockup of Akamatsu. And on the right, we have Petitioner's mockup of Bourque. And you can see on Bourque that the green inflow tube is attached to the apex of the heart. And that's the diaphragm right underneath it. He labels the diaphragm. It's adjacent to the apex of the heart.

And so then, if you look back at Akamatsu, there's no way. There's just no way that it's implanted in the manner they draw. There's not room there for that gigantic pump. This pump is a bigger volume than the Bourque pump. It's actually bigger. There's no way it could be implanted

there. This is a hope and dream. A person of ordinary skill in the art would know that. And that's what our expert says.

So could we go to our slide 37? So here we have a chart with Akamatsu on it. And you can see the volume is actually bigger than the Bourque pump. It's actually bigger. It's massively larger, for example, in the HeartWare pump. So a person of ordinary skill in the art would know. This has to go in a pocket the way the Bourque one does.

And fascinatingly, before we talk about the product prior art, we go to slide 40. So the petitioner says that the Akamatsu pump was implanted as DuraHeart. Well, we see DuraHeart here, and they configured it just like Bourque. So now the inflow tube is not axially aligned. It's perpendicular. In the bottom picture, it's the tube on the top right. Petitioner's expert confirmed that. And you can see it in the picture at the top that has it pulled apart. The inflow is perpendicular to the impeller.

So the people who actually implanted the Akamatsu pump, they did it exactly the way Bourque did. Not the hope and dream that you can't tell in the picture that the petitioner was in.

JUDGE TARTAL: Can you just address for me the way in which you distinguish what the reference discloses and the size of what the reference discloses for purposes of motivation to combine? Because it seems like a lot of your argument is driven by the idea that this particular pump shown with this particular size and volume wouldn't fit somewhere in particular. But isn't that a little bit narrow of a reading of a reference if you were trying to

limit its disclosure to something like dimensions? Is there more to your argument than, it's too big, that would be relevant to our analysis of a motivation to combine?

MR. CAHILL: So it is too big. And that is an important part of our analysis. The petitioners say it needs to be implanted in the body a certain way.

JUDGE TARTAL: And I realize this is hypothetical, but what is your argument in terms of how big is too big, how small is too small? There's nothing in the claim that requires any performance level, any size, any volume, any rate of operation. And I'm not sure what the evidence is that if I make it 75 percent smaller, does that fit? Does it not fit? Or are we looking more at what does this disclose in terms of structure that would be relevant to the combination?

MR. CAHILL: So I beg and plead with you to read the *Intelligent Bio-Systems* case. Because the point is not that the claims are requirements. The point is the petitioner's motivation is to fit the pump between the apex of the heart and the diaphragm. And we know a lot about what in the art works for that. And we know that because Wampler tells us.

JUDGE TARTAL: But you just said what works in the art for that. And I'm not sure what works in the art is distinguishable from what the structure is that's claimed. So are you arguing that a person of ordinary skill in the art would somehow implicitly know that a pump that's half as big

wouldn't work as well as a pump that's twice the size, and so that refutes the motivation to combine? Or where is the --

MR. CAHILL: Yes, they did know. And so you can look at this chart, for example, that shows the sizes and where they're implanted. Mr. Bourque knew. He knew in 2006 his pump was too big. And we looked at the quotes. His pump was too big to be implanted at the apex of the heart. When he made it half the size, and you can see the numbers on here, the weight dropped from 474 to 200. The volume dropped from 168 to 80.

And now he says, he says this in 2021, but he says, now we can implant it at the apex of the heart. Now we meet the petitioner's motivation. We can take out the peripheral hardware. We don't have to do the preperitoneal pocket. So our experts never went to, here's the size that works and here's the size that doesn't, because I think that's too hard to do. But if you look at the examples, below a certain threshold, they go to the apex of the heart, and above that threshold, they end up in the preperitoneal pocket.

And this isn't about the claims. This can't be about the claims. This is about the petitioner's stated motivation. The evidence is, a person of ordinary skill in the art would not be so motivated with the Bourque pump or the Akamatsu pump, because they're too big to fit.

JUDGE TARTAL: Isn't the teaching of Bourque broader than the specific size of Bourque's pump? Is there nothing that a person of ordinary skill in the art could take from how an apparatus is configured that would be

relevant to how you would design a pump that isn't completely constrained by the pump shown in Bourque has a volume of 100 or whatever it is?

MR. CAHILL: So there's a couple of things about that. One is, the Wampler patent tells us compact disc size fit between the apex and the adjacent diaphragm. Bourque isn't that. Richard Wampler tells us, magnetic suspension, like the Bourque design, heavy and too big.

Mr. Bourque realized his pump was too big. When you read Bourque 2001, he's clear about what it takes for anatomic compatibility. You've got to put it in a pocket, and you've got to put it up and down with the elbow on it. He realized, after they went through a many-year redesign project that resulted in patents on the new design, now it was small enough to move it to the apex.

JUDGE TARTAL: But isn't that sort of part of the question, which is, the claim doesn't require any performance? You say that it took two years to make it smaller, but it took two years to make it smaller presumably in the context of some level of performance that matched what was done before. But the claim doesn't require that. It doesn't require any particular size or performance level. I don't want to overstate the case, but that's correct, right? Isn't it correct?

It's a little disingenuous to say it took him five years to make it smaller, because I think that would inherently take into consideration some level of performance. He's trying to make a product smaller that does the same thing. Is that consistent with your understanding?

MR. CAHILL: That's not -- it's not in the record. And I don't know what to tell you about that, but that's not in the record. They suggest, oh, just make it smaller.

JUDGE TARTAL: And why is that wrong? Because if they say just make it smaller, if there's nothing claimed that has anything to do with how well this works, all you're saying is, here's a pump, make it smaller, doesn't have to meet any claimed performance, why is that argument wrong from them? And why isn't your argument just a bodily incorporation argument, it's too big?

MR. CAHILL: This isn't about claiming performance. This is about failure of motivation.

JUDGE TARTAL: I understand --

MR. CAHILL: There's no motivation to combine. The reason drops out if you don't combine. Now, these are -- I mean, Bourque's pump is carefully designed. Just saying make it smaller, and it doesn't have to perform, but what pump is it then? There is no suggested pump that's smaller. The only thing they say about make it smaller is the chips shrink. But the problem isn't the chips. The problem is the magnets. Wampler points that out. And Bourque points that out when he did change it, he had to flip over the whole thing and fit it differently. The problem is the size of the magnets.

And, no, nobody knew how to make it smaller and still have a magnetic suspension. That just wasn't known. Our point is, a person of

ordinary skill in the art, looking at that Bourque pump, would realize there was no chance you were going to fit that at the apex of the heart. So, to the extent that their motivation relies on fitting it to the apex of the heart, it's a failure of evidence, exactly like Intelligent Bio-Systems.

And it doesn't have to be in the claims. They have to prove the motivation. It's their burden to prove the motivation, and we think they've failed because a person of ordinary skill in the art would look at their motivation and wouldn't believe it. Thank you.

JUDGE HAMANN: Counsel, this is Judge Hamann. Just real quick, just to make sure I'm following the argument fully. And without the smaller pump allowing it to move to the apex of the heart, you don't lose the elbow. You don't get to axially align with the claim. Is that basically the crux of it?

MR. CAHILL: So when you say of the claim, no. This argument is exclusively about the motivation to combine.

JUDGE HAMANN: I understand that, but I guess my point is, the motivation -- the reason that you want to have a small pump is so you can move to the apex of the heart so you can get rid of the elbow in Bourque, and therefore you can be axially aligned. That's what the claims require.

MR. CAHILL: That's fair. That's the purpose of the combination, yes.

JUDGE HAMANN: Okay. Thank you.

JUDGE TARTAL: Okay. Thank you, Counsel. We're going to go off the record and take a break, but a brief break. So I think ten minutes.

And then I know you went a little bit over the original 75 minutes you requested. Do you have an amount of time for the surrebuttal that you had hoped to have?

MR. CAHILL: Yes. I'd love to have ten minutes. I think I have five and a half left. On the other hand, if you'd like to limit me to the time, I'm not inclined to complain.

JUDGE TARTAL: I would just give Petitioner an extra five minutes, if you want an extra five minutes.

MR. CAHILL: They already have it all figured out.

JUDGE TARTAL: Do you want to stick with it?

MR. CAHILL: I'll stick with it.

JUDGE TARTAL: Okay. Then we'll start again in roughly ten minutes. I think that is 4:00 o'clock.

(Whereupon, the above-entitled matter went off the record at 3:50 p.m. and resumed at 4:00 p.m.)

JUDGE TARTAL: I have you at 34 minutes. Does that sound right to you?

MS. WICKRAMASEKERA: That sounds -- yes, that sounds right.

JUDGE TARTAL: What you were at -- or thereabouts.

MS. WICKRAMASEKERA: We're hoping for less, but --

JUDGE TARTAL: You don't have to use all 34. Although, we do get to hear from the LEAP practitioner, or we'll be --

MS. WICKRAMASEKERA: Yes, no, we will, yes.

JUDGE TARTAL: -- subtracting 15 very shortly.

MS. WICKRAMASEKERA: Yes, that we --

JUDGE TARTAL: Okay. We are back on the record for the hearing, and you may begin when you are ready.

MS. WICKRAMASEKERA: Thank you, Your Honor. Nimalka Wickramasekera, again, for Petitioner. I want to address a few quick points regarding Grounds 1, 3, and 4, and then I'm going to turn it to my colleague Mr. Boyle, who will address the objections.

JUDGE TARTAL: And we'll just remind you that the arguments should be directed primarily to issues that were addressed by Patent Owner in their argument in response since this is in reply.

MS. WICKRAMASEKERA: Yes. Yes, thank you, Your Honor. So I'm going to raise this particular issue with respect to Akamatsu and a common -- and the motivation to combine Akamatsu and Schima, which they addressed Akamatsu; that's Ground 4.

Again, Your Honor, and I think that Your Honor's questions are directed to the right issue. The motivation to combine is not to implant the device at the apex of the heart. The motivation to combine is to provide a device that has the suction end of the inflow tube inserted into the ventricle. That's what's required in the claims, and that's what the motivation to combine relates to with respect to Akamatsu and Schima for Ground 4.

My colleague Ms. Raghavan will address the questions directed to the Bourque references.

But I wanted to remind Your Honors, what they are attempting to distinguish the motivation to combine for, for Akamatsu, is outside the scope of the claims. Now, they continuously refer to the Intelligent Bio-Systems case. Your Honor, I know, Judge Tartal, I know Your Honor was involved with the Axonics Medtronic case. I was as well. That was recent. The Federal Circuit was very, very clear. You have -- the Patent Owner cannot distinguish it on the basis of unclaimed features. Those are outside the scope of the claims.

Here, they are stretching the motivation to combine to suggest that it is not what we are arguing. The motivation to combine needs to be only for the purpose of having the suction end of the inflow tube inserted into the ventricle. That's the motivation to combine related to Akamatsu and Schima. My colleague will address their specific criticisms of Borque. But what they are doing is expressly not permitted by the Federal Circuit's decision in Axonics Medtronic.

The next quick point I'd like to make is they started their argument regarding their infringement contentions, and they spent a few minutes on that, and I just want to make one point related to that.

They seem to concede, or at least acknowledge, that they have accused a permanent magnet inside a rotor as meeting the requirement of axially adjacent. But -- and they seem to concede this because what they did

was they pointed to it, and they said this was a mistake in our contentions. That was not a mistake. It appears on pages 9 and 14 of their contentions at 1036, and it appears three times in their complaints. There is no mistake. They recognize that their argument to distinguish the prior art directly conflicts with their position in the district court.

Now, as to their argument for axially adjacent, what my colleague here stood up and argued for on behalf of the Patent Owner was that what we are doing is we are looking at it in the lateral direction. That is exactly what they are doing. It is not what we are doing. So what they are -- what we do is we take the longitudinal axis, and we find the location of the permanent magnet and the rotor along that longitudinal axis.

What the Patent Owner does is the exact opposite. They find a point on the central axis. They then draw a 90-degree line from that point on the central axis to create another axis. And then they say, if you overlap on those two -- on that axis, which is 90 degrees from the central axis, then you are not axially aligned. So what they are doing is they are actually looking at the lateral direction, and we are looking at the longitudinal direction.

JUDGE TARTAL: Counsel, can you address their argument that if you look at what's disclosed in the patent -- and I believe it's Figure 2 in particular -- it's consistent with what their argument is, which is axially aligned means aligned along an axis in a direction where one follows the other?

MS. WICKRAMASEKERA: We agree with that. We agree with that. What I'm saying, Your Honor, is that when they are doing that with respect to the patent, they're looking at a figure that's looking at a longitudinal axis. Again, it's the axis. You need to look at the correct axis in order to determine whether they are one next to each other or overlapping. So, along the longitudinal axis, so an axis that's parallel to the central axis, the prior art and the patent are all adjacent one another along that longitudinal axis.

For purposes of distinguishing the prior art, what they're doing is they're taking the central axis, they're drawing a line from a point on that central axis up 90 degrees, and then they're saying, if you overlap in that direction, then you are not axially adjacent. That's the wrong axis. They're not looking at the correct axis.

So what we are doing is consistent with what's shown in the patent, which is if you take a longitudinal axis, you can see that the permanent magnet and the rotor are next to one another. They're not spaced apart. There's no gap. They're next to each other. So we're consistent with what they described. The patent is correct.

What they're saying, though, is they're flipping the axes in order to distinguish the prior art. So they are actually looking at it in the wrong direction. Did that answer Your Honor's question?

JUDGE TARTAL: I think so. Thank you.

MS. WICKRAMASEKERA: Okay. Thank you. The next point I wanted to make addresses the Wampler reference.

Now, they say that we are mixing -- that we are mixing embodiments in the Wampler reference. And this is for purposes of Ground 1, and they -- yeah, I don't know if this is an issue for Ground 2, but I'll address it for Ground 1. They say that we were missing embodiments. And what they are pointing to is, clearly, Wampler has two embodiments. And we have been very clear that we were looking at one embodiment, but they say there needs to be a motivation to combine.

Wampler is express about the features that are common between the two embodiments, and it is express about using the features from one embodiment for the other. For example, in Wampler, it says, in paragraph 80, that the pump casing is the same between the first and the second embodiment. So the size is the same between the first and the second embodiment according to Wampler's own express teachings.

And then, in paragraph 102, Wampler expressly states: various elements from the Figures 1 through 8 embodiment can be used in the Figures 11 through 20 embodiments. That is the express teaching from Wampler in paragraph 102 of Wampler. And so, Wampler is express about using the various features from one and applying them to the other. Without a motivation to combine, it is a description issue. Wampler describes these features for the first embodiment and then does not repeat them for the

second embodiment, though it makes clear that those features can be used in the second embodiment.

And with that, Your Honor, I think I've addressed the issues that I'm going to address for Grounds 1, 3, and 4. I'm going to turn it over to my colleague Mr. Boyle.

MR. BOYLE: Thank you, Your Honor. Kevin Boyle for Petitioner. Now, I was prepared to argue a few other points, but those didn't come up, so I'm going to just address the motion to exclude from Patent Owner.

Patent Owner argues that Petitioner's public use evidence is admissible. And this is a -- this is an argument that Patent Owner made at Slide 44 of its demonstratives. But Your Honor hit the nail on the head with your question earlier to Counsel on this issue. Patent Owner's argument should be denied for the simple fact that Patent Owner fails to identify any public use evidence. The exhibits that Patent Owner seeks to exclude are all printed prior art publications and related testimony concerning the same.

For example, these are some of the exhibits Patent Owner wishes to exclude: Exhibit 1015, 1038, 1046, and 1050. These are all published journal articles and journal abstracts from peer-reviewed scientific journals. These are quintessential printed publications. And Counsel said, a few times, that their experts did not have an opportunity to respond to that evidence. Well, Exhibit 1015, that was included in the petition, so plenty of time for Patent Owner's experts to respond to something included in the petition.

As another example, Patent Owner seeks to exclude Exhibit 1044, which is a published prior art press release about the HeartWare device, but Patent Owner made no argument that Exhibit 1044 wasn't published or that it wasn't available to persons of skill in the art, or that it -- so it's not public use evidence. It's a printed publication.

So, some context here helps explain why Patent Owner is trying to exclude printed publications, and nearly all of this evidence relates to the Ground 2 motivation to combine analysis. In its Patent Owner Response, Patent Owner and its experts argued that as of the priority date, implanting an LVAD at the apex to the heart would be, quote, impossible.

Now, my Co-Counsel addressed this argument at Slide 32. And then Patent Owner's Counsel got up and said that their argument is more subtle than that, right? So let's look at the subtlety of their argument. I'm referring to Slide 32 of our demonstratives. And this is the quote from the Patent Owner Response, quote, no clinical LVADS placed at the apex of the heart as Petitioner's motivation requires, end quote.

We have another quote from Patent Owner's Mr. Leschinsky that said, quote, It took over 10 years from the publication of Wampler (many more from its priority date) and 5 years after the priority date of the '356 Patent before an LVAD was actually made small enough to be implanted at the apex of the heart.

And a similar quote from Dr. Gallegos, who's the expert that Patent Owner's Counsel said, you know, has a busy clinical practice, he said, quote,

Contrary to Petitioner's contentions, as of the priority date, I was not aware of any LVADS that were positioned at the apex of the heart, end quote.

JUDGE TARTAL: Counsel, for purposes of supporting your motivation to combine, is there any relevance to whether and which devices and all that was placed at the apex of the heart was publicly disclosed or addressed in a way in which a person of ordinary skill in the art would have been aware, as opposed to situations where, for example, something may have been done in a clinical practice that was not known to the public at the time?

MR. BOYLE: Yeah. So, Exhibits 1015 and Exhibit 1044 describe the device's structure, and that the device's structure allowed for clinical implantation at the apex of the heart.

JUDGE TARTAL: Thank you, Counsel.

MR. BOYLE: So that was in their Patent Owner Response. In our reply to that argument, we identified what I just mentioned: numerous contemporaneous printed prior art publications evidencing that LVADS had been implanted in humans at the apex of the heart years before the priority date. And so, that's why we cited at Slide 39 of our argument that Patent Owner's expert's testimony is plainly inconsistent with the record and should be disregarded. So that's the context for why Patent Owner is now seeking to exclude this evidence, because it undermines their expert's opinions on this matter.

So, referring to back to Slide 44 of Patent Owner's demonstratives, which is when they outlined their arguments for why this evidence should be excluded, there is four bullet points in Patent Owner's demonstrative Slide 44. And briefly, I'll just explain why each of those four bullets fail.

So, in the first bullet, Patent Owner concedes that the evidence we're talking about here is rebuttal evidence, and it's rebuttal evidence that we rely on to corroborate that persons of skill in the art would be motivated to make the Ground 2 combination.

Because it's rebuttal evidence, as Patent Owner concedes in the first point, its argument in the second bullet point fails that. And its argument in the second bullet point is about Section 311(b). Section 311(b) states only that the ground for the IPR must be based on prior art consisting of patents or printed publications, but none of the exhibits they're trying to exclude are the grounds for our -- are our grounds. So the Section 311(b) does not provide a basis to exclude this evidence.

The third bullet point that Counsel has raised was that, well, the devices described in the evidence that they're trying to exclude, those devices are different devices than the grounds. Well, that also doesn't provide a basis to exclude the evidence. And as an initial matter, many of these devices are the same or fundamentally the same. Exhibits 1015 and Exhibits 1044 describe the HeartWare HVAD, and that is the pump that progressed from the Wampler pump. And that's not in dispute that it progressed from that design.

So, even if these devices aren't the same as the grounds, that does not matter because the evidence nevertheless shows the known options that were available to persons of skill in the art. So it is, you know, well-settled law under KSR that a motivation to combine depends on reasons to pursue known options. So, Patent Owner can dispute that these options were known, or that they would provide a basis for motivation, but that is not a basis to exclude the evidence altogether.

And the fourth and final point, Patent Owner argued that this evidence is irrelevant under Rules 401 and 403, but the evidence and related testimony certainly sheds light as to the devices known at the time to persons of skill in the art. And Patent Owner identified no danger of confusing the issues or unfair prejudice or any other of the concerns under Rule 403, especially here for a bench proceeding.

And finally, under Rule 702, even if this is public use evidence, which I've already explained that it's not, Rule 702 would not -- Rule 702 would plainly permit public use evidence. There's no dispute here that the experts are qualified. Dr. Wieselthaler and Mr. Crosby are qualified experts. And as experts, they may base their opinions on their experiences in the field under Rule 702. So, in sum, none of the arguments they raise provide a proper basis to exclude this evidence.

And unless there is any questions on that point, quickly, Your Honor, there was a Slide 38 in Petitioner's demonstratives that we did not include in our opening, but we plan to include it now, and that's the slide that they

object to. I believe Your Honor addressed this already at the beginning of the hearing, so stop me if this is unnecessary, but I will just --

JUDGE TARTAL: Sure. Were you planning on using Slide 38?

MR. BOYLE: We are going to use it. My Co-Counsel is going to use it.

JUDGE TARTAL: Well, we'll take their objections under advisement, and you're welcome to make comments if you have something in support of the notion that their objections are unfounded.

MR. BOYLE: Well, quickly, I think their main objection is that it's a new argument based on new evidence and brief. It's not -- it's not Petitioner's new argument. It's Patent Owner's new argument that is being addressed.

Exhibit 1015, for context again, is an exhibit that was submitted with the petition. They waited to -- until the filing of their sur-reply, to call Exhibit 1015, quote, a press release. And this is via an argument they make at Slide 29 at their demonstratives, Patent Owner's demonstratives. And the evidence that we cited just contradicts that Exhibit 1015 is, quote, press release. The deposition testimony that we cite shows it's not a press release. It's a journal abstract from a peer-reviewed journal that was presented at a conference in 2004.

So, unless there is any other questions, I will let my Co-Counsel Saranya take over.

JUDGE TARTAL: Seeing no other questions, thank you, Counsel.

(Pause.)

JUDGE TARTAL: Can I ask a question? And this is off the -- off of my recollection, but -- and it's sort of a tangential question, but I think, on the ordinary level of ordinary skill in the art, I think Patent Owner may have proposed experience of five years with compatible heart devices or something to that extent, as opposed to medical devices more broadly. Does Petitioner have a response to their proposal of level of ordinary skill in the art, or any reason why you disagreed with what their assertion was, or why that was relevant to any of the grounds that you're asserting?

MS. RAGHAVAN: Yes, Your Honor.

JUDGE TARTAL: Or your expert testimony?

MS. RAGHAVAN: I'm happy to address that as well. If we could get our demonstratives back up at Slide 88.

JUDGE TARTAL: I apologize this comes up in reply, but you'll have a chance to address it if you need to.

MS. RAGHAVAN: So, Slide 88 of our demonstratives, Your Honor, answers your question regarding our position on the person of ordinary skill in the art and the appropriate definition here. We believe that after much briefing on this topic, there is actually no remaining dispute as to a definition.

So, just to provide some context here, Petitioner proposed the definition in the first bullet point here. So, as part of that, it looks like the

dispute revolves around developing implantable medical devices, and Your Honors accepted or adopted that definition in the Institution Decision.

In their Patent Owner Response, the Patent Owner proposed further tailoring that definition to include at least five years of experience designing and developing implantable cardiac assist devices, in particular, not just medical devices. But our understanding, based on their sur-reply at page 1, is that Patent Owner no longer disputes whether either of the experts fall under the -- either definition.

So there's no dispute as to whether either side's experts actually qualify as experts in these proceedings. There is no dispute over whether the cited prior art reflects the understanding of a POSA. There is no dispute as to whether a motivation to combine is affected by the definition of a POSA. So we think that, at bottom, this is just a definition that the parties are arguing over as to just provide a bit of definition, but we are -- we agree with the definition that the Board adopted in the Institution Decision, ultimately.

We also take the position that it's unnecessary to craft a narrow description or a narrow definition, as Patent Owner has proposed here, to be limited to at least five years of experience in developing implantable cardiac assist devices, and we have two reasons for that. These are laid out in our reply brief at page 2, I believe.

So, the first reason is that Patent Owner's POSA definition would exclude Mr. Kevin Bourque, who is the author of Bourque-2001. And under the Daiichi v. Apotex Federal Circuit case -- this is a 2007 decision -- if a

narrower -- if a definition fails to consider the educational level of active workers in the field, then it is not the appropriate definition. There can be no -- there can be no doubt that Mr. Bourque, who we've discussed at length at this proceeding, throughout the papers, at the hearing today, is the -- is someone of active level of understanding in the field.

The other point that we raised in our reply as well is that Dr. Leschinsky previously opined in a similar case involving patents by the same named inventor as the challenged patents here. So Dr. Werner Mohl has several other patents. He expressed some opinions about what would be the appropriate definition of a POSA in those cases, and there, he said just two years of experience was sufficient. We asked him about this at cross-examination, and he didn't really have a reasoning as to why he was proposing a different definition here.

So those are, ultimately, our reasons for why we don't think it matters substantively as to it -- why there remains no dispute as to why -- the operative definition, but either way, we think that a narrower definition is improper here.

JUDGE TARTAL: Okay. Thank you.

MS. RAGHAVAN: And with that, I'll move on to address some of the points that Counsel raised with regard to Ground 2. And I'll back up and address the Bourque-only portion of Ground 2 first because, as I said earlier, if the Board agrees with our interpretation of axially aligned, then Bourque alone is sufficient to invalidate the claims.

So, with that, let's turn to Slide 93 of our demonstratives. So Slide 93 has an excerpt of Figure 1 from one of the challenged patents. I heard opposing Counsel mention that they were surprised, or they were confused by the diagrammatic nature of the inflow tube as shown in Figure 1, but we wanted to assure the Board that this is -- there is no surprise as to the bend in the inflow tube 9 here.

If we look at the disclosures in the patent itself, and also as confirmed by the Institution Decision, and by the Patent Owner's own expert, as shown on Slide 93, you can see that the invention revolves around a catheter-based system. And of course, a catheter is a flexible tube, and that's what is shown in Figure 1.

And if we could go back to Slide 14, we pointed out earlier, as part of Ground 2, that if Patent Owner is correct that Figure 2 shows axial alignment, as they contended in their sur-reply, then, certainly, we can -- it's appropriate for the definition or the interpretation of axially aligned to just look at a portion of the tube. That's what Figure 2 does.

The Counsel then expressed some concern over how much of a portion it was. They said perhaps it was a little portion, perhaps it was a large portion. I don't think that the degree of the portionality matters. The point is, the patent -- if they're correct, the Figure 2 is enough to show axial alignment, and they only need to look at a portion of the inflow tube to determine axial alignment, then certainly, we can just look at the -- of the

area of Bourque that is in this square, red -- this red square, and say that portion is axially aligned.

Counsel also made a confusing remark that Bourque cannot -- is totally perpendicular; the Bourque inflow subassembly is totally perpendicular. So, I think what they're referring to is the fact that the green rectangle sits on top of the pink impeller portion of Bourque, but just common sense would dictate that -- and the flow -- and the flow diagrams dictate as well that it's not just two elements sitting on top of each other. Indeed, the blood flows through the tube and has to turn in at some point in order to enter the rotor. And so, at least at that portion, it is axially aligned. And as we talked about earlier, that is a fundamental and central feature of all centrifugal pumps.

JUDGE TARTAL: If there's only a hole in a tube?

MS. RAGHAVAN: Repeat that, please.

JUDGE TARTAL: If there's only a hole in a tube that's otherwise perpendicular, what portion of that tube is axially aligned, if that --

MS. RAGHAVAN: Well, Your Honor, I don't think it needs to be that limited in this particular circumstance because the tube here, that is shown here, actually does make a turn. So, if we look at the gray portion behind the red arrows, there is some portion that actually turns, if I can attempt to use the laser pointer here. This portion that turns down is a reflection that there is a turn. It is not, in fact, just a hole in the tube.

JUDGE TARTAL: Okay.

MS. RAGHAVAN: Okay. Let's go to Slide 17 of our demonstratives. So I want to get the motivation to combine story right here. So there was a lot of repetition about the language in the Wampler reference, as shown in Slide 17. And in particular, Counsel focused on the sentence that we don't have highlighted here, but is towards the bottom of this excerpt, that says, Good anatomic compatibility is possible since the pump casing is compact, disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm.

Now, they said this language was purportedly cited several times. I think they said 20 in their briefing. But this real -- only focusing on this aspect of Wampler ignores the earlier disclosure that we -- that I talked about in my opening remarks. First, that a centrifugal design of the pump allows a considerable amount of flexibility during implantation. So, when Counsel was talking about a dinner plate being, you know, inserted in at one angle versus another angle, these are the type of flexibilities that Wampler is readily contemplating.

And then the second part of that is the actual motivation to combine, which is saying expressly that you can take out the flow-restrictive elbow fitting. And so, concentrating just on one example of how this device can be implanted is improper, and that's not our motivation to combine.

If we can take a look at one of the portions of the Institution Decision that Counsel cited, let's go to the Institution Decision at pages 34 and 35, please.

(Pause.)

So, if we go down to the last paragraph of page 34 of the Institution Decision, it appeared that Counsel was referring to the quote from Wampler that again talks about good anatomic compatibility is possible, fitting well between the apex of the heart and the adjacent diaphragm.

But as the section continues -- and the Board acknowledges what Petitioner's motivation to combine are, first of all, the Board correctly acknowledged that Petitioner offered several reasons that these references can be combined. Second of all, towards the end of that page, the bottom of page 34, the Institution Decision correctly identifies that we have proposed the motivation to be eliminating the flow-restrictive elbow.

And then I would like to point the Board's attention to the end of the second paragraph on page 35. Actually, it's highlighted for us helpfully here. So it says that there were a finite number, i.e., two options for LVAD implantation. The device would be implanted at a preperitoneal pocket or at the cardiac apex. So it is simply just false that we have proposed a combination that relies on implantation at the apex of the heart, setting aside even the fact that none, as Your Honors have correctly acknowledged, that there is no requirement to do so in the claims.

Let's go to Slide 22 of our demonstratives, please. So there was much discussion about the weight, volume, location of several of the pumps that are discussed as part of our evidenced reasonable expectation of success. But again, we would submit that weight, volume, size, et cetera, are not any

-- are not constraints that are expressed anywhere in the claims. And in fact, this table shows the opposite of what Patent Owner contends. It shows that a variety of different size of pumps were known in the art before the priority date of the patent, and POSAs would have recognized that there were multiple locations at which to implant these types of pumps.

And so, we can see here in the chart that we excerpted from Patent Owner's response that certain pumps were placed in the pocket, others were placed at the apex, and there are a variety of different sizes of pumps, ranging from perhaps the HeartWare HVAD pump that could be implanted at the apex, to all the way to the Bourque-2001 pump that could be implanted in the pocket. And there is no dispute that the Bourque-2001 could have been implanted in the pocket, at least in some alignment.

I'd like to pull up an admission from Patent Owner's expert, Mr. Leschinsky, his deposition transcript, Exhibit 1040, at page 38. And the point that I would like to make for the Board here is that while pumps are different sizes and can be implanted in different locations, it is also true that humans are of different sizes. And so, this isn't a one patient fits all type of equation.

We see here that Mr. Leschinsky says, if you're talking about a large male patient, you could implant a larger implant, correct? And so, there are smaller implants that would be suitable for pediatric uses, for example, in children, and then there are larger implants that can be placed in different

locations of an adult male body, in this case, and their mechanical engineer agrees, and I believe their surgeon expert agreed as well.

JUDGE TARTAL: You have about a minute left.

MS. RAGHAVAN: So I think that the last point I will make is that this isn't about whether Mr. Bourque himself contemplated modifying his pump or the design that was in Bourque-2001. This isn't about any one company or Abbott or Thoratec or whoever in 2001. It's about a POSA being able to combine the various teachings that were present in the prior art. Bourque himself, actually, in the 1008 -- 1007 Exhibit at page 405 says that he would -- he himself was aiming to make a compact design out of the design of the pump that he disclosed in his patent.

So, with that, I will stop there and address any other questions in follow up. Thank you.

JUDGE TARTAL: Thank you, Counsel. I don't think our Panel has any additional questions for you at this time.

I have you at about seven minutes, we won't be absolute sticklers. And then, if you could start just by briefly addressing or confirming whether or not there is any dispute over the level of skill in the art that's relevant to any of our determinations, that would be good.

MR. CAHILL: So, I would like to discuss that, and I plan to discuss it.

JUDGE TARTAL: Good.

MR. CAHILL: I may wait a minute before I do.

JUDGE TARTAL: That's fine.

MR. CAHILL: But I'll make sure I set a minute to talk about it.

Anatomy has to matter. The first thing Counsel said when she got up for rebuttal was to talk about motivation, specifically in the context of Akamatsu, and to say that the motivation is inserting the suction end of the inflow tube into the ventricle of the heart because that's what the claim says. The claim says more than that.

So, the claim says the first step in Claim 1A of the '356 Patent is delivering a heart assist pump device to the heart so that a suction end of the inflow tube is inserted into the ventricle of the heart. So, this is a method for assisting the blood circulation of a heart. It has to matter how the device is sized and shaped to be deliverable to the heart so that there is an axial inflow tube with all the characteristics that follow, and there are a lot of them. The inflow tube has to be axially aligned. The rotor has to be -- has to have gap between it and the housing that's filled by the blood.

There are a lot of things you have to do in this pump, and it has to be deliverable to the heart so that that inflow tube that's axially aligned is inserted into the ventricle. It can't be just any. You can't do this with a lawnmower. You can't do it with a refrigerator. A person of ordinary skill in the art would understand that there are some specific requirements, and a lot of them have to do with the anatomy.

And one of the critical issues with the anatomy, as we've seen all over the art, is that the apex of the heart, where the suction end of the inflow tube

goes, it's right next to the diaphragm. And a person of ordinary skill in the art knows you have to deal with that.

And so, it's not the case that it can be any size. And I think it's also not the case that you can just say make Bourque smaller. How? How do you make Bourque smaller and still have it be meeting the elements of the claims? How do you still have it? Do you still have magnetic suspension, which seems to be the problem with size? And if you take it away, how do you -- how do you then separate the rotor from the housing so there's always a gap of blood between them?

Wampler, in his first embodiment, did it a different way, and he had bearings that actually made contact. So, it's not simply that a person of ordinary skill in the art would not see it as so easy as, well, if it's too big, make it smaller. They would know that there are requirements in order to deliver it to the heart and have it fit to the heart the way that it's recited, and to meet all of the other configuration requirements of the claims. It's not so simple as make it smaller, and it's not so simple as it doesn't matter what size it is; the claims don't require size. It doesn't say in here how many cubic centimeters. It just doesn't say.

But a person of ordinary skill in the art, meeting the active step in this claim -- there are other claims that are system claims, and the language is functional. It says deliverable to a heart, insertable into the ventricle. For those claims, there has to be a presently existing capability of the pump to be able to meet those requirements. And we think there's not that much

difference. But the anatomy has to matter, and how the pump interacts with the patient has to matter.

So let's go to the person of ordinary skill in the art, Slide 51. So this has our definition in it, and Counsel was exactly correct. The difference between our definition as to theirs is we say implantable cardiac assist devices, and they say implantable medical devices.

But the person of ordinary skill in the art, the person who is going to be motivated, the person who is going to look at the statements in Bourque about how it fits with anatomy, the statements in Wampler, how it fits with the anatomy, that person has experience in the human circulatory system anatomy and physiology and five years of experience of implanting medical devices. They know that the anatomy drives how the pump is configured, how big it is, and where it fits. They know that.

Now, we say implantable cardiac assist devices. We think it's clear from the subject matter that we've been discussing today that that's what a person of ordinary skill in the art is. I'm not sure why they say Mr. Bourque would be outside this definition.

JUDGE TARTAL: Can you just clarify, is there -- what is the issue that we need to resolve that turns on whether we adopt your proposed construction or not? I understand if you were trying to exclude their experts or had some other issue that this was tied to that would then require us to make some further determination. I just want to be clear that --

MR. CAHILL: Yeah, we're --

JUDGE TARTAL: -- I understand sort of the context of what the issues are that we as a Panel need to address because it has some effect on how the case is determined.

MR. CAHILL: We do not seek to exclude anyone based on this definition. This is the person through who's eyes we interpret the prior art, and this is the person that the evidence for the motivation to combine applies to. So it's how that person sees the evidence. We've obviously put implantable medical devices because -- implantable cardiac assist devices, because we think that the subject matter is specifically technical, and that drives how that person would see the requirements for building this heart assist pump device that's delivered to the heart with the axially aligned inflow tube inserted into the ventricle.

JUDGE TARTAL: Understood.

MR. CAHILL: The last comment I'd like to make is I ran out of time before I addressed any of the -- and it's my fault. I ran out of time before I addressed the dependent claims, but we subscribe to Your Honor's theory that we stand by comments in our Patent Owner's Response.

JUDGE TARTAL: Right, understood.

MR. CAHILL: Thank you.

JUDGE TARTAL: The arguments weren't waived, whether -- regardless of whether you addressed them in the sur-reply or not, is what you're referring to, correct?

MR. CAHILL: Yes, sir.

JUDGE TARTAL: Understood.

MR. CAHILL: Thank you.

JUDGE TARTAL: Any additional questions from the Panel? I think they are indicating they don't have any additional questions. So I will just say thank you for appearing today and for answering our numerous questions.

We would like to especially thank our LEAP practitioner, Mr. Boyle, for appearing today and participating in oral argument. We certainly hope it was a valuable experience.

We'll take the case under advisement and issue our decision in due course. This hearing is adjourned.

(Whereupon, the above-entitled matter went off the record at 4:44 p.m.)

IPR2025-00096 (Patent 11,351,356 B2)
IPR2025-00112 (Patent 11,351,357 B2)
IPR2025-00113 (Patent 11,376,415 B2)
IPR2025-00114 (Patent 11,572,879 B2)
IPR2025-00115 (Patent 11,674,517 B2)
IPR2025-00116 (Patent 11,754,077 B1)

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