PATENT AND TRIAL APPEAL BOARD

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ABBOTT LABORATORIES,

Petitioner

vs. NO. IPR202500096 (PTAB)

MIRACOR MEDICAL SA,

Patent Owner

****

DEPOSITION OF: BORIS LESCHINSKY

BARNES & THORNBURG LLP

One Marina Park

Boston, Massachusetts

December 10, 2025 9:09 a.m.

Darlene M. Coppola

Registered Merit Reporter

Certified Realtime Reporter

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P R O C E E D I N G

(Commencing at 9:09 a.m.)

BORIS LESCHINSKY,

a witness called for examination by counsel for the Petitioner, having been satisfactorily identified by the production of his driver's license and being first duly sworn by the Notary Public, was examined and testified as follows:

THE STENOGRAPHER: Thank you. You may proceed.

DIRECT EXAMINATION

BY MS. RAGHAVAN:

Q. Good morning, Mr. Leschinsky.

A. Good morning.

Q. My name is Saranya Raghavan. I am counsel for petitioner in the IPRs that I believe you submitted a declaration for.

Nice to meet you.

A. Nice to meet you too.

Q. Could you please state your name for the record.
A. Yes. My name is Boris Leschinsky.
Q. A few moments ago, you just took an oath to tell the truth today, correct?
A. Yes.
Q. Is there any reason why you would not be able to offer truthful, complete, and accurate testimony today?
A. No.
Q. Have you been deposed before?
A. Yes.
Q. How many times?
A. Four, six.
Q. Four or six?
A. Four to six.
Q. You don't recall?
A. Not really.
Q. When were those four to six depositions?
A. In the last five years.
Q. Were they in IPR proceedings?
A. No.
Q. Were they in district court

proceedings?

A. I believe so, yeah.

Q. Were they in patent litigations?

A. Some were.

Q. What were the other ones?

A. Product liability.

Q. So I understand that you've been deposed a few times before, but just so that we're on the same page, I just want to go through some general rules for the deposition today.

Just to make our lives easier and life easier for our court reporter, who is taking down everything that all of us say today in the room, it's very important that you answer my questions with words as opposed to gestures or head nods and so on; is that fair?

A. Understood.

Q. It's also important that we don't interrupt each other so we have a clean record. So I will wait until you finish your answers to ask my next question, and I would appreciate it if you let me finish my questions before you begin your answer; is

that fair?

A. Okay.

Q. If at any time I ask a question and you do not understand my question, would you please let me know, and I will try to rephrase or clarify; is that fair?

A. I will.

Q. And I will plan to take a break approximately every hour or so. If you need a break sooner than that, please let me know. Unless there's a question pending that I would like you to answer, we can accommodate; is that fair?

A. Understood.

Q. Your counsel here from time to time may object to some of my questions. And unless your counsel instructs you not to answer, you must answer my questions; is that your understanding?

A. Understood.

Q. Did you bring any notes or materials with you today?

A. No.

Q. Mr. Leschinsky, you were retained by

Miracor, the patent owner, as a technical expert in these proceedings; is that correct?

A. It is.

Q. And you submitted a declaration in six IPRs that were filed by the petitioner, Abbott, against six Miracor patents; is that your understanding?

A. That is correct.

Q. And you understand that the six Miracor patents at issue in those six IPRs are related patents, correct?

A. Yes.

Q. They're all from the same patent family?

A. I believe so.

Q. Just for efficiency sake today, I will be referring to your declaration in IPR 2025-00096, which relates to the '356 patent, and asking you questions based on that declaration as a representative declaration; is that fair?

A. That's fine.

Q. So to get things started, I'm going to

hand you a copy of that declaration, which was previously marked as Exhibit 2015.

Do you recognize this document?

A. Yes, it's -- seems like my declaration.

Q. If you could, turn to the very last page of this document. That is your signature, correct?

A. Yes.

Q. It was applied electronically?

A. I believe so.

Q. Did you apply your signature to the document?

A. Yes.

Q. Did you sign it on September 30, 2025?

A. That's what the date says, yes.

Q. Do you recall signing it on September 30, 2025?

A. I recall putting the date when I signed it, so it must be the right date.

Q. Do you know if you reviewed the final version of the declaration when you signed it?

A. Yes.

Q. Going back to the overall landscape. So if at any point you believe that you offered a different opinion in one of the other five declarations that you submitted in the other five IPRs, will you point that out?

A. That sort of is a broad statement. I'm not sure if I can accurately do it every time because there are -- there are differences, but they're subtle differences. If I recall a specific difference, I will point it out.

Q. Sitting here today, are you aware of what the differences are among the different declarations that you submitted?

A. They are based on the claims of these patents, and they are somewhat different in certain aspects.

Q. Do you recall the specific aspects in which they are different?

A. Well, yeah, there's some language differences. I can -- I don't know how I can answer that question. I mean, we have to look at side by side, you know, different claims

with the patent and see what the differences are. But there are some differences.

Q. Would you agree that the six declarations are substantially the same?

MR. CAHILL: Object to form.

A. To the extent that they address each individual patent, there is an overlap. There's certainly an overlap.

BY MS. RAGHAVAN:

Q. Mr. Leschinsky, I understand that you're not a medical practitioner; is that correct?

A. That is correct.

Q. And you're not a surgeon?

A. I'm not a surgeon.

Q. You're offering opinions in this proceeding as an engineer and an inventor, correct?

A. Yes. Engineer and inventor, in a broad sense of the word, I guess. I guess that's correct.

MR. CAHILL: Mr. Leschinsky, if you could just wait a beat before you answer so I can interpose objections, if necessary.

THE WITNESS: I'm sorry. Yes.

MR. CAHILL: I'll object to the form for that last question.

BY MS. RAGHAVAN:

Q. What, if anything, did you do to prepare for today's deposition?

A. I reviewed my reports.

Q. You reviewed all six declarations?

A. Yes, I did.

Q. What else did you do to prepare?

A. I reviewed citations, materials that were discussed in these -- in these reports.

Q. Anything else?

A. No.

Q. Did you meet with your counsel?

A. I did.

Q. Who was the counsel you met with?

A. These two gentlemen here.

Q. Anybody else?

A. Todd was on the phone at some point, so -- but it was a remote connection.

Q. By "Todd," you mean Todd Vare?

A. Yes.

Q. When did you meet with your counsel?

A. Over the last two days.
Q. How many meetings would you say you had with your counsel in preparation for this deposition?
A. Two.
Q. How long were each of those meetings?
A. Most of the day.
Q. Is that eight hours each?
A. Approximately.
Q. Are you aware that Dr. Gallegos also submitted a declaration in these IPR proceedings?
A. I heard about this, yes.
Q. Do you know Dr. Gallegos?
A. No.
Q. So you didn't meet with Dr. Gallegos, correct?
A. No.
Q. Anything else that you did to prepare for your deposition that we haven't discussed?
A. No.
Q. Let's turn to Paragraph 2 of your declaration. And again, that's Exhibit 2015.

Let me know when you're there.
A. Yes.
Q. You say here that you're being compensated at your usual consulting rate.
Do you see that?
A. Yes.
Q. What is your usual consulting rate?
THE WITNESS: Should I disclose?
MR. CAHILL: Yes.
A. $400 an hour.
BY MS. RAGHAVAN:
Q. Okay. Let's turn to Paragraph 33 of your declaration.
It's your opinion that Mr. Crosby's definition of an LVAD is too narrow; is that correct?
A. Yes.
Q. What does LVAD stand for?
A. The definition is left ventricular assist device.
Q. In your opinion, the definition of LVAD should include intra-aortic balloons?
A. Yes.
Q. In your opinion, the definition of

LVAD should include direct cardiac compression devices?

A. Yes, it is.

Q. In your opinion, the definition of LVAD should include aortic counterpulsation devices?

A. Yes.

Q. In your opinion, the definition of LVAD should also include an inflow cannula placed in the left atrium rather than the left ventricle; is that correct?

A. Yes.

Q. You told me earlier that LVAD stands for left ventricular assist device, correct?

A. Yes.

Q. That expansion of LVAD doesn't include the word "atrium" or variations of the word "atrium," correct?

A. Just a second. Can you clarify? What do you mean by "expansion"?

Q. Any variations -- or sorry.

By "expansion," I meant the expansion of the acronym "LVAD," left ventricular assist device.

A. Oh, well, the acronym stands for what it stands for.

Q. So it doesn't include the word "atrium," correct?

A. Not in that four letters, no. But functionally, I believe that other systems would be considered as assisting left ventricle and therefore should be included here as well.

Q. The atrium is a different portion of the heart than the ventricle, correct?

A. Atrium is a different anatomical entity from the left ventricle.

Q. If you could, turn to Paragraph 4 of your declaration.

A. Yeah.

Q. This paragraph appears under the heading "Background and Qualifications," correct?

A. Correct.

Q. And in this section, you aim to summarize your technical background and qualifications; is that fair?

A. That is correct.

Q. In Paragraphs 4 through 9 of your declaration, you cover your education and experience through 2009; is that accurate?

A. Which paragraphs?

Q. Paragraphs 4 through 9?

A. 4 through 9. Well, no, it's actually not just limited to that period of time. Paragraph 7 talks about my experience in 2009 to '13 and so on. So I think it covers -- these paragraphs together cover more than that period of time.

Q. Any experience that you had prior to the priority date of the patent, which is 2007, would have been summarized in Paragraphs 4 through 9, correct?

MR. CAHILL: Object to form.

THE WITNESS: These paragraphs do not separate my experience prior to and after the filing date of the patent. They summarize my experience overall.

BY MS. RAGHAVAN:

Q. But if I were to try to understand what your experience was prior to the priority date of the patent in 2007, I would look to

Paragraphs 4 through 9, correct?

A. Well, no. Some of them talk about in the later period, so I don't know which period -- but I would say probably 4 through 6 is more accurate because they go through 2009.

Q. Fair enough.

Let's look specifically at Paragraph 5.

A. Yes.

Q. In this paragraph, you are talking about your master's degree in mechanical engineering from Moscow State Technical University, which you received in 1987; is that correct?

A. Yes.

Q. And the remainder of this paragraph is discussing work that you did while earning your master's degree?

A. No. It was afterwards.

Q. So the remainder of this paragraph is talking about your experience out of college after you earned your master's degree?

A. Correct.

Q. And roughly what time frame were you

performing those activities?

A. So I finished my education in 1997. Then I was recruited by the Scientific Institute, where I worked through 1990. And then I left Moscow, and I came here, and I started working at Datascope in 1990. And so from that point on, I worked at Datascope on various projects.

Q. So in the third sentence of Paragraph 3, you say, "While at the Scientific Institute, I developed new concepts for centrifugal blood pumps."

Do you see that?

A. Well, it's Paragraph 5, yes.

Q. Sorry. Yes, Paragraph 5.

A. Yes.

Q. What new concepts did you develop for centrifugal blood pumps?

A. I had applied for, I believe, five Russian patents describing various innovations that I came up with, and that was the result of my actually couple of last years in college and work at the Scientific Institute. So I was closely interested in centrifugal blood

pumps at the time, and I was devising different concepts how to make them better.

Q. What concepts specifically did you devise?

A. Well, one of them had an idea of soft blades versus the rigid blades that usually -- that these devices usually have.

Another concept had an idea of seeping blood-compatible fluid through the surfaces of the device such that there is no direct contact between blood and the plastic of these devices.

There's different concepts.

Q. And to the extent that you came up with any new concepts, they were summarized in the Russian patents --

A. That is correct.

Q. -- that you mentioned?

And you did this work between 1987 and 1990, correct?

A. '85. I was doing this when I was in college, yeah, in 1990.

Your work on centrifugal blood pumps was for extracorporeal devices; is that

right?

A. I didn't really separate them at the time into --

(Stenographer clarification.)

A. I did not separate into extracorporeal and implantable devices as far as I recall, so they might have been applied to either one. The tests that we did were primarily with bench tests, so we didn't really proceed too far to human implantation.

BY MS. RAGHAVAN:

Q. So is it fair to say that sometimes centrifugal blood pumps could be used for extracorporeal applications and as implantable devices?

A. That's a broad statement. I would say conceptually, whenever the new idea is developed, it's developed for, like, a broad idea of the centrifugal blood pump, and then it finds its way into a specific application at some later time.

Q. So at least for the devices that you

were developing, you believe they were applicable for both extracorporeal applications and as implantable pumps, correct?

A. I don't remember. It's been a long time.

What I do remember is that we didn't really separate initially where it will go. It was just looking at the ideas whether they were practical or not.

Q. Do you think that's a common philosophy in the industry?

A. I can't say. I can't tell. That's what we did at the time. What other people do, I don't know.

Q. The blood pumps you were testing, you tested them on artificial heart pumps, correct -- or artificial hearts, correct?

A. I didn't quite understand the question.

Q. I'll rephrase.

The blood pumps that you were designing were tested on artificial hearts, correct?

A. Again, I don't understand the question.

The heart pumps that we were developing were used as a substitute for a natural heart, so in that sense, they were, broadly speaking, artificial hearts. So -- but we were not testing one pump on another pump, if that's what you mean. That's why I don't understand what you're asking me about.

Q. Did you ever implant any of the centrifugal blood pumps that you designed?

A. No.

Q. Other than the patents that you filed, were people in the field aware of the concepts that you developed for centrifugal blood pumps?

A. We published a paper or two.

Q. Why were you interested in developing centrifugal blood pumps at that time?

A. Well, the laboratory that I worked at already had a significant project on the total artificial heart which was a device similar to the Jarvik device, and so I was looking at alternative ways to assist the heart, and

centrifugal blood pumps would constitute one of these alternatives, so I was interested in that.

Q. Do you know if others were interested in centrifugal blood pump designs at the time as well?

A. Like worldwide? Or -- I don't quite understand the question.

Q. Yes --

A. My laboratory or like broader? Can you specify what you're looking for?

Q. Sure. Let's start with in your laboratory.

Were others interested in the designs that you were coming up with for centrifugal blood pumps?

A. My boss was interested in this, yes. He supported the project.

Q. Did you know of others worldwide outside your laboratory who were also working on designs for centrifugal blood pumps at the time?

A. Oh, yeah, many laboratories in different places around the world were

developing these devices.

Q. Why do you think they were interested in developing centrifugal blood pumps at that time?

A. Well, it was a -- and it still is a promising technology that can provide significant clinical benefits.

Q. Can you turn to Paragraph 6 of your declaration?

A. Yes.

Q. In this paragraph, you reference the percutaneous heart assist PHP project, right?

A. Yes.

Q. This is an intravascular heart pump; is that right?

A. Yes.

Q. It's inserted percutaneously, as the name suggests, correct?

A. Yes.

Q. Under your definition of LVAD, this is an alternative LVAD configuration, correct?

A. That's one of the LVADs that would fall into this -- into that broad

category, my definition. I wouldn't call it alternative. It's one of.

Q. Would the PHP device be considered an LVAD under Mr. Crosby's definition of an LVAD?

A. I don't know.

Q. But it is an LVAD under your broad definition that you're proposing?

A. Yes.

Q. The PHP is a balloon pump; is that correct?

A. No.

Q. What kind of pump is it?

A. It's a catheter pump. It is designed to be inserted in a small compressed diameter state, and when it's inside, it expands to increase its size, and then it operates by rotation of the impeller, and then when it's done, it goes back to a small size to be removed.

Q. So you wouldn't describe that expansion process as a balloon?

A. No.

Q. How does that device impact the pumping function of the heart?

A. Well, it provides what's called unloading, which is it assumes a portion of the blood flow that the left heart usually expels into the aorta. So for hearts that have impaired left ventricle function, it would assist in that process, which is why I believe it's -- it can be called a left ventricular assist device.

Q. Let's look at Paragraph 7 of your declaration.

This paragraph talks about work you did from 2009 to 2013, correct?

A. Yes.

Q. And this is after the priority date of the patents that we're discussing?

A. Apparently.

Q. From 2009 to 2013, you were just -- you were part of a team developing devices for treating brain aneurysms; is that correct?

A. That is correct.

Q. You were not working on any cardiac assist devices at that time?

A. That is correct.

Q. Let's look at Paragraph 8 next.

So in 2009, you also cofounded LifeCuff Technologies; is that right?

A. Yes.

Q. When did you start at CorInnova?

A. Well, it says 2013. That is when I actually formally joined CorInnova, but I worked as a consultant before then.

Q. What years did you work as a consultant for CorInnova?

A. Probably in the previous couple of years, so 2011 to '13. I'm generalizing here.

Q. So as you say in Paragraph 9, "The CorInnova device is a minimally invasive nonblood-contacting direct cardiac compression cardiac assist device"; is that correct?

A. That is correct.

Q. Can we shorten that to say that it's a direct cardiac compression device?

A. Yes.

Q. It's not a blood pump, correct?

A. It is not a blood pump.

Q. Would the CorInnova device be considered an LVAD under Mr. Crosby's definition of an LVAD?

A. I'm not sure how to answer that question.

Q. But you thought that Mr. Crosby's definition was too narrow, correct?

A. Yes.

Q. But you haven't considered whether the CorInnova device would have been considered an LVAD under his definition?

A. I say what I say, which is the concept of left ventricular assist device. I see it as a functional definition, not a narrow definition that's related -- that only describes blood pumps.

For example, CorInnova device also assists the heart, and in that sense, it assists left ventricle, and for that reason, I believe that it can be considered a left ventricular assist device.

Q. I understand your definition of an LVAD, but I'm asking you a different question, which is whether the CorInnova device would be considered an LVAD under Mr. Crosby's definition of an LVAD.

A. You can ask Mr. Crosby.

Q. Do you recall, sitting here today, that Mr. Crosby had a different definition of an LVAD?

A. Well, I say in my report that it was a narrow definition, and I expanded this to include compensation devices and the direct cardiac compression devices, so I don't remember exactly the detail of his definition, which is why I'm now hesitant to answer that question.

But since I included these examples, which he did not, I assume that under his more narrow definition, it would not -- it would not include these devices.

Q. So you needed to propose a broader definition of LVAD in order to include these other devices that you worked on, correct?

MR. CAHILL: Object. Object to form.

A. The report says what it says.

BY MS. RAGHAVAN:

Q. You started working on this CorInnova device in 2013, correct?

A. I formally joined the company in 2013,

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correct.

Q. When did you first start working on the CorInnova device?

A. As I mentioned before, I believe I consulted for the company for a couple of years before that here and there, but it was not a full-time engagement.

Q. At the time you were consulting, were you working on designs for the device?

A. I suppose so. I don't remember exactly what I did.

Q. You would agree, though, that your work on the CorInnova device was after the priority date of the challenged patents?

MR. CAHILL: Object to form.

A. Yes, I would agree with that.

BY MS. RAGHAVAN:

Q. Let's look at the last sentence of Paragraph 9 of your declaration. You state here that "The device is positioned in the pericardial space immediately surrounding the heart and through this work I have developed expertise related to delivering cardiac assist devices to this space that is relevant to this

proceeding."

Do you see that?

A. Yes.

Q. By "this space," you're referring to the pericardial space; is that right?

A. Yes, and also the area around the apex of the heart, which is important in this case.

Q. But prior to 2013, you did not have any experience relating to implanting devices in the pericardial space or at the apex of the heart?

MR. CAHILL: Object to form.

A. I wouldn't characterize it that way. I mean, I was aware of these -- of these devices and how they're implanted. I did not have personal experience putting them in.

I never had personal experience putting them in, but I understand how it works, and so this work in particular was instrumental in better understanding of what the pericardial tissue is and how it's used and how the procedure is performed usually, what the mechanical properties of the pericardium are, so I knew them in general,

but this work obviously gave me a better understanding.

BY MS. RAGHAVAN:

Q. In 2013, that was the first time you have direct experience with devices that were implanted or designed to be implanted in the pericardial space, correct?

A. No, that's not correct because my work in the Russian institute and since then work at DataScope. I was aware of these procedures before then.

Q. So you're aware of other devices that could have been implanted in the pericardial space earlier than 2013?

A. Oh, yes.

Q. Were they blood pumps?

A. Some were. Some weren't.

An early example of a direct cardio compression device is an Anstadt cup, Anstadt, A-n-s-d-a-d [sic] -- d-t at the end, Anstadt cup, which was in development since the '60s.

So it was well understood that it can be done.

Q. You said Anstadt?

A. Anstadt. Let me just write it down so I can spell it properly.

A-n-s-t-a-d-t, A-n-s-t-a-d-t.

Q. And you said this is a direct compression device?

A. Correct, direct -- early direct cardio compression device.

Q. Do you know how big this device was?

A. All of them are the same size, the size of the heart. They surround the heart. So I'm not sure. Big in terms of, like, diameter or height or -- it's a cup, you know. They come in different sizes, depending on the size of the patient's heart.

Q. So whether a device is appropriate to be placed in the pericardial space depends on the patient and the size of the patient's heart, correct?

A. I wouldn't say it that way. The ability to place in the pericardial space depends on the thickness of the device primarily. Again, there's a difference between LVADs that are implanted at the apex versus direct cardiac compression devices that

go all the way around the heart. So we're talking about different areas of the heart, and so different requirements apply.

Q. But those requirements are determined on a patient-by-patient basis. Would you agree with that?

A. Well, there are generally -- I mean, it depends on the ability of the device to adapt to the size of the heart. Some adapt better than others. But broadly speaking, the size of the heart and the size of the patient are certainly an important consideration.

Q. Prior to 2007, you never worked on an LVAD that uses a centrifugal pump, correct?

A. Well, no, we just discussed the work that I did at the -- in Moscow. That was -- that was that work.

Q. Was that an LVAD?

A. Yes, it could have been.

Q. Is that an LVAD under your definition or under Mr. Crosby's definition?

A. Oh, I think it probably applies to both, but it can also be used on the right side. It would be RVAD. It can be used in

children. It can be used on both sides of the heart. So there's flexibility there.

Q. And you said the device could have been an extracorporeal device, or it could have been an implantable device?

A. That is correct.

Q. Prior to 2007, did you work on an LVAD that used magneto coupling?

A. We certainly used devices that used magneto coupling in animal tests. It was an extracorporeal device produced by Medicus [sic]. BP-50 was the pump that we used extensively as an extracorporeal device for tests and actually in human clinical trials as well.

Q. Was that an LAD?

A. I would say so, yes.

Q. Could you have implanted the centrifugal blood pump that you developed when you were in Moscow at the apex of the heart?

A. We didn't get that far. That -- the answer to that question is it depends on the size of the heart -- the size of the pump, rather.

Q. But you designed that pump, correct?
A. Yes.
Q. So you knew how big it was?
A. I really didn't because, again, we were doing conceptual development and the specs were not defined in terms of the specific cardio output and location. We didn't get that far. We just looked at different ways to make the pumping mechanism more gentle on blood, and so that was more of a sort of paper exercise really. We didn't go too far from that.
Q. Do you think it could have been implanted at the apex of the heart?
A. It's hard to speculate.
Q. Any reason why it couldn't have been implanted at the apex of the heart?
A. Well, again, the position of the device in the body for an implantable device highly depends on the size and the weight of the device. So we didn't get far in prototyping, and so it was hard to really predict accurately how big and how heavy it would be. So if it turned out to be small

enough, then certainly.

Q. Does it also depend on the size of the patient?

A. Yes, it does. Obviously for smaller patients, for small women or children, it -- the space available is less. So that's true now of any heart assist device. In fact, most of them are applied in men rather than women even today.

The heart rate failure -- the rate of heart failure is about even between men and women. However, men get three to one these devices than women because -- in part, because of the size consideration.

Q. So if we're talking about a larger male patient, you can implant a larger pump, correct?

A. Yes.

Q. Mr. Leschinsky, I'm going to hand you a copy of the U.S. Patent 11,351,356. And this was previously marked as Exhibit 1001.

A. Okay.

Q. You've reviewed this patent, correct?

A. Yes.

Q. This is the patent on -- this is one of the patents on which you submitted a declaration?

A. Correct.

Q. Let's look at Figures 1 and 2 of this patent.

A. Yeah.

Q. This is a catheter-based configuration, correct?

MR. CAHILL: Object to form.

A. This embodiment here that's illustrated is a catheter pump, yes.

BY MS. RAGHAVAN:

Q. Is this an intra-aortic balloon device?

A. I wouldn't call it an intra-aortic balloon device in the classic counterpulsation sense of the word, but it does have a balloon that is inflated inside the aorta.

Q. Have you considered whether the device shown in Figures 1 and 2 of the '356 patent can be considered an LVAD under Mr. Crosby's definition of an LVAD?

A. I don't know how to answer that

question. Again, I reviewed Mr. Crosby's declaration at some point. I don't remember exactly the wording of how he defines the LVAD. All I say -- and I stand by this statement that in my definition, other devices, including this device, can be considered an LVAD.

Q. So under your proposed definition for an LVAD, the embodiment shown in Figures 1 and 2 of the '356 patent would be an LVAD, correct?

A. Yes.

MS. RAGHAVAN: We're ready for our first new exhibit of the day.

(Exhibit No. 1033 marked for identification.)

BY MS. RAGHAVAN:

Q. This is an article you coauthored; is that correct?

A. Yes, that is correct.

Q. You're discussing the CorInnova device that you were talking about earlier, in this

article?

A. That is correct.

Q. I'm going to specifically refer you to the last sentence on the first page. Let me know when you've had a chance to read it.

A. (Witness reviews document.)

Yes.

Q. You see here that it mentions mechanical cardiac assist devices; is that right?

A. Uh-huh.

Q. Then it talks about intra-aortic balloon pumps.

Do you see that?

A. Yes.

Q. And percutaneous catheter-based heart pumps, correct?

A. Yes.

Q. Left ventricle assist devices.

Do you see that?

A. Yes.

Q. And so presumably, those are three different categories or examples of devices that would be considered mechanical cardiac

assist devices, correct?

A. Well, people use the word "left ventricle assist device" differently in different contexts. This one refers to 3,000 long-term implantable devices. So that's what this sentence says.

However, I would still consider intra-aortic balloon pumps and percutaneous devices as left ventricle assist devices in the functional definition of the word. In other words, they all support left heart.

So this one should have said probably implantable long-term or durable left ventricle assist devices, but it's only a part of it. I still say that, you know, other devices should be considered as well in this definition.

Q. But reading it here today, that's not what it says, correct?

A. Well, the text says what it says.

Q. And you authored this article -- or coauthored this article?

A. Yes.

MS. RAGHAVAN: We'll mark our

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next exhibit, marked as Exhibit 1034.

(Exhibit No. 1034 marked for identification.)

BY MS. RAGHAVAN:

Q. Do you recognize this document, Mr. Leschinsky?

A. Yes. It is a copy of my declaration from a number of years ago -- a couple of years ago.

Q. And this is a declaration you submitted in PTR 2021-00107, correct?

A. Sounds about right.

Q. I mean, that's what it says on the cover page?

A. Yes, yes.

Q. You were retained by the patent owner in this case, correct?

A. Correct.

Q. Do you normally represent the patent owner as opposed to the patent challenger?

A. No, not necessarily.

Q. The patent at issue in this

proceeding, in this PGR, was U.S. Patent No. 10,926,069.

Do you see that?

A. Yes, I see that.

Q. Do you recall this patent?

A. No. I have to look at it again frankly. It's been a while ago.

Q. If you could turn to Paragraph 32 of Exhibit 1034, you start here with a summary of the '069 patent, correct?

A. Yes, that's what the text says. But it would be actually useful if you can give me that patent to look at. Do you have it?

Q. I do have it. I can give it to you.

A. Okay.

MS. RAGHAVAN: Let's mark this as Exhibit 1035.

(Exhibit No. 1035 marked for identification.)

BY MS. RAGHAVAN:

Q. Exhibit 1035 is a copy of U.S. Patent 926,069 [sic].

Do you see that?

A. Yes.

Q. And this is the White Swell Medical Limited patent that you opined on in Exhibit 1034; is that correct?

A. Yes.

Q. Would you agree that this is a catheter device?

A. That seems to be the case, yes. Again, it's been a while.

Q. If we go back to Paragraph 32 of your declaration, Exhibit 1034, the first sentence says, "The invention of the '069 patent relates to an inventive treatment that helps avoid the risk of developing acute heart failure and compromised renal function in certain patients such as those experiencing edema."

Do you see that?

A. Yes.

Q. Is that your understanding of the '069 patent?

A. I believe so.

Q. Does the -- to your recollection does

the '069 patent relate to a catheter device that includes sensors and a controller to adjust the device?

MR. CAHILL: Object to the form.

A. I have to look more closely to recall this, but it would not surprise me if it does.

MR. CAHILL: Object to form.

BY MS. RAGHAVAN:

Q. If you could look at Paragraph 33 of your declaration -- excuse me -- of your declaration in the PGR, which is Exhibit 1034, you provide a few more details about the '069 patent.

Do you see that?

A. Yes.

Q. And we'll read through the rest of the paragraph. It mentions that "This catheter device has pressure sensors, and it also has a control module that can include multiple feedback loops to adjust the performance of the system."

Do you see that?

A. Yes.

Q. So you would agree that the catheter

device generally includes sensors and a control module, correct?

A. Catheter devices in general?

Q. No. The one that's described in the '069 patent.

A. Oh, yeah, yeah. Yeah, uh-huh, yes.

Q. If we look at Paragraph 34 of Exhibit 1034, in the first sentence, it says, "The '069 patent describes a catheter device that would be placed in the superior vena cava"; is that correct?

A. Yes, SVC.

Q. Where is the SVC?

A. In the second line of Paragraph 34, superior vena cava.

Q. Where is that in the human body?

A. Oh, it's a part of the venous return to the heart. It's above the heart, superior.

Q. Would you agree that the '069 patent describes a catheter device that was meant to support the heart and the associated circulatory system?

MR. CAHILL: Object to form.

A. I have to think about this. It's not

really designed for -- I mean, it -- it assists the heart in a -- in one way, but it's not unloading the heart in the sense that left ventricle assist devices do. So I wouldn't call it an LVAD, if that's what you're asking.

BY MS. RAGHAVAN:

Q. Would you agree that it's a heart assist device?

A. Probably in a broad sense, yes. It helps patients with edema, so that's one of the signs of a heart failure. So in that sense, it does.

Q. But your testimony is that it's not an LVAD; is that right?

A. I wouldn't call it an LVAD, no.

Q. What is the distinction you're making between the device that's described in the '069 patent and your definition of an LVAD?

A. Well, I have to think about this more. I think that different systems that alleviate heart failure symptoms can be called that -- that they are assisting the heart in alleviating the symptoms. Now, an LVAD is a more direct unloading of the heart or helping

the heart to pump blood.

Heart failure is a broad category of different conditions, and they cause different symptoms and different ailments throughout the body. So anything that helps that will help the heart as well indirectly. But an LVAD, in my opinion, is something that actually promotes blood pumping.

Q. So not all heart assist devices are LVADs; is that correct?

A. Probably true if you extend that logic.

Q. And generally an LVAD is a device that helps the heart pump blood?

A. I would say so, yes.

Q. Let's go to Paragraph 36 of Exhibit 1034. In this declaration, you offered a definition of a POSA.

Do you see that?

A. I do see that.

Q. And in the first portion of your definition of a POSA, you say, "It could be an MD or a bachelor's or a master's degree in mechanical engineering, biomedical

engineering, or a similar field as well as two or more years of work experience with catheters or similar medical devices."

Do you see that?

A. I do see that.

Q. I'm going to refer you to the part that says "catheter or similar medical devices."

A. Uh-huh.

Q. What are you referring to when you say "similar medical devices"?

A. Well, again, this was a number of years ago, and this was in reference to this particular patent. And the particular patent here has a catheter with balloons that are inflatable in the body. So there may be a possibility of delivering balloons or inflating them with catheters or with other means, I suppose.

The definition here is that a person would have two or more years of experience developing these devices directly. For example, anybody with a pharmaceutical experience with not qualify.

Q. For this particular technology in the '069 patent, you felt that two years of work experience was sufficient; is that right?

A. Correct. In the field with these particular devices.

Q. But that work experience didn't need to be limited to catheters?

A. Well, it has to be related to similar technologies.

Q. Which are still balloon-based catheters, correct?

A. I have to look at it again, but broadly speaking, you are correct.

Q. We saw earlier that the catheter described in the '069 patent was meant to be placed at the superior vena cava, correct?

A. Yes.

Q. Your definition of a POSA, though, did not specifically require work experience with a catheter that had to be placed at the superior vena cava, correct?

A. That is correct. If a person has experience with placing catheters and balloons in other places than in the venous system or

the arterial system, that would still qualify.

Q. Why would that still qualify?

A. Well, a person who would understand how to position a catheter in a blood vessel would know sufficiently well what this whole thing is all about.

Q. Going back to your declaration in this particular IPR that we're discussing today, you say that a POSA must have had five years of experience designing and developing implantable cardiac assist devices, correct?

A. Which portion are we referring to?

Q. We can turn back to your declaration in this case.

I believe it's on page 38 in Paragraph 57 of your declaration.

A. Yes.

Q. So you see here you say that "A POSA would be a person with at least a bachelor's degree in engineering" -- or -- sorry -- that's the definition that's offered by the petitioner.

Do you see that?

A. Yes.

Q. And then in Paragraph 59, you offer your definition of a POSA.

Do you see that?

A. (Witness reviews document.)

Yes.

Q. And in your definition, you're requiring a POSA to have "at least five years experience designing and developing implantable cardiac assist devices in particular."

Do you see that?

A. Yes.

Q. What is your basis for opining that a POSA in this context needs at least five years of work experience?

A. Well, it's not only years of experience. It's experience in this particular field. Implantable cardiac assist devices are extraordinarily complex and difficult to make and to design. So if a person has five years of experience designing another implant, I don't know, a knee replacement prosthesis, that would not really be relevant to this particular technology. So

you have to be in this field for a while to understand all the nuances that are required to appreciate the complexity and the difficulty making these devices.

Q. So I believe that explains the cardiac assist devices portion of your definition, but if you could explain your basis for requiring five years of experience designing and developing specifically implantable cardiac assist devices.

A. Right. What is it that you want me to explain?

Q. Why would a POSA need to have specific experience with implantable cardiac assist devices in particular?

A. Well, again, that's what I said. It's a -- making such a device is a very difficult task, and so you need to be well experienced to understand all the difficulties.

Q. Do you have that experience?

A. I believe I do.

Q. How so?

A. Well, I have 30-plus experience in this field.

(Stenographer clarification.)

A. 30-plus experience in this field.

I participated in a number of animal trials and clinical applications of these devices throughout the years. I spoke with many physicians about this. I observed many procedures. I learned a lot from publications, participating in conferences, what have you.

BY MS. RAGHAVAN:

Q. So implanting cardiac assist devices in animals is helpful work experience?

A. Of course.

Q. And you think that's relevant work experience to the definition of a POSA in this case?

A. Of course.

Q. Are you counting your experience with designing centrifugal blood pumps in Moscow as part of your experience with implantable cardiac assist devices?

A. Yes, I do.

Q. Even though those devices that you were designing were not specifically meant for implantable use, correct?

MR. CAHILL: Object to form.

A. Again, I would not necessarily limit this to what they call durable left ventricle assist devices. We have to define the terms a little bit better here.

The experience that I think is necessary is to design -- is the designing of the circulatory assist devices. Implantable, if you -- it certainly would be useful to have implantable long-term durable LVAD experience. But if a person has experience designing blood pumps that are implanted in a way that they are connected to the heart but the pumps itself are extracorporeal, for example, that would still be useful.

BY MS. RAGHAVAN:

Q. So your definition covers extracorporeal use of a heart assist device as well?

A. Yes.

Q. Is your definition of a POSA limited

to those who have work experience developing and designing totally implantable cardiac assist devices?

A. How do you define "totally implantable"?

Q. As in every portion of the devices must be implantable?

A. No, that's not -- that's a very -- that's -- it would be certainly nice, but it's a more narrow definition. I would accept people who develop extracorporeal devices. Anything that pumps blood to assist the heart would be useful.

Q. Let's go back to Paragraph 6 of your declaration in this case, which, again, is the patent owner's Exhibit 2015.

And I'm going to refer you back to the portion of Paragraph 6 that talks about the PHP project.

A. Okay.

Q. Is the PHP an axial flow catheter pump?

A. Yes.

Q. Did the PHP use a drive shaft to drive

the rotor?

A. Yes.

Q. It didn't use magneto coupling to drive the rotor, correct?

A. It did not.

Q. When designing the PHP device, why did you choose to design an axial flow pump rather than using a drive shaft that was controlled by magneto coupling?

A. You mixed two technologies in one question.

Q. Well, so let me break it up.

Why did you choose to design an axial flow pump rather than a centrifugal flow pump, for example?

A. That was the choice based on the intended use.

Q. What was the intended use?

A. Well, the use was to -- you have to thread it through the vessels, and so the diameter was very limited. And an axial flow pump in that sense wouldn't have been advantageous.

Q. Just to clarify, did you say would

have been advantageous --

A. Yes, was.

Q. -- or would not?

A. Yes, would. Would, would, yes.

Q. Okay. So an axial flow pump in that sense would have been advantageous?

A. That is correct.

Q. So knowing that it needed to fit in a smaller space, you knew how to design a smaller device, correct?

MR. CAHILL: Object to form.

A. That was one of the objectives of the project.

BY MS. RAGHAVAN:

Q. Why did you choose to use a drive shaft to drive the rotor?

A. The project was -- at the time when we were developing it, the main idea was to develop a prototype that would expand and collapse properly. And then a drive shaft was just a choice to turn it. It was not really developed at the time when I was there to a clinically useful version of the product. So it was just a convenient way to turn the

shaft, turn the impeller.

Q. Because you were actually developing a different portion of that device, correct?

A. The most difficult portion was to make a product that would expand and collapse properly. And so the turning, it was sort of the convenient off-the-shelf tool that we used. We did not develop it at the time further than this.

We were trying to solve the most difficult problem, which was how to make a plastic impeller that would -- that would collapse and expand properly and housing around it. So we just had -- it's a bicycle shaft basically that we used to power it and see how it works.

Q. So in focusing on making the -- making a plastic impeller, you mixed and matched other portions of the system that would have been required, but you were not specifically focused on those other parts of the system, correct?

A. At the time of the development, the main objective was to show the feasibility of

the implantable portion which would expand and collapse. And so that was the extent of the project that we developed.

Q. But you knew that if that plastic impeller were ever to be implantable or implanted in a patient, you needed other parts to be able to make that work?

A. Of course.

Q. How did you know where to look for those our parts that would work with that impeller?

A. It's a design choice.

Q. How so?

A. Well, you need to have something that would make the impeller turn, and so a drive shaft was a convenient way to do that. But I would assume that it can propagate to clinical prototype as well. It was not something that's entirely prohibitive. So it was a convenient way for us to start with this, but there was no reason to change it afterwards.

Q. Would you have also needed some sort of a controller to go with that -- those components?

A. Of course.
Q. And where would you have found such a controller?
A. We were building the controller. Every controller is closely matched with the device that it's pumping.
Q. But you were focused specifically on the impeller, correct?
A. That was the most innovative and difficult part to design, so that is what we tackled first.
Q. What about a battery to support the device?
A. The motor was outside. So once -- once you're outside the body, you have a lot of options for controllers, for thermal management of the motor, et cetera.
Q. So is it fair to say that you could have just used battery technology that was generally applicable to pumps and used it with the impeller that you were designing?
A. The controller would be designed to operate the motor based on a number of different feedback loops and what have you.

And so the controller would typically include a battery of some sort that would sustain its operation when the patient is being transported, for example.

So we didn't design the controller to a full extent. But the assumption was that it would not be dissimilar to other devices on the market.

Q. But you knew generally it needed to have a controller?

A. Yes.

Q. And so when you were writing publications that described the PHP device, did you describe the controller that would be used with the PHP device in great detail?

A. Well, I described the principles of what the controller would do in significant detail. Something that would define that particular controller functionality would be useful to describe. But I did not describe, I don't know, the position of the display, for example. Some of the details there were not important at the time.

Q. Going back to your design choice of

using a drive shaft for the PHP device, was there a reason you didn't use an electromagnet to drive the motor?

A. Yes.

Q. What was that reason?

A. The electrical -- miniaturized electrical motors that would use magnets were used by our competitor, and they had patents on them.

Q. So it was not a technical reason?

A. Well, among other things, it was a technical reason also because it was difficult to make a small device. But patents would just -- I mean, they had so many patents on this that we were not really trying to break through the...

Q. Do you recall which competitor?

A. Abiomed.

(Stenographer clarification.)

A. Abiomed.

Q. A-b-i-o-m-e-d?

A. Yes. Some people say it "Abiomed." Some people say it differently.

Q. And you chose not to use a rotating

permanent magnet to drive the rotor, correct?
A. We chose a drive shaft.
Q. Say that one more time?
A. We chose a drive shaft as a way to rotate the impeller.
Q. Why did you not choose to use a rotating permanent magnet?
A. Well, that's what I said. The motor -- the miniaturized motor that would have permanent magnets was used by our competitor and was covered in many patents. We just talked about this.
Q. Do you know of others besides Abiomed that had patents in this space?
A. Define "space."
Q. Using electromagnets to drive rotor movement.
MR. CAHILL: Objection. Outside the scope.
A. I have to think about this. I'm sure there are others.
BY MS. RAGHAVAN:
Q. But you don't recall them sitting here today?

A. Well, Mohl describes one of them in this patent, right?
Q. You're talking about the patent that's described in the '356 --
A. Yes.
Q. -- patent?
A. Yes. That has magneto coupling.
Q. You're referring to Schima?
A. No. I mean, Mohl and Schima are the people -- I mean publications that I reviewed here for this declaration. Many of them is described magnetic coupling.
Q. Got it.
You say in Paragraph 6 of your declaration that the PHP project was a result of seven years of development, correct?
A. I'm sorry. I closed it.
(Witness reviews document.)
Yes.
Q. And you considered it to be pioneering technology at the time?
A. Yes.
Q. Did you lead this effort?
A. Yes, I would say so.

Q. Were there others involved, though, with the design?
A. Yes.
Q. But were you the lead innovator on the design?
A. Well, I was named as one of the inventors on the patents, but there are other coinventors.
Q. You said here that the project was bought by Abbott in 2016.
Do you see that?
A. Yeah.
Q. Do you recall for how much?
A. Well, the project was initially bought by Thoratec, which then later became part of Abbott. And I believe that they sold the project for $8 1/2 million in 2010, something like that.
Q. Were you personally compensated for the sale of PHP to Abbott or Thoratec?
A. No.
Q. Who was compensated?
A. The company got the money, and that's it. I was working for the company.

Q. So you, as the inventor, were not compensated in any way for the sale?
A. No.
Q. Did you think that was fair?
A. Yes, because I worked for the company.
Q. Let's turn to Paragraph 86 of your declaration.
In this section, you're discussing the Wampler prior art, correct?
A. Wampler, yes. Uh-huh.
Q. Wampler.
And in Paragraph 86 specifically, you are discussing the rotor and magnets that are disclosed in the Wampler device, correct?
A. Yes.
Q. And specifically the magnets are referred to as the arcuate, permanent magnetic segments.
Do you see that?
A. Oh, yes. Uh-huh.
Q. And below Paragraph 86, you have a copy of Figure 13 from the Wampler reference.
Do you see that?
A. Yes.

Q. Figure 13 shows a rotor impeller, correct?

MR. CAHILL: Object to the form.

A. Figure 13 shows what exactly again?

BY MS. RAGHAVAN:

Q. A rotor?

A. Yes.

Q. Okay. And it includes the impeller, correct?

A. You could say that.

Q. Which element would you consider to be the rotor impeller?

MR. CAHILL: Object to form.

A. Well, let's separate into rotor and impeller.

BY MS. RAGHAVAN:

Q. Well, so in Paragraph 86, you say, "The rotor impeller is disclosed."

A. Oh, I see, yes. Uh-huh.

Well, the rotational part, the part that rotates is the rotor.

Q. And which part would that be?

A. Well, I don't know how to -- do you want the number here, the position number? I

don't know how to answer that question.

Q. Sure, you can include the position numbers.

A. Well, I mean, if you look at Figure 13 --

Q. Sure.

A. -- you have a part that rotates, and the part that is the housing is stationary. So everything that rotates is a rotor.

Q. Okay. And then referring to Figure 13 specifically, you see that the permanent magnets that we were referring to earlier are labeled as Element 88.

Do you see that?

A. Yes.

Q. You'd agree that the magnetic pieces, 88, are in the rotor, correct?

A. They're a part of the rotor, yes.

Q. They're embedded within each impeller blade sector? That's what it says in the Wampler reference?

A. Yes.

Q. You'd agree that the magnetic pieces, 88, and the rotor are axially

aligned?

A. I don't know if I agree with that. How do you define "axially aligned"?

Q. Well, how do you define "axially aligned"?

MR. CAHILL: Object to form.

A. I have to think about -- well, magnets are positioned around an axial line of symmetry, I guess, central access.

BY MS. RAGHAVAN:

Q. Okay. And where is the central access if you were to refer to Figure 13?

A. Well, there is a rotor that rotates around a central axis.

Q. So taking that as a central axis, would you agree the magnetic pieces, 88, and the rotor are axially aligned?

A. I would say that magnets are positioned with their lengths parallel to the central axis of the rotor.

Q. Is that different from being axially aligned?

A. Are you talking axially aligned in the sense of the mold patent?

I mean, I'm not sure if I understand the question correctly.

Q. Do you not understand the phrase "axially aligned" separate from the mold patent?

A. I have to think about that.

Q. So that's not something you have an opinion on?

A. I say what I say here about this. Like, do you -- I mean, do I -- do we talk about this somewhere here in this paragraph that you can show me.

Q. Not specifically here, but I was just asking you a question about whether you have an opinion about this.

A. Well, I said what I said about their position with regard to the central axis, so that would be a technically accurate description.

Q. Okay. And you'd agree that the magnetic pieces, 88, are rectangular in shape, correct?

A. They have a complex shape here actually. I wouldn't call them rectangular

necessarily.

Q. Well, how would you describe their shape?

A. Well, they -- the patent describes them as arcuate segments, so some of them -- I mean, some shape here resembles a rectangle, but they have -- they have this sort of expanding shape from the center to the periphery, which is not necessarily rectangular.

Q. So it has some sort of an arc, correct?

A. Yes.

Q. In addition to being somewhat rectangular?

A. Yes.

Q. And you're saying it expands kind of in a trapezoidal geometry as well?

A. Again, different surfaces of these magnets have different shapes.

Q. And by "different surfaces," you're talking about like the outer surface versus the inner surface?

A. Well, if you cut out one of these

magnets from the rotor you would -- you would have a surface that would be curved on the outside, maybe curved on the inside. The inside curve would be probably smaller than the outside curve because of the expansion from the center.

The side -- side walls probably would be rectangular.

Q. Are those side walls touching the rotor?

A. They are embedded in the rotor.

Q. So are they touching the rotor?

A. Well, they're inside the rotor. I'm not sure how to define "touching."

Q. Well, if they're inside, are they touching or no?

A. Well, I mean, when I touch it like a piece of paper, then -- then -- then my hand is one, you know, item, and then the piece of paper is the other.

The magnets are inside. They're embedded. So if you include the word, you know, "touching" to mean embedded, then they are.

I wouldn't necessarily call them touching.

Q. Is it fair to say that the magnetic pieces share at least one common side with the rotor?

MR. CAHILL: Object to form.

A. How do you define that?

BY MS. RAGHAVAN:

Q. Are they in contact at at least one side?

A. Well, they are embedded, so they clearly are in contact with the rotor because they're inside it.

Q. At least the inner surface of the magnetic piece is in contact with the rotor, correct?

A. Well, all sides of the -- of the magnetic pieces are in contact with the internal volume of the rotor, I suppose.

Q. Okay. Let's turn to Paragraph 191 of your declaration.

A. Are we coming up on a break?

MS. RAGHAVAN: Yes. If you -- we can take a break now if that's good for

you.

THE WITNESS: That's okay.

MS. RAGHAVAN: Let's go off the record. 10:34 a.m.

(Recess taken from 10:34 a.m. to 10:51 a.m.)

BY MS. RAGHAVAN:

Q. Welcome back, Mr. Leschinsky.

A. Thank you.

Q. Let's turn to Paragraph 191. I believe that's where we were when we left off.

This is -- in this section, you discuss the Akamatsu reference, correct?

A. Yes.

Q. And in particular, you're discussing the impeller and the permanent magnets that are disclosed in Akamatsu; is that right?

A. Yes.

Q. And below Paragraph 191, you have Figure 2 from Akamatsu with some annotations by petitioner; is that correct?

A. Yes.

Q. And then the annotations, the purple represents the permanent magnets, and the pink represents the impeller; is that your understanding?

A. Yes. It's hard to distinguish between purple and pink, but I understand what you're saying.

Q. I can appreciate that.

Would you agree that, as outlined here, the permanent magnets that are outlined in the smaller purple box are embedded within the impeller, which is in the larger pink box?

A. Yes.

Q. Do you see the annotation for central axis on Figure 2?

A. Yes.

Q. Would you agree that if that's where the central axis is, then the impeller and the permanent magnets are axially aligned?

A. Well, the central axis of the impeller is the same as the central axis of the magnets, so in that sense, they are axially aligned, but -- I guess I'll stop there.

Q. Would you agree that, as drawn, the inner surface of the permanent magnet is touching the impeller?

A. What do you call an inner surface?

Q. So I'll make it more general.

So is the permanent magnet touching the impeller?

A. Well, it's the same answer as with the previous one where the permanent magnet is embedded in the impeller, so to that extent, they're touching.

Q. Does the permanent magnet then share at least one common side with the impeller?

A. I don't understand that question.

Q. The permanent magnet is resting within the impeller, correct?

A. It's embedded within the impeller.

Q. Let's turn to Paragraph 77 and 78 of your declaration.

These paragraphs are under a heading titled "At a Position Axially Adjacent"

Do you see that?

A. Yes.

Q. And you understand that's one of the

claim terms?

A. Yes.

Q. In Paragraph 77, you quote from the board's institution decision to say that "The board has adopted a construction for the term 'at a position axially adjacent' to mean adjacent to one another as measured along a central axis."

Do you see that?

A. Yes.

Q. Is that the construction that you applied in your analysis?

A. Yes.

Q. So let's take a look back at Paragraph 113 of your declaration, and this is your analysis of limitation 1H for the Wampler reference, correct?

A. Yes.

Q. And at the start of Paragraph 113, you refer back to your Section VIII.C regarding claim construction of the term "at a position axially adjacent" which we just looked at, correct?

A. Yes.

Q. Further down in Paragraph 113, you say that you "do not believe a POSA would have understood this term," so at a position axially adjacent, "to include adjacency along different axes or components that are embedded within one another such that they overlap or occupy the same space as measured along a central axis."

Is that right?

A. That's what it says.

Q. You still -- is that still your opinion?

A. Yes.

Q. And then you say that "The board has adopted this construction in the institution decision."

Do you see that?

A. Yes.

Q. But the board's construction that we looked at that you quoted in Paragraph 77 doesn't expressly exclude elements that overlap, correct?

A. Well, the text says what it says. I believe that the POSA would understand it the

way I describe it here.

Q. But you've expanded on the definition that the board provided, correct?

A. I don't think so.

Q. The board's definition does not say anything about components overlapping, correct?

A. The understanding -- my understanding of what the board's definition is is what is expressed here.

Q. But you're extrapolating on the board's definition? That's not actually what the board defined the term to be?

MR. CAHILL: Object to form.

A. Well, they define -- let's go back to this definition.

BY MS. RAGHAVAN:

Q. Sure. It's on Paragraph 77.

A. Yeah.

So the meaning is "adjacent to one another as measured along a central axis."

So my understanding of that language is what I describe here in Paragraph 113, and I do not believe that "overlap" is included in

that definition.

Q. The board's definition did not expressly say anything about overlapping elements, correct?

A. Well, the text is what the text is.

Q. And the same question as to elements that occupy the same space.

The board's definition does not expressly say anything about elements occupying the same space?

A. The meaning is expressed I think quite clearly, and my understanding of that meaning is what I express here in this paragraph.

Q. When you say "quite clearly," where are you extracting these --

A. Well --

Q. -- these additional requirements from?

A. I'm sorry.

MR. CAHILL: Object to form.

A. The board's definition says that a position axially adjacent means "adjacent to one another as measured along a central axis," and so the text in 113 is my understanding of

what a POSA would understand this to mean, and I stand by that definition.

BY MS. RAGHAVAN:

Q. Which part of the board's definition are you relying on to say that it excludes components that are overlapping?

MR. CAHILL: Object to form.

A. I do not rely on any particular part. I rely on my understanding of this wording, of these words.

BY MS. RAGHAVAN:

Q. Well, let's look back at the board's definition.

The board's definition says "adjacent to one another as measured along a central axis."

A. Right, yeah.

Q. Okay. And then you read -- you reviewed that definition, correct?

A. Right.

Q. And you do not believe that that definition includes elements that overlap or occupy the same space as measured along a central axis?

A. I believe that the POSA would see it that way, yes.
Q. Why?
A. Well, that's the -- that's how I understand this text to describe it.
Q. In your declaration, you don't offer any evidence to support your opinion that a POSA would have understood the term "axially adjacent" to include elements that -- that do not include elements that overlap or occupy the same space, correct?
A. The meaning is -- I believe I expressed the meaning of these words as I believe a POSA would understand.
Q. So looking at Paragraph 113, you're not citing any evidence here to support your understanding of what -- how a POSA would have understood this term?
A. I'm not sure what evidence I could possibly cite.
Q. But you didn't cite any?
A. Well, the text says what it says.
Q. You don't cite any dictionary definitions, for example?

A. Well, again, the report says what it says.

Q. Did you consider any dictionary definitions?

A. I did not.

Q. Is it possible that two POSAs would interpret the board's meaning of "at a position axially adjacent" differently?

MR. CAHILL: Object to form.

A. That's a speculative question. People can think of, you know, all kinds of different things, I suppose. I provided this definition the way I understand a POSA would interpret this.

BY MS. RAGHAVAN:

Q. And that's just based on your own personal understanding, correct?

A. I agree with what the board says.

Q. But as for elements that are overlapping or occupying the same space, you believe such elements are not included within the definition of "at a position axially adjacent" based on your own personal understanding, correct?

A. Well, adjacent to one another is next to each over, not overlapping.

Q. And that's your personal understanding?

A. That's my understanding, but that's my understanding of what a POSA would understand.

Q. Let's turn to Paragraph 152 of your declaration.

A. Yes.

Q. And specifically I'm going to refer you to the table that starts on page 85 and continues on page 86.

Do you see that?

A. Yes.

Q. The purpose of this table is to compare different pumps to the size of the HeartWare HVAD pump; is that right?

A. No. The purpose of this table is just to list different devices, their relative sizes and weights, and their position of implantation to show which device goes where.

Q. So in this table, you've listed the weight and volume of different pumps; is that

correct?

A. Yes.

Q. And you've listed the location at which you understand those pumps to be implantable, correct?

A. Correct.

Q. And you list the year of publication or approval of those pumps per your understanding, correct?

A. Yes.

Q. When you say "approval," what are you referring to?

A. FDA approval or any regulatory approval.

Q. Is that limited to the United States?

A. No, but I believe that the years listed are referring to the United States.

Not all pumps were approved, so that's why sometimes the numbers refer to publication year and sometimes to the actual approval.

Q. Got it.

Throughout your declaration in this case, you compare the purported size of the

various pumps cited in a prior art to the purported size of the HeartWare HVAD pump; is that correct?

A. Well, it's one point of comparison. Again, I wouldn't characterize the table as listing everything else versus HeartWare.

This is just a list of available technologies to then compare them against each other.

Q. Sure. But in other portions of the declaration, you did compare the relative sizes of the pumps in the prior art to the HeartWare HVAD pump, correct?

A. That's true, yes.

Q. Is it your opinion that the HeartWare HVAD pump is the maximum size of a pump that can be implanted at the apex of the heart?

A. Well, there was another one. At least the Wampler device was one of the devices. There are two of them there described in the patent.

The one that he later developed to a prototype was intended for this implantation as well.

(Stenographer clarification.)

A. For this implantation as well, meaning at the apex of the heart.

It was a little larger but not that much larger.

BY MS. RAGHAVAN:

Q. When you say he later developed it, what are you referring to?

A. Well, the patent -- I don't remember exactly the dates when the patent was published, but then there was also publications of actual development of prototypes, and they refer -- the publication that I reviewed was, I believe, published after the patent was published or applied for.

And so that represents the continuation of that effort chronologically, and so that device that was already -- that was in further development is one of the two main prototype embodiments that were described in the patent of Wampler.

Q. So based on that, a pump larger than

the HeartWare HVAD pump can be implanted at the apex of the heart, correct?

A. A little large -- larger but not too big. And, you know, the question's what's -- the whole point of that table is to show that larger pumps cannot be implanted at the apex of the heart whereas the smaller ones can.

So the point here is to show that both the size and the weight of the pump are important considerations when it comes to attaching the device at the apex of the heart to the heart itself. The heart can tolerate smaller pumps, but cannot tolerate larger pumps, and there's no space for larger pumps in that location.

Q. And is that applicable to all patients?

A. Well, again, a design of an LVAD is a balance of conflicting requirements. Clearly the smaller, the better, the lighter, the better.

So the lighter and the smaller the pump is, the broader the range of patients that it can be implanted in. So broadly

speaking, the demarcation here is that a couple of pumps that were small enough, which is the Wampler prototype and HeartWare, are suitable for implantation at the apex of the heart whereas larger pumps that are listed here are not.

Q. But to clarify, when you're saying they're small enough, you're saying they're small enough to be implanted at the apex of the heart for a larger portion of patients?

A. For a sizeable portion of patients, yes, to be practical and useful.

Q. But in your mind, is it possible for there to be a patient for whom a larger device can be implanted at the apex of the heart?

A. It's a speculative question. It depends on the size of the patient. It depends on the size of the pump.

Q. Do you have an opinion as to what the maximum size of a pump can be that can be implanted at the apex of any patient -- apex of the heart of any patient?

A. It is hard to actually draw a straight line because, again, a POSA would want to

develop a pump that would be useful for not just the largest patients but for a reasonable number of patients, for at least half of the patients or more than half of the patients.

So in that sense, I think that the Wampler device is at the -- is sort of at the end of this line where the weight of the pump is about 200 grams, so anything under 200 grams would probably be suitable for this. And the same goes for volume and size because there's only limited space between the apex of the heart and the diaphragm.

Q. Separate from reading these prior art references and devices that you've summarized in this table in Paragraph 152, have you independently done an analysis of the weight and volume that -- of a pump that can be implanted at the apex of the heart?

A. Well, the table represents that analysis.

Q. But aside from this table, you have not done a separate analysis, correct?

A. Prior to the separate --

Q. Yes.

A. -- to this whole declaration, no, I have not.

Q. As part of this declaration, you have not done that analysis either, correct?

A. Well, that table is that analysis.

Q. But separate from the table, you have not conducted a different analysis that you don't speak of in your declaration?

A. The analysis is here in the table. I'm not sure how to answer that question differently.

Q. When you said earlier that a POSA would have wanted to design a pump that can be implanted at the apex of the heart for a wide range of patients, that's a commercial consideration, correct?

A. Well, it's not just a commercial consideration. It's a consideration for why these devices are being developed in the first place, which is to help people with heart failure. So a POSA -- I mean, it takes ten years or more to develop a product like this. And so a POSA would understand that to develop a pump that can be implanted in a particular

location for the largest, biggest man and not for somebody else is sort of not very useful.

Q. So usability aside, would a POSA understand that a larger pump could be implantable at the apex of the heart of a large male patient, for example?

A. To an extent. Again, I believe that some of these pumps are still too large even for that to happen.

Q. But you don't know what the maximum size would be for such a pump to be implanted in a large male patient?

A. Well, the consideration is not just the size. The consideration for a larger pump is twofold. One is the larger the pump, the more risk there is to impede on the volume that's available for the heart itself.

So as you grow the size of the pump, there is less and less room that's left for the heart. So you will sort of start to impede on the movement and the free sort of physiological expansion and contraction of the heart itself. I don't know if I can draw a line to say, you know, X number of ccs will

kill somebody or -- but at some point, it will start to impede more and more. So it's a little bit of a gray area right there, number one.

And, number two, the same goes for the weight. You are sort of hanging something onto the heart when you implant it to the apex, and the same consideration applies. The larger it is, the more difficult it is for the heart to move and not to notice there is a brick attached to it. So it's a continuous sort of process. It's not like before and after.

Q. So there's no clear line as to what weight or volume a pump needs to be after which it becomes possible or impossible to implant a particular pump at the apex of the heart?

A. Well, again, we have to make a judgment call here somehow, and clinical experience shows that HeartWare clearly was implanted successfully in a number of -- in a large number of patients, so that's a yes.

Wampler is a little bit of a stretch

from that and never implanted, but I would probably say it's a yes. But beyond that, it's hard to say that it will be a yes without significant clinical evidence.

Again, it depends. I mean, patients come along a distribution curve also, so it's -- plus it's not just the size. It's the consideration of how strong the heart is, how -- you know, how much assist is needed. There's a whole bunch of factors here. Medicine is not a precise science.

Q. So in your view, the Wampler prototype and the HeartWare HVAD are examples of pumps that can be implanted at the apex of the heart of some patients?

A. Of a good enough, large enough number of patients, yes.

Q. Referring back to the table here, you have a row for HeartMate III and then "clinical" in parentheses.

Do you see that?

A. Yes.

Q. What are you referring to when you say "clinical" in parentheses?

A. Well, HeartMate III has been in development for many years and up and until about 2006 was the pump configuration that I refer to as HeartMate III prototype.

And then after that, they redesigned the pump significantly, made it significantly smaller by certain innovations about the, you know, design of the pump, and commercialized that as a clinical version of HeartMate III. So literature refers to HeartMate III throughout an entirely, you know, sort of long period of time, but these are two different pumps.

So my demarcation here is to refer to an earlier device as a prototype and to a later device, which was significantly different than the first device, as a clinical device because both of them are called HeartMate III as compared to HeartMate II, which was a totally different pump altogether.

Q. So "clinical" refers to the commercial embodiment of HeartMate III?

A. Correct.

Q. Are you aware that the patent owner,

Miracor, has asserted the challenged patents that are at issue in these IPRs in district court litigation as well?

A. I believe that was mentioned once, but I don't know the details.

Q. Did you review or consider Miracor's infringement contentions from the district court litigation in preparing your opinion for the IPRs?

A. No.

Q. Did you consider, for example, how Miracor understands certain claim terms in alleging infringement of the HeartMate III product in district court litigation in forming your opinion as to how those same terms should be interpreted in the IPRs?

A. No.

Q. I'm going to hand you what we'll be marking as Exhibit 1036.

(Exhibit No. 1036 marked for identification.)

BY MS. RAGHAVAN:

Q. Sorry. I understand you're not familiar with this document, correct?

A. (Witness reviews document.)

I don't think I am.

Q. So I will represent to you that this is the publicly filed version of Miracor's infringement chart for the '879 patent, which is one of the other patents that you submitted a declaration for.

A. Okay.

Q. Do you generally understand how infringement claim charts work?

A. Generally.

Q. Do you understand this to be an infringement chart?

A. It looks like it.

Q. Then you can see here that there are limitations -- claim limitations from the '879 patent on the left side, correct?

A. It appears like it. Again, I have not seen this before, so I -- I cannot go beyond what the text says.

MR. CAHILL: I'm going to object generally to this line of questioning as

outside the scope and outside of Mr. Leschinsky's expertise.

BY MS. RAGHAVAN:

Q. And then on the right side, there are some disclosures that relate to the HeartMate III clinical pump, as you're referring to it, correct?

A. They look like it.

Q. Let's turn to page 20 of this document.

There are some diagrams here of the HeartMate III clinical pump, correct?

A. It seems that way. Diagrams and -- the diagram here has a lot of small details. I have to study it closely to understand more of what it actually says.

Q. Got it. So those are annotations that were added by Miracor that relate to the claim limitations.

A. If you say so.

Q. Do you see a box there sort of in the middle of the diagram that says "magnetically driven rotor within a first chamber"?

A. I see that box.

Q. You understand that to be one of the claim limitations that you analyzed, correct?

A. Are we talking about -- I mean, you're asking me to comment on a diagram that I've never seen before.

Q. I'm just asking to comment on the text. So there's a box that says "magnetically driven rotor within a first chamber," correct?

A. Yes, the text says what it says.

Q. And there's an arrow pointing to the left that identifies a portion that Miracor alleges is the "magnetically driven rotor within a first chamber."

Do you see that?

A. That's what you said, yes.

Q. Would you be able to annotate the figure on the left to draw a box around the element that corresponds to the magnetically driven rotor?

MR. CAHILL: I'm going to object to this as specifically being misleading, that this is one set of labels on one diagram out of 20 pages that has a lot of annotation to

it. And the one that you've selected is not representative of the others.

MS. RAGHAVAN: Well, Counsel, if you would like to testify. You're not the one being deposed, but I understand your objection.

A. So am I supposed to answer?

BY MS. RAGHAVAN:

Q. Yes. So I would like you to annotate on this particular diagram what you believe to be the magnetically driven rotor within a first chamber that the box with the blue arrow is pointing to.

A. I can't do that. I have to -- I don't understand the details. It's very small. The picture is blurry. And I have to study what the first chamber is versus the second chamber. I haven't studied this as part of my report here. So it will be -- I mean, I can possibly do that, but I can't do it right now.

Q. So you can't tell me where in this pump the magnetically driven rotor is?

A. Well, the text says "magnetically driven rotor within the first chamber." I

need to understand what the first chamber versus the second or third or fifth chamber is. I -- you're, you know, asking me to point at small detail here that I don't understand the entire context of.

Q. So you can't tell me where just the rotor is in this clinical pump?

A. I can, but I need to study this more closely, and I'm not comfortable doing it right now.

Q. But you've expressed opinions in your declaration about the HeartMate III clinical pump, correct?

A. My opinions about the HeartMate clinical pump are limited to the size and the weight of the device.

Q. So you cannot -- you're declining to identify where the magnetically driven rotor is in this diagram?

A. At this point, yes.

Q. Can you turn to page 9 of this document. And I'm going to refer you specifically to the box with the text with the rectangle around it.

Do you see that? It starts with "The rotor is fully supported by magnetic levitation."

A. Oh, yes, uh-huh.

Q. Then towards the middle of that text, it says -- starts saying, "By measuring the position of a permanent magnet in the rotor and appropriately controlling the current and the drive and levitation coils, the radial position and rotational speed of the rotor is actively controlled."

Do you see that sentence?

A. Yes, I do.

Q. Is it your understanding that the permanent magnet in the rotor of the HeartMate III clinical pump is embedded within the rotor?

MR. CAHILL: Objection. Outside the scope and misleading.

A. You're asking me to comment on a document that I have not seen before. I have to study this. I can come to a certain conclusion, but I cannot do it right now.

BY MS. RAGHAVAN:

Q. Are you aware of how the permanent magnet in the HeartMate III clinical pump is configured within the rotor of the HeartMate III clinical pump?

A. Not in great detail.

Q. Did you consider how the HeartMate III clinical pump is designed, separate from its weight and volume, in coming to a conclusion as to how you understand the claims as part of your declaration in the IPRs?

A. In broad terms.

Q. How so?

A. Well, I understand they have magnets. They have magnetic suspension of some sort. They have a way to rotate the rotor, and it pumps blood. I didn't go much beyond that.

Q. So you didn't understand that the permanent magnet was embedded within the rotor of the HeartMate III clinical pump?

MR. CAHILL: Same objections.

A. Again, we're talking about specific definitions here, which I did not analyze closely to confirm or agree or not agree with that statement. I have to do more work on

that.

BY MS. RAGHAVAN:

Q. Within the diagrams of the HeartMate III clinical pump that we looked at, are you able to identify where the permanent magnet is?

A. Again, I'm sure I can. I'm not comfortable just pointing out to a particular, you know, component on a small diagram with many details. I have to understand what's what more closely.

Q. So you haven't done that analysis as part of arriving at your opinions that you presented in your declaration?

A. My analysis was limited to a broad understanding of what that pump is and its size and weight. That's the extent of what I looked at.

Q. You're saying that if you were to try to identify the permanent magnet within the HeartMate III clinical pump in this diagram, you would have to do that analysis sitting here today?

A. I cannot do that sitting here today,

but I can do that.

Q. You haven't done that?

A. I have not done it.

Q. You can set that document aside.

Let's go back to your declaration, which is Exhibit 2015.

I'm going to turn you to your table of contents, which is on the second page of the document.

Your declaration, starting with Ground 10, is structured so your analysis is organized by the grounds that are alleged by the petitioner, correct?

A. Yes.

Q. So you address Ground 1 first, followed by Ground 2, then Ground 3, then Ground 4; is that correct?

A. Yes.

Q. Does your -- does the table of contents accurately present that you only express opinions that Wampler fails to disclose claim limitations 1A, 1B, 1H, 1M, 1N and 1O?

A. Repeat the question again. Wampler

what?

Q. Sure. So based on the table of contents --

A. Yes.

Q. -- your declaration only expresses opinions that Wampler fails to disclose the claim limitations listed here, so 1A, 1B, 1H, 1M, 1N, and 1O?

A. Yes.

Q. Nowhere in your report do you dispute that Wampler discloses the remaining limitations and claims that are challenged by the petitioner, correct?

A. I don't talk about this, so I talk about what I talk about.

Q. So I'll refer you to Ground 2. Similarly, you only express opinions that Bourque 2001, in view of Wampler, fails to disclose Claim Limitations 1C, and then dependent Claims 5 and 7?

A. Correct.

Q. And nowhere in your report do you dispute that Bourque 2001, in view of Wampler, discloses the remaining limitations and

claims?

A. The report is silent on that.

Q. Let's turn to Ground 3. For Ground 3, you only express opinions that Akamatsu fails to disclose Claim Limitations 1A, 1H, 1N, and 1O; is that correct?

A. That's what the report says.

Q. Then nowhere in your report do you dispute that Akamatsu discloses the remaining limitations and claims, correct?

A. The report is silent on the other limitations.

Q. And turning to Ground 4, you only express opinions that Schima, in view of Akamatsu, fails to disclose Claim Limitations 1A, 1N, 1O, and then dependent Claims 5 and 7; is that right?

A. Correct.

Q. Nowhere in your report do you dispute that Schima discloses the remaining limitations and claims, correct?

A. I do not discuss other limitations.

(Stenographer clarification.)

A. I do not discuss other limitations in the report.

BY MS. RAGHAVAN:

Q. So with that, let's turn to Paragraph 87 of your declaration.

So in Paragraph 87, you say, "Wampler discloses different embodiments of blood pumps."

Do you see that?

A. Yes.

Q. Okay. And you say, "A first embodiment is shown in Figures 1 through 8," yes?

A. Yes.

Q. And then you say, "Alternative embodiments are shown in Figures 11 through 20," correct?

A. Yes.

Q. The embodiment that's shown in Figures 1 through 8, that uses mechanical thrust bearings; is that correct?

A. Correct.

Q. And the alternative embodiment that's

shown in Figures 11 and 13, for example, does not use mechanical thrust bearings; is that correct?

A. I believe that's correct.

Q. And just to be clear, you've opined that these are alternative embodiments, correct?

A. That's what the report says, yes.

Q. You are not disputing that the embodiment of Figures 1 through 8, which is partially illustrated in Figure 5, can be implanted in a heart, correct?

MR. CAHILL: Object to form.

THE WITNESS: I am not disputing that it can be implanted in the heart, even at the apex of the heart. The way it's shown in Figure 5, right? No, I'm not disputing that. That's what it shows.

BY MS. RAGHAVAN:

Q. So your -- your dispute is that the alternative embodiment that's shown in Figures 11 through 13 does not disclose that it can be implanted at the apex of the heart, correct?

MR. CAHILL: Objection.

A. That is correct.

MR. CAHILL: Object to form.

BY MS. RAGHAVAN:

Q. In your opinion, where would a POSA understand that the embodiment of Figures 11 through 13 should be implanted?

A. Well, the fact it doesn't say where they are to be implanted. But based on the size and the relative components that are here, I would think that the only position that it can be implanted is in the preperitoneal pocket.

Q. You would agree that the patent doesn't explicitly say that about Figures 11 through 13, correct?

A. It doesn't.

Q. As a POSA, as a general matter, would you agree that when you're reading a patent or another publication, you would review all of the teachings together?

MR. CAHILL: Object to form.

A. Broadly speaking, that's correct.

BY MS. RAGHAVAN:

Q. So as a POSA, when you're reviewing the embodiment of Figures 11 through 13 and the corresponding description, would a POSA look to the other parts of the patent or the publication to learn about what the patent teaches about anatomical placement?

MR. CAHILL: Object to form.

A. It depends.

I don't -- frankly, I don't know how to implant that -- these additional embodiments because the front portion implies that the blood goes directly into it, but how would you put it in the pocket is not clear to me either. So I don't know how they would implant it.

And the patent is silent on that too. It was never developed to a prototype that was actually implanted in anything, so I don't know what to make of it.

BY MS. RAGHAVAN:

Q. Does Wampler prohibit using the Figure 5 placement approach with the alternative embodiment depicted in Figures 11 through 13?

A. The patent describes a placement for the embodiment that it does, and it doesn't say anything else, so it's silent on that.

So I think that it would be not feasible to implant other devices in the same position because of what I described in the report what I believe a POSA would understand as well. And it's indirectly confirmed by the fact that that pump was never developed further other than the paper exercise.

Q. Let's turn to Paragraph 101 of your declaration.

This is part of your analysis of Ground 1, correct?

A. Correct.

Q. So here you're continuing to analyze the Wampler reference?

A. Yes.

Q. At the bottom of Paragraph 101, you have two side-by-side figures from Wampler, namely Figure 5 and Figure 13.

Do you see that?

A. Yes.

Q. And they have various annotations that

were added by the petitioner?

A. Correct.

Q. Okay. If the embodiment that's shown in Figure 13 were inserted into the apex of the heart as shown in Figure 5, would you agree that the Impeller 74 would be positioned outside the ventricle of the heart?

MR. CAHILL: Object to form.

A. (Witness reviews document.)

74 refers to impeller; is that correct?

BY MS. RAGHAVAN:

Q. Yes.

A. I don't -- I need to look at this. But the entire part that is pink, which is what you call the impeller, I suppose, would be outside the heart. That's correct.

Q. I'm going to hand you a copy of the Wampler reference, which was Exhibit 1008.

A. Okay.

Q. If you could, turn to Paragraph 18 of Wampler.

And, in particular, I'm going to refer you to the sentence that says, "Torque drive

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is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments embedded within each impeller blade sector," and then it goes on.

Do you see that?

A. No. Just a second.

Q. It's the second sentence of Paragraph 18.

A. Yeah. I can see the text, yes.

Q. Okay. So you would agree here that Paragraph 18 is describing that the impeller is driven by the permanent magnetic segments.

Do you see that?

A. Well, the torque is transmitted to the rotor by interaction between the permanent magnets that are embedded within the rotor and the electrical coils.

Q. So are you disputing that the impeller is driven by the permanent magnetic segments?

A. I don't understand what you mean by "driven by" because "driven by" is an interaction between different components, right? So permanent magnetic -- permanent magnets are one of these components that cause

the rotor to be turned, but I wouldn't necessarily call that the rotor is driven by the permanent magnets outside of the other component that actually imparts the torque on them.

Q. What is the component that's imparting the torque on the --

A. Well, the coils.

Q. -- impeller?

A. It refers to a circular electromagnetic stator [sic]. So the interaction between the electromagnetic stator and the permanent magnet is what causes the rotor to rotate.

Q. Okay. You see that there's a description here of magnetic interaction --

A. Uh-huh.

Q. -- right?

A. Yes.

Q. Is that, in your mind, the same as magneto coupling?

MR. CAHILL: Object to form.

A. That's one of them, yes. Part of magnetic coupling would be magnetic

interaction.

BY MS. RAGHAVAN:

Q. So magnetic interaction is an example of magneto coupling?

A. Yes.

Q. In describing this magnetic interaction, Wampler is only referring to the Impeller 74 and not to the Rotor 17, correct?

A. I don't see any reference to one and not the other.

Q. Well, you see that it says "impeller," correct?

A. Well, it talks about impeller blades.

Q. Well, in the second sentence, it says "impeller," correct?

A. Yes.

Q. It doesn't say "rotor," correct?

A. Well, impeller is part of the rotor.

Q. But it doesn't say "rotor," correct?

A. The text says what it says.

Q. So would you agree that the Impeller 74 of Figure 13 is what is being used to act on the blood?

A. The entire rotor acts on the blood. The entire pump acts on the blood, for that matter. I'm not sure how you define "act on the blood."

Q. Is the impeller performing the pumping function?

A. Certainly is part of the pump.

The impeller is part of the rotor as well. Other parts of the rotor perform other functions that help -- that make -- make possible for the impeller to do what the impeller does. So rotation of the impeller is the same as the rotation of other parts of the rotor.

Q. Which part of the pump specifically is imparting acceleration to the blood?

A. The rotor.

Q. The entire rotor?

A. Yes.

Q. Is there a specific aspect of the rotor that is imparting acceleration to the blood?

A. Well, the rotor has basically two components, the impeller and the spindle. The

spindle certainly applies acceleration to the blood because it rotates, and the blood that comes in does not rotate. So it makes a -- makes the blood into -- into -- you know, imparts some rotational movement on the blood just by drag.

Clearly the impeller itself is the one that imparts centrifugal force and forces the flow of blood to turn and then to go towards the outlet.

(Stenographer clarification.)

A. Towards the outlet.

THE STENOGRAPHER: If you could, just keep your voice up just a bit.

BY MS. RAGHAVAN:

Q. And you would agree that Wampler discloses a centrifugal pump, correct?

A. Of course.

Q. So is it your position that Element 18, which is the shaft of Figure 13, contributes to imparting acceleration to the blood?

A. I think 18 refers to a spindle.
Q. Yes.
A. And does it change the movement of the blood? Of course it does. It creates some drag and starts to sort of cause the blood to rotate around the axis -- central axis. And then most of the centrifugal pumping action is imparted at the impeller part, but the spindle certainly affects blood flow in some way.
Q. I understand you're saying that it impacts the blood flow, but is it imparting acceleration to the blood such that the device operates as a centrifugal pump?
A. I'm trying to think about how to accurately answer your question.
Any blood particle that travels through the pump experiences a change in motion as compared to what it was seen when it was in the heart. So it starts to turn already at the spindle, and it turns more at the impeller, so they work in tandem. I don't know how to separate them to say that one does something and the other one doesn't.
Q. What is the primary purpose of the

spindle?

A. The spindle has a number of purposes. It starts, I think, the motion of the blood flow into the rotational motion. It also has magnets that are embedded in the spindle and then corresponding magnets in the housing that create stability for the impeller. So it has a number of different functions.

Q. Does the spindle contribute to the rise in pressure between the inflow and the outflow of the pump?

A. Again, I don't know how to answer that accurately.

The spindle and the impeller are both parts of the rotor, and blood goes through the rotor -- or around the rotor, rather, and through the blades to get the momentum that it gets and to sort of transform that momentum into pressure. That's -- I mean, they work in tandem. I wouldn't know how -- I mean, if you cut off the spindle, the impeller will not work by itself. The same is true for the spindle. If you cut out the impeller, the spindle by itself will not work as a pump.

They work together.

Q. So going back to Figure 13...

Let me actually turn you to Paragraphs 117 and 118 of your declaration.

So in Paragraph 117, you have an analysis that says "if relying on the first embodiment of Wampler," correct?

A. Yes.

Q. And then in Paragraph 118, you say "if relying on the second embodiment of Wampler," correct?

A. Yes.

Q. Do you have any analysis where the two embodiments -- or the teachings in the two embodiments are taken together?

MR. CAHILL: Object to form.

THE WITNESS: I'm not sure how to answer that question accurately.

Some parts of the entire patent talk about, let's say, the spindle. The spindle is similar between the two devices, right, embodiments whereas other parts are different. So the thrust bearing of the first embodiment are not the same as the magnetic suspension in

the second embodiment.

So there are some parts that overlap, which is why it's one patent, but there are other parts that are significantly different.

BY MS. RAGHAVAN:

Q. You agreed earlier that Figures 11 through 13, the alternative embodiment, don't use mechanical thrust bearing, correct?

A. Correct.

Q. They use hydrodynamic bearings instead?

A. Well, they use magnetic bearing and magnetic suspension and hydrodynamic bearings.

Q. So would you agree that when the pump is working in -- when it's in motion, that the rotor of Figures 11 through 13 is entirely spaced apart from its housing?

A. Yes, which is not the case in the first embodiment. That's the point of these two paragraphs.

Q. So let's turn to Paragraph 122 of your declaration.

This is your analysis of Wampler in

connection with limitation 1N; is that correct?

A. Yes.

Q. Okay. You don't dispute that the first embodiment of Wampler, as shown in Figure 5, is connected to an external control unit for operating the pump, correct?

A. It looks like it, yes.

Q. And a POSA would understand that the control unit that's shown in Figure 5 is external because it's connected via percutaneous wires?

A. It's hard to say. I mean, the box is just a black box. I assume it can be external, but it's -- it's hard to say.

The size and, you know -- like, the battery here is shown as a separate component. Again, in a controller, typically a battery will be part of the controller. So it's a schematic representation. I give it the benefit of the doubt to say it's external.

Q. If it is connected via percutaneous wires, you would agree that it's external, correct?

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A. Define "percutaneous wires."
Q. Do you understand what the term "percutaneous" means?
A. Well, percutaneous is through the skin. So what you -- what I assume you mean is the wire, the cable that connects directly the pump inside the body, and then the controller outside the body goes through the skin somewhere.
Are we on the same page?
Q. Yes.
A. Okay. So -- yes. So in that sense, that would be an external controller.
Q. Because the wires are piercing through the skin, correct?
A. Right. Well, and the controller is not inside.
Q. So you don't dispute that for purposes of Figure 5 of Wampler?
A. That it shows an external controller?
Q. Correct.
A. It may have been an external controller.
Q. Okay.

A. I think what Figure 5 shows is the controller is not part of the pump. That's all pretty much what it shows. In other words, if everything would be inside the pump, then it would be no picture like this.

Q. Okay. And you're saying one possibility of Figure 5 is that the controller is external to the body?

A. Yes. Correct.

Q. Would a POSA understand that the embodiment of Figures 11 through 13 could be connected to a controller?

A. They could be.

Q. Could it be -- withdrawn.

Could it be connected to an external controller?

A. It doesn't say anything about this.

Q. But could it be connected to an external controller?

MR. CAHILL: Object to form.

A. It could, but it could be connected to some internal controller, or maybe everything is embedded within the pump, I mean, for all I know. It's completely silent on that.

BY MS. RAGHAVAN:

Q. It's a design choice, correct?

MR. CAHILL: Object to form.

THE WITNESS: Well, everything is a design choice.

BY MS. RAGHAVAN:

Q. So whether it's to use an internal controller or an external controller would be a design choice as well?

MR. CAHILL: Object to form.

A. It depends on the limitations of controlling what in particular. For example, a controller for the second embodiment or group of embodiments would be different than that for the first embodiment. So I -- the patent doesn't say anything about that.

BY MS. RAGHAVAN:

Q. But if you were to try to design a way to control the operation of the pump shown in Figures 11 through 13, a POSA would understand one way to do it would be to use an internal controller, correct?

A. One way would be to use an internal controller. One way is to use an external

controller. One way is to incorporate within the, you know, pump. You know, I -- it's a speculative answer here because there's nothing in the patent that describes that.

Q. So you would agree that the descriptions corresponding to Figures 11 through 13 don't specifically prohibit using an external controller, correct?

A. It doesn't say anything about it.

Q. Regardless of whether the embodiment of Figures 11 through 13 uses an internal controller or an external controller, where would that pump get power from?

A. There are different ways to provide electricity. It may be an implantable battery. It may be supplemented by external battery. It may be with coil transmission through the skin, maybe with cable transmission through the skin. There are different ways of doing this.

Q. Were all those options known in the art before 2007?

A. Well, known in the art conceptually.

Q. Were internal and external controllers

generally known in the art prior to 2007?

A. I'm hesitant to broadly characterize the field because different pumps require different controllers. So something that may be possible for one controller may not be possible for another pump in another controller. So it's not -- there's no way to answer that question accurately.

Q. But generally the concept of having controllers be either internal or external was known in the art prior to 2007, correct?

A. Broadly speaking.

Q. Do you have any personal experience or knowledge about how much electrical power a typical implantable LVAD would need?

A. Well, it's a question that depends on the efficacy of the pumping and the efficacy of the motor that is powering it or whatever the source of rotation is.

Yeah, generally I understand that, but, like, measured and -- and also it depends on the output of the pump and a whole bunch of factors that -- but, yes, I understand that.

Q. Do you know how much electrical power

the pump shown in Figures 11 through 13 would need?

A. There is no way to tell just looking at the figures.

Q. Can you provide a range?

A. I -- probably more than 20 watts and less than, I don't know, 200. I mean, it's a broad range.

Q. Is that specific to the embodiments of Figures 11 through 13? Or would you -- would you attribute the same range to the embodiment of Figure 5?

A. I don't know. I have to think about this a little more. I didn't -- I gave you an off-the-cuff answer here, but it's really -- I need to think about it more.

One thing that is probably true about the embodiment, the second embodiment, is that since it has electrical coils, it will probably use more power than the first one because it needs also power to suspend and to support the rotor.

But how much power? It's a very difficult question to answer.

Q. Can we look at Paragraph 80 of the Wampler reference?

MS. RAGHAVAN: It's Exhibit 1008 for the record.

A. (Witness reviews document.)

Okay.

BY MS. RAGHAVAN:

Q. Okay. I'm going to refer you to the second sentence of Paragraph 80, which says, "Referring to Figures 11, 11A, 12, 13, and 14, the Blood Pump 11 prime shown therein, is similar to many respects to Blood Pump 11 illustrated in Figures 1 through 8."

Do you see that?

A. Yes.

Q. Did you consider that statement in forming your opinion that the two embodiments were disjoined?

MR. CAHILL: Object to form.

A. Well, it says what it says, and I agree with what it says. It's similar. For example, the spindle is similar. We talked about this.

And the shape of the pump, broadly

speaking, at least in the portion that goes into the ventricle is similar, but there are differences. So there's nothing -- I mean, I don't see any contradiction here.

BY MS. RAGHAVAN:

Q. Okay. So you agree that there are similarities between the two embodiments?

A. Yes, there are similarities.

Q. Do you already -- did I already give you a copy of the '356 patent? I believe so.

A. Yes.

Q. Okay. Can you pull that out for me, please.

A. Yes.

Q. This is Exhibit 1001. If you could turn to Figure 1 of the '356 patent, would you -- would you say you've had an opportunity to analyze this patent in detail?

A. Yes.

Q. On Figure 1, if you could, take your pen and draw the central axis of the rotation that extends through the entirety of the figure.

MR. CAHILL: Object to form.

A. I don't understand the question. Say it again.

BY MS. RAGHAVAN:

Q. So do you see where the heart is depicted in Figure 1?

A. Yes.

Q. And then you see where the device is implanted into the heart?

A. Yes.

Q. Do you know where the central axis of rotation of the device would be as it's shown on Figure 1?

MR. CAHILL: Object to form.

A. Well, the representation here is schematic, the entire pump shown as Position 6, I believe. And so Figure 2 is a better representation of that and is a central axis of rotation here, which is clearly identifiable.

(Stenographer clarification.)

A. I don't know how to make a central axis through the line. Like, we went to

line 9. How would I make a central axis through that? I don't quite know how to mark it.

BY MS. RAGHAVAN:

Q. Can you explain the difficulty in marking the central axis on this diagram?

A. Well, you're asking me to make a central -- I mean, line 9 shows the inlet portion of the pump.

And so you're asking me to make a central axis through the line. I mean, I can make a central axis through a figure for a square or rectangle or triangle, but a line itself is a central axis of itself, right?

Q. If I understand you correctly, you're saying the actual line that forms Element 9 is the central axis?

A. Of itself.

Q. And Element 9, as shown here, has some flexibility or curvature, correct?

A. You're referring to Position 10?

Q. Yes.

A. Well, it's a little curved from a straight line, yes.

Q. So if we start at the portion of 9 that's closer to Element 6 and we follow that line all the way down to where it's marked 10, you would agree that the central axis follows Element 9, correct?

A. I would agree.

Q. So you would agree that the central axis of a tube is not necessarily a straight line?

MR. CAHILL: Object to form.

A. It's mostly straight here. Again, it's a cartoon representation. I wouldn't necessarily make too many conclusions from -- from -- I mean, it does show a little curve, but I --

(Stenographer clarification.)

A. I would not make much conclusion from this small curvature at 10.

BY MS. RAGHAVAN:

Q. But generally the axis follows the curve of the tube, correct?

MR. CAHILL: Object to the form.

A. Generally in what sense?
BY MS. RAGHAVAN:
Q. In a physics sense.
A. So for this picture?
Q. Sure, in the picture.
A. Yes. The picture shows what it shows.
Q. Okay. Let's turn to Paragraph 50 of your declaration again.
A. Okay.
Q. Okay. And here you're describing the '356 patent, correct?
A. Yes.
Q. And you're saying that the figures and the description of the '356 patent provide an example embodiment, correct?
A. Yes.
Q. And the example -- withdrawn.
The example embodiment is what you're describing as "a catheter device having a fluid-driven rotary pump," correct?
A. Yes.
Q. Would you agree that this is the only example embodiment that's provided in the '356 patent?

A. Examples -- I mean, it describes what it describes, so it has this particular example. So in that sense, it does -- that is correct.

Q. So the only example that the '356 patent provides is of a catheter-based device, correct?

MR. CAHILL: Object to form.

A. That is an example of a particular configuration.

BY MS. RAGHAVAN:

Q. But that's the only example configuration it provides?

A. It says what it says.

Q. Let's turn to Paragraph 96 of your report next.

If we go to the end of Paragraph 96, the last sentence, you say here that "The first device, the HeartWare HVAD, that was clinically implanted in the pericardial space years after the publication of Akamatsu (and the priority date of '356 patent)."

Do you see that?

A. Uh-huh, yes.

Q. What do you mean by "clinically implanted"?

A. Well, HeartWare was a commercially available device for a number of years, and so it went through conventional clinical studies when it was implanted in human patients after, I suppose, some animal trials, and then it was commercialized and was sold to be implanted in patients with heart failure.

Q. Do you know whether the inlet tube of Akamatsu was placed within the apex of the heart?

A. I don't.

Q. You don't know?

A. I don't know.

Q. Is there a difference between the inlet tube being placed at the apex of the heart and the pump being placed in the pericardial space?

A. Well, it goes one way but not the other. In other words, if the pump is in the pericardial space, the likelihood is that the inlet tube will be placed in the apex of the heart because it's quite close to it. That's

the whole point of putting it there.

But if the inlet tube is placed in the apex or anywhere else in the heart, it doesn't mean that the pump is there, so it can be extended somewhere else.

Q. So the two are not necessarily synonymous, right?

A. Well, it can be one way but not the other.

Q. Got it.

So let's turn to Paragraph 150 Of your report next -- sorry -- of your declaration.

Towards the end of this paragraph, you say, "This means Wampler only proposed an unachievable concept of such a pump and placement." And then it goes on to say that "It took over ten years from the publication of Wampler (many more from its priority date) and five 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."

Do you see that?

A. I see the text. Let me review the

entire paragraph.

Q. Sure.

A. Just one second, please.

Q. Take your time.

A. (Witness reviews document.)

Yes, I understand.

Q. Okay. When you say "such a pump and placement," what is the placement you're referring to?

A. A pump that would be small enough to be implanted at the apex of the heart.

Q. So are you saying a pump that would be small enough to be placed within the pericardial space?

A. We say that, within the pericardial space. I think what we really need to say is at the apex of the heart because the pericardium is sort of cut open at that point.

So pericardial space better -- is better defined as the space around the entire heart. So clearly that's not part of what we're talking about here.

So we're not closing the pericardium around the pump. They're just cutting it open

to have access to the heart. So I just want to be accurate here.

So in order to position that pump and to have an inflow cannula in the apex of the left ventricle, it has to be small enough to fit in that space even though the pericardium may not be completely surrounding that pump.

Pericardial space refers to space at the apex of the heart. I think that would be a more accurate way to describe that.

Q. But the claim only requires that an inflow tube of the heart assist pump device is inserted into a ventricle of the heart, right?

MR. CAHILL: Object to form.

A. A claim -- claim what? Claim 1 of the '356 patent?

BY MS. RAGHAVAN:

Q. Yes. So if you look at Claim 1 of the '356 patent and look at the first limitation after the preamble.

A. (Witness reviews document.)

Well, it's listed this way, but it's not the only thing that the claim requires.

The claim requires a number of different limitations.

Q. Sure. But as for placement specifically, it says, "An inflow tube of the heart assist pump device is inserted into a ventricle of the heart," correct?

A. Well, it does. It does say that, but that's not the only thing that's required with an inflow tube. I think there is some axial alignment somewhere else.

The inflow tube is mentioned somewhere else here, right?

Q. Sure. I understand that there are other requirements for the inflow tube, but as for just placement alone, it just says it's inserted into a ventricle of the heart, correct?

A. For the placement, yes, that's correct, but you would not place it anywhere else, along the side wall of the ventricle, for example. That would not be physical -- physically useful.

Q. The claim, for example, doesn't say that the heart assist pump device needs to be

placed in the pericardial space?
A. Well, the claim says what it says.
Q. But it doesn't say "pericardial space," correct?
A. It has limitations that it lists, which is the suction end -- suction end of the inflow tube on the heart assist pump is inserted in the ventricle -- into a ventricle of the heart. That's the -- that's what it says.
Q. That's what it says about placement, correct?
A. Well, again, it's not the only limitation for the inflow tube, but in terms of placing it, it says that it has to go into the -- into the left ventricle of the heart.
Q. The other limitations that you're referring to, you're talking about, like, alignment of the various elements --
A. Right.
Q. -- of the pump, correct?
A. Correct.
Q. But I just want to focus in on the limitations that relate to placement of the

devices.

A. Yes.

Q. As for placement, what does the claim require?

A. Well, the placement requires that the device is delivered to the heart so that a suction end of an inflow tube of the heart assist pump device is inserted into a ventricle of the heart.

Q. Okay. Let's go back to Paragraph 150 of your declaration.

A. Yeah.

Q. You say here that you believed Wampler's concept was unachievable, correct?

A. Well, the second embodiment.

Q. Okay. So you're saying the second embodiment of Wampler describes an unachievable concept, in your view?

A. Correct.

Q. Is that accurate?

A. Correct.

Q. Are you disputing that Wampler disclosed the concepts of such a pump and placement at the apex of the heart?

MR. CAHILL: Object to form.

A. As any patents strive to do, they describe all possible combinations and variations of the invention, right?

And then rarely all of them are practical and actually used. So I believe that Wampler discloses to be complete, and I don't know what you make of this configuration in 11 through 15 as to how it's placed and what -- Wampler is silent about this. It was never developed into anything.

So I don't know what to make of it beyond what the pictures show, which they don't show that placement of the pump at the apex of the heart. So I don't know what to make of it.

BY MS. RAGHAVAN:

Q. Okay. So still staying in the same paragraph, you say it took five years after the priority date of the '356 patent for the HVAD to be actually made small enough to be implanted at the apex of the heart, right?

A. That's what I said.

Q. Why -- explain the phrase "actually

made."

A. Well, it's one thing to show a picture or a cartoon in an article or in a patent, and the other one is to actually make a prototype of the device or actually a clinical version, clinical prototype of the device that would be useful to be implanted in a human.

Q. Is that your understanding of what is required to show obviousness of a claim?

MR. CAHILL: Objection.

A. I'm not commenting on the obviousness. I'm just commenting on -- I'm explaining what I mean by this text.

BY MS. RAGHAVAN:

Q. When you say this event happened five years after the priority date of the '356 patent, is it correct that you're referring to the 2012 U.S. FDA approval date for the HeartWare HVAD pump?

A. Yes, that's correct.

Q. Okay. And then earlier in the same paragraph, you said, "This pump received FDA approval for such implantation in 2012, years after the priority date of the '356 patent,"

correct?

A. I say that, yes.

Q. And then you cite two exhibits in support of that sentence?

A. Yes.

Q. So I'd like to take a look at those two exhibits.

The first one you cite is Exhibit 2003.

A. (Witness reviews document.)

Q. You reviewed this article, correct?

A. Yes.

Q. If you could, turn to page 729 of this article, which is what you cited in your declaration at Paragraph 150.

Let me know when you're there.

A. (Witness reviews document.)

Yes, I'm here.

Q. And is it correct that you're referring to the paragraph that says, "Initial clinical trials of the HeartWare LVAD began," that paragraph?

A. Yes, uh-huh.

Q. And it says here that "The pump

received FDA approval for implantation as bridge-to-heart transplantation in 2012."

Do you see that?

A. Yes.

Q. Is it your view that FDA approval of a device that's described in a patent or a publication is required for the patent to be valid?

MR. CAHILL: Objection. Outside the scope.

A. I did not consider that question before.

BY MS. RAGHAVAN:

Q. Is it your view that FDA approval of a device described in a patent is required for a POSA to be able to appreciate the disclosure of that patent?

MR. CAHILL: Objection. Outside the scope. Object to form.

A. Well, it's a question I need to think about. I mean, I could make a drawing of something and show it to somebody. And then I can make a prototype, and then I can make a clinical prototype and if it works or not

works and it -- it's not -- it's not very clear at what point -- I mean, I need -- certainly FDA approval would mean that the device is workable because it's approved by the FDA, so it's a good, practical, safe, and effective device, right? So that certainly would be one measure by which a POSA would understand that the disclosure of something is sort of -- you know, it works.

But I have to think about at what point a POSA would actually consider something viable or not viable. From a sketch to the FDA approval, there's a lot of steps in between. I didn't consider that question carefully, but I can, I suppose.

BY MS. RAGHAVAN:

Q. So you would agree that there are at least some circumstances in which a POSA would not necessarily need to wait until the FDA approval date to consider a disclosure in a patent to be a viable disclosure?

MR. CAHILL: Objection. Outside the scope. Object to form.

A. I have to think about how to answer

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that question more. I can't really -- I wouldn't speculate off the cuff.

BY MS. RAGHAVAN:

Q. But you're relying on the 2012 FDA approval date, correct?

A. Well, FDA approval date will certainly be a good indication for a POSA that the device is viable, you know, commercial, safe, and effective product because FDA said so. That would be a strong indication of this.

Q. But prior to obtaining an FDA approval, you understand that devices go through clinical trials, correct?

A. Yes.

Q. If you can actually turn back to Exhibit 2003 and stay at Paragraph 729, I have a few further questions for you.

A. Okay.

Q. So same paragraph we were talking about earlier refers to initial clinical trials of the HeartWare LVAD, correct?

A. Yes.

Q. Did you consider the date of those initial clinical trials in forming your

opinions for this IPR?

A. No, I did not.

Q. Are you aware of the date at which the initial clinical trials started?

A. What relevance does it have as to when the trial started?

Q. You don't see a relevance of that, do you?

MR. CAHILL: Objection.

A. I don't know. I have to think about this. I -- I didn't consider that as part of my report.

BY MS. RAGHAVAN:

Q. Do you see that the article says that "The initial clinical trials of the HeartWare LVAD is as a bridge-to-heart transplant showed patients 30-day and one-year survival rates were 99 and 86 percent, respectively"?

A. Yes.

Q. Those are pretty high rates, right?

A. Well, I suppose they were high enough for the FDA to approve it.

Q. So if you saw those numbers as a POSA, would you consider the device that achieves

such rates to be a viable device?

A. Again, I have to consider -- it goes back to the same question as to at what point the POSA would understand something is good. And I -- I just can't speculate and tell you exactly after the clinical trial, at the beginning of the clinical trial, before the clinical trial, after an animal study.

At the end of day, even though the FDA approved the device -- by the way, it came off the market even years afterwards. So it was not -- as it turned out, it was not good enough. So it's a question that requires more consideration.

Q. But the HeartWare LVAD device that you're now saying was not good enough formed the basis of your understanding of the size and volume of pump that would be appropriate to be placed in the pericardial space, correct?

A. Oh, absolutely.

MR. CAHILL: Object to form.

BY MS. RAGHAVAN:

Q. And if that pump had a 30-day and a

one-year survival rate of 99 and 86 percent, respectively, much earlier than 2007, would that surprise you?

MR. CAHILL: Object to form. Outside the scope.

A. Again, these pumps have been -- are usually in development for decades sometimes. And so one test, one, you know, publication may say something -- one thing, and then the other may say something else. Indications change. Designs change. It's a continuum. I have to think about, you know, your question before, which is at what point it becomes viable? It's a question that you -- that's a complicated question.

BY MS. RAGHAVAN:

Q. In order for a device to get approval -- well, I will back up.

In order to start a clinical trial, a device needs to get initial approval, correct?

A. Well, IDE is the investigational device exemption, the process by which FDA regulates this. So it's not an approval for a

device to be sold. It's an approval for the study to start. So they have to have some basic safety measures, I suppose, that need to be demonstrated.

Q. Are you aware that to get approval for an IDE, there has to be a reasonable expectation that the disclosed device will work?

MR. CAHILL: Objection. Outside the scope.

A. Broadly speaking, that is a -- that sounds right.

BY MS. RAGHAVAN:

Q. But you didn't consider the date of the IDE submission, correct?

A. I did not look at the date of the IDE submission.

Q. You did not look at the date of the initial clinical trials, correct?

A. We covered that ground already. As I said before, the -- I had to draw a line somewhere. So the FDA approval was a good enough indication for me that the device was safe and effective because FDA said so. So in

that sense, I referred to -- my point here was not about the specific dates. My point was that Wampler device was not -- I did not consider this to be implantable at the apex of the heart. That was the point of the whole paragraph.

Q. But you're comparing the dates of the Wampler device to the 2012 date, correct?

A. I compared because I compare it to HeartWare. HeartWare was a device that was implanted at the apex of the heart. And even though it was removed from the market later for reasons that had to do with the performance of the pump, not the weight and the size of the heart -- of the device.

So in that sense, I think it's a fair comparison to use the HeartWare device because it was implanted, and the size and the weight of the device did not cause problems. And they never did. What caused problems was something else. That's a different story.

But my point here was to rely on this date as an indication that a practical device is implantable at the apex of the heart.

Q. And the fact that the patients' 30-day and one-year survival rates were high much earlier than that 2012 date, you didn't factor that into your analysis?

MR. CAHILL: Object to form.

A. The report says what it says.

BY MS. RAGHAVAN:

Q. Let's take a look at the second article that you cite on Paragraph 150, and then after that, maybe it's time for a break.

This is the Symalla article, and it's Exhibit 2020.

A. (Witness reviews document.)

Q. You cite page S-258 of this article, right?

A. Yes.

Q. Can you turn to that page, please.

A. Uh-huh.

Q. And I believe you cited the paragraph that starts with "a third generation of LVADs," et cetera, correct?

A. Okay.

Q. Is that accurate?

A. Yes. Well, it describes "the HVAD."

Q. Sure. This generally starts off by describing what's called the third generation of LVADs, correct?

A. Correct.

Q. You understand that the third generation of LVADs are devices with centrifugal flow, correct?

A. Yes.

Q. As opposed to the second generation of LVADs, which you understand have continuous flow?

A. Centrifugal flow is also continuous flow.

Q. Would you -- so would you characterize the second generation, then, as axial flow?

A. Well, I think that the third generation is suspension of the rotor where the second generation are thrust bearings.

(Stenographer clarification.)

A. Thrust bearings of some sort. So I think that's the difference. But both of them are continuous flow devices as compared to the

first generation, which was a pulsatile device.

BY MS. RAGHAVAN:

Q. Do you think that either generation is attributed to being either axial or centrifugal flow?

A. In my mind, the distinction is what I said, which is the way that the rotor is suspended or not suspended.

Q. Have you worked on the design or development of a second-generation LVAD prior to 2007?

A. Well, my work in -- with centrifugal pumps at the beginning of my career would be probably considered second generation.

Q. So you've never worked on the design or development of a third-generation LVAD prior to 2007, correct?

A. Magnetic suspension and then, like, spaced apart?

Q. That's right.

A. No, I have not.

Both articles, by the way, say the same thing as I say here, which is the size is

what made it possible to implant it at the apex, which is the main point of that paragraph.

Q. Do you see that in the Symalla article, Exhibit 2020, it says, "The HVAD was initially evaluated as a BTT device in a European pivotal trial"?

A. Yes.

Q. And "BTT" stands for bridge to transplant, correct?

A. That is correct.

Q. And it goes on to say that that trial enrolled 50 patients who received a HVAD as a BTT, correct.

A. Where -- oh, yes, on the second page, yes, or second column.

Q. It also says towards the end of that long paragraph that "An important finding in the HVAD trial was the decreased incidence of pump thrombosis, and then the HVAD received European CE mark for BTT in 2009 and FDA approval for BTT in 2012."

Do you see that?

A. Yes.

Q. And you rely on the 2012 date for FDA approval, correct?

A. Yes.

Q. Do you cite the 2009 European CE mark date at all in your declaration?

A. I don't.

Q. Do you rely at all on the European pivotal trial that's described in the Symalla article you cite?

A. It may be considered to be reasonable to have a CE mark as well as FDA approval. So it may be considered that 2009 would be a more appropriate date than 2012. I will give you that.

But again, the point of this article was that it still took years afterwards one way or another. And the main -- the main issue here is the size and the weight, not when it was approved. I don't see any relevance as to whether it was approved in one jurisdiction in one year and the other jurisdiction in the other. I cite this as an example that it took years afterward.

So the key thing, the key finding that

is confirmed by both articles and is what I say here, which is the size and weight of the device is the primary factor that impacts its ability to be implanted at the apex of the heart.

Q. Is there any indication from this article or from your other understanding that the size of the HeartWare HVAD was changed from its initial design to it receiving its European CE mark in 2009?

MR. CAHILL: Objection. Outside the scope. Objection to form.

A. I did not consider that level of detail.

BY MS. RAGHAVAN:

Q. Is there any indication from this article or otherwise in your personal understanding that there was any change in the size of the HeartWare HVAD pump from the time it received its European CE mark to the time it received USA FDA approval?

MR. CAHILL: Same objection.

A. I do not know if there is a difference or not.

MS. RAGHAVAN: We can set that aside.

Do you want to take a break now or...

MR. ROLLER: They say lunch is here, so it might be a good time.

MS. RAGHAVAN: Let's break, then.

(Recess taken from 12:36 p.m. to 1:19 p.m.)

BY MS. RAGHAVAN:

Q. Mr. Leschinsky, welcome back from lunch.

A. Thank you.

Q. Just some general questions for you.

Both the Bourque 2001 and Wampler references describe third-generation LVADs, correct?

A. Bourque, yes. And then Wampler -- well, there are two different embodiments in Wampler. I would consider them differently. The first embodiment is, I would consider, second generation. The third embodiment would

be a third generation.

Q. Okay. Both Bourque 2001 and Wampler describe implantable LVADs, correct?

A. They intend to go inside the body, so in that sense, they're implantable, yes.

Q. Both Bourque 2001 and Wampler describe LVADs using magnetic coupling to drive centrifugal -- drive a centrifugal blood pump, correct?

A. Well, Wampler, again, there are two different embodiments there. But both embodiments use magnetic torque generation, if you will, to cause the rotation of the rotor. So in that sense, they are similar to Bourque.

Q. So I think I heard you agree that they both use magneto coupling to drive the rotor, correct?

A. That would be correct.

Q. They both use magneto coupling to suspend the rotor?

A. "Both" meaning Bourque and Wampler?

Q. Correct.

A. Well, Bourque, yes, but not both embodiments in Wampler. Only one embodiment,

and the second one is suspended.

Q. So Bourque 2001 and the second embodiment of Wampler both use magneto coupling to suspend the rotor?

A. In both cases, the rotor is suspended by more than just the magneto coupling.

Q. Okay. Do they both at least use magneto coupling to suspend the rotor?

A. Yeah, that's probably fair.

Q. Do both Bourque 2001 and Wampler describe a puck- or disc-shaped elements of the pump -- of the pump? Sorry.

A. The only -- of the three pumps, which is the Bourque and the two embodiments of Wampler, I would say that the first embodiment of Wampler is the only disc shape that I can think of. I wouldn't describe others as disc shape, at least the portion that's outside the heart.

Q. Do you agree that both Bourque 2001 and Wampler sought to improve on some of the drawbacks with second-generation devices?

A. Well, the same caveat applies to Wampler: two different embodiments, two

different generations.

So, broadly speaking, the third generation, which is a full suspension of the rotor, that seek to improve on the second generation, which has thrust bearings, by eliminating them and -- and making the pump safer.

Q. And what about for Bourque?

A. That's broadly true for all third-generation devices.

Q. Would you agree that both Bourque 2001 and Wampler aim to reduce thrombosis?

A. It's an overarching sort of objective of any pump to not have thrombosis. Reduced thrombosis questions is from what to what. So minimizing thrombosis would probably be a better way to say it.

So every -- every design of every blood pump seeks to minimize thrombosis.

Q. Is it your opinion that in order for a POSA to combine teachings from different prior art references relating to heart pumps, those pumps must be both implantable and of the same size or volume?

A. It's a broad question that needs to be broken down to specifics as to what is common and what is not common.

Certain elements may be transferable from one device to another, and certain elements may not be.

Q. So just focusing in on the size of the pump, is it your opinion that teachings from two prior art references are not combinable if they talk about pumps of different sizes?

A. The same answer. Depends on the specifics.

Q. You would agree that before the priority date of the challenged patents, a POSA was generally motivated to make LVAD devices smaller, yes?

A. Generally.

Q. You would agree that second-generation LVADs are generally smaller than first-generation LVADs?

A. Broadly speaking, that's correct.

Q. And you would agree that third-generation LVADs are generally smaller than first- and second-generation LVADs?

A. On that, I would not necessarily agree with. I think that the third generation would be smaller than the first generation. But in terms of the second generation, that's not clear to me that it would be universally smaller.

Q. Can you think of some examples of second-generation devices that are smaller than third-generation LVADs devices?

A. Yes. HeartMate II was not necessarily that much different from Bourque Prototype 3. Different shape, but the volume and the weight was probably comparable.

Q. The large size of first-generation devices was one factor that was associated with infection rates, correct?

MR. CAHILL: Objection. Outside the scope.

A. I don't know how to answer that question accurately because, again, we're broadly combining a number of different devices that would be considered first generation, and some had more infection rates than others. So I -- you know, it's not a

definitive enough question to -- that I can answer yes or no.

BY MS. RAGHAVAN:

Q. So let's look at Paragraph 34 of your declaration.

A. Yes.

Q. You do agree here that size may have been one factor at play?

A. Well, as I said before, there is a number of different factors. Size may be one factor. But infection rate is a complicated issue that has to do with the devices, with the implantation technique, with following clinical progression of the patient, the patient's condition. There are many different factors.

Q. And size is one of them?

A. It may be one of them.

Q. Would a POSA have been motivated to make LVAD devices smaller to hope to minimize the risk of infection?

A. I wouldn't see it that way necessarily. Generally speaking, smaller is better. Safer is better. Less intrusive is

better. So I think the motivation is not necessarily infection but the ability to implant these devices in broader range of patients and with less trauma.

Q. What are some motivations for a POSA to design an LVAD device to be smaller?

A. Well, that's what I said. To provide assistance to a broader range of patients and to minimize the extent of surgery that is required.

Q. So, for example, a POSA may have been motivated to make LVADs that were smaller to treat smaller patients, correct?

A. That would be one factor. Again, there is not a single factor that is at the core of optimization when a POSA would be -- would design a blood pump.

A blood pump has to satisfy a long list of contradicting requirements. And the ability to implant it and actually explant it afterwards would be one of those requirements. But also the device has to be safe. It has to minimize thrombosis, or it has to provide adequate output. It has to do all kinds of

things.

So size would be one of the factors that certainly, given everything else the same, nobody will try to design a larger pump. But again, I wouldn't think that size is one critical thing that is more important than other requirements.

Q. Do you think that placement at the apex of the heart minimizes the extent of surgery compared to placement in the preperitoneal pocket?

A. It may.

Q. What are the factors that play into that?

A. Well, it depends on the size of the incision, for example.

Generally speaking, if you have a small pump that is implantable at the apex, you can go through a particular location between the ribs and implant the entire thing without much of a -- cutting the chest open. First-generation devices require open chest to put them in. So that certainly would be minimizing the extent of damage and then

postoperation recovery. So that's certainly one factor. Again, it's one of many.

Q. So size is just one factor to keep in mind when it comes to placement in designing pumps generally?

A. Size is one factor in designing the pumps generally. Location is another factor. And so small enough size allows for certain locations that larger sizes do not.

Q. And again, that's a patient-by-patient consideration, correct?

A. Well, I mean, they generally separate adults from children, for example, right? So clearly a small child has a different anatomy available for placement for a pump than a large adult.

So among adults, one -- a POSA would want to, you know, minimize the size as one of the factors that would allow for easier placement, but that does not mean that they would sacrifice safety, for example, or thrombogenicity of the pump. It's a balancing act.

Q. But even within adults, there's a lot

of variation in patient size, correct?

A. Of course.

Q. Would you agree that the '356 patent doesn't specify the size of the pump?

A. I don't think it does.

Q. Would you agree that the claims don't require a certain size or weight of the pump?

A. Well, the claims speak for themselves.

Q. If a POSA wanted to keep everything -- all the elements of the Bourque 2001 pump intact but remove the inflow elbow such that there is no 90-degree turn, from an engineering perspective, do you consider that to be a complex swap?

A. You mean, like, to put Wampler-type inlet on the pump? I don't know. I have to think about the complexity from a technical point of view.

But from the POSA point of view, that would be a nonstarter configuration.

(Stenographer clarification.)

A. Nonstarter configuration.

BY MS. RAGHAVAN:

Q. I don't think I'm understanding --

A. Nonstarter.

Q. Nonstarter?

A. Yeah.

Q. Why?

A. Well, many -- a POSA would want to devise -- to design a device that would be practical and would consider implantation technique, for example, as to how to put it in.

If you have a large enough size of the pump such as Bourque and you put an intraventricular inflow cannula such as Wampler, how would you put it in? It would not fit in the place next to the apex of the heart, so it would not be implantable like the first embodiment of Wampler.

And at the same time, if you remove the elbow, it would also not be implantable in the way Bourque actually implanted his device in the pocket below the diaphragm.

So I don't know what you would

actually do with this thing once you -- even if you design it.

Q. In either situation, though, with or without the elbow, the inflow tube goes into the apex of the heart, correct?

A. Well, the device has to take blood from somewhere, so -- from somewhere. It may take blood from the left atrium or the left ventricle.

In case of Bourque, there was a connector that goes inside the heart, inside the apex of the upper left ventricle. So in that sense, that statement is correct.

Q. Prior to 2007, it was known in the art to have a centrifugal LVAD without an elbow, correct?

A. I don't know if it was known in the art. Meaning that it would be implanted at the apex?

Q. I'm not asking about the apex. I'm just asking you about whether it was known in the art prior to 2006 to have a centrifugal LVAD without an elbow.

A. Well, we need to clarify what that

means. "Without an elbow" means that there was a straight tube that goes into the -- into the -- so no elbow means straight, right? So the inlet tube has to be straight.

So the inlet tube is usually pointing at the center of the centrifugal pump. So if you have a straight tube -- again, if we're talking about Bourque plus Wampler, for example, if it's a big enough thing, I don't know how you implant that. So in that sense, no, it was not commonly known because it would be a nonsensical configuration.

So by definition, to be useful, it has to be small enough and then have the inflow tube that would go into the ventricle of the heart by the apex. So I don't know if it was actually known before.

I mean, HeartWare had some probably initial tests around that time -- I don't know before or after -- so that would be probably one example. But I can't think of any -- certainly not commercially available LVADs that would have that feature.

Q. The Wampler reference doesn't have an

elbow, correct?

A. Well, the first embodiment does not. The second embodiment, I don't know how you would implant that. So again, it doesn't really say much.

Q. Even with the second embodiment, as you said, the pump would have to have an inflow tube, correct?

A. Well, any pump would have an inflow tube.

Q. And is it possible that the inflow tube could be one without an elbow?

A. Possible.

Well, again, a POSA would design something with a clinical application in mind. So I know that the drawing shows that -- that similar spindle in the front of both embodiments, but I don't know how you would actually implant that device. And it doesn't say -- the patent itself doesn't really discuss it either. So it's not something that I would necessarily think a POSA would take as a -- as a guidance.

Q. When you say the patent itself doesn't

disclose that, you're just talking about Figures 11 through 13 --

A. Yes.

Q. -- specifically, right?

A. Yes.

Q. Because it does disclose that for the first embodiment?

A. Correct.

Q. Akamatsu also describes and shows a centrifugal LVAD that doesn't have an elbow in the inflow tube, correct?

A. Well, Akamatsu article describes a number of different configurations of the pump, and it doesn't really specify one way or another how they're implanted.

The aspirational figure that we're all talking about doesn't show what the inflow of the pump look like. It's a grainy picture that is, again, a schematical representation of the fact that the pump will be positioned somewhere near the heart. That's all I can tell you.

It doesn't really say -- it doesn't show clearly the inflow cannula. It doesn't

show clearly the position of the pump. The pump itself is -- at least the embodiments that were discussed are the versions -- the configurations were large and would not fit in the apex of the heart. So I don't know what to make of that.

Q. Are you familiar with the VentrAssist pump?

A. Yes.

Q. Is that a centrifugal LVAD without an elbow at the inflow tube?

A. I have to look at the -- there was some publication that I believe I looked at. I would like to look at this again just to see what it is.

Q. Are you aware of any other pumps that were disclosed prior to 2007 that did not have an elbow at the inflow tube?

A. Nothing comes to mind.

Q. So let's take a look at Paragraph 176 of your declaration and talk about Akamatsu.

A. Okay.

Q. This is the figure you were referring to earlier, right? Figure 1 is of Akamatsu?

A. Yes.
Q. In this figure, do you agree that it shows an inflow tube that is inserted into a ventricle of the heart?
A. No, I do not.
Q. Where else would it be inserted?
A. Well, now we're speculating. It doesn't show anything. And so several factors tell me that it may not be even possible to put it this way because of the size of the pump that is disclosed, and the figure doesn't show the inflow cannula at all.
I know that you showed it in green here. Nothing in the article points me in that direction.
Q. So I understand that you don't believe it's possible, but I'm just asking what is shown in the image?
So setting aside the fact that you don't think it's practical -- practically possible, does this image show an inflow tube that's inserted into a ventricle?
A. It doesn't.
Q. What does it show?

A. It doesn't show any inflow tube. I don't know what -- it's just completely silent on that feature.

Q. Okay. So how is the pump that's shown in this photograph attached to the heart?

A. All right. Well, now you're asking me to speculate. You're asking me what is shown here, and I don't know what it shows.

So speculation is it may have -- it may have a graft connecting the inflow tube to some side wall. I don't know what it shows. Like, it doesn't really specify.

Q. In Paragraph 177 of your declaration, you refer to Figure 1 of Akamatsu as "a low-resolution conceptual and aspirational drawing."

Do you see that?

A. Yes.

Q. Is it your opinion as a POSA that a drawing can't provide the basis for an obviousness ground?

MR. CAHILL: Object to form.

A. I'm not taking that position. It all depends on the specifics.

BY MS. RAGHAVAN:

Q. Is it your opinion that an aspirational drawing can't provide the basis for an obviousness ground?

A. Same answer.

Q. But your position is that this photograph in particular is too grainy and unclear for you to understand?

A. I do not see an inflow cannula in this image at all. I know that it's shown here in green, but that's -- that's speculative.

Q. Can you see the outlet port in this photograph?

A. Yes. The outlet port seems to have a conventional graft that goes from the periphery of the pump and winds itself into a position in the ascending aorta.

Q. Just so that we're talking about the same thing, can you circle what you're looking at within the photograph.

A. Well, I don't know how I can circle this.

Q. I can give you a pen, if you want.

A. So how do you want to record this?

Q. She'll get a copy of the exhibits afterwards.

A. Okay. Well, then this is the -- sort of the position of the outflow graft to the ascending aorta.

Q. Okay. Can you circle the outlet port itself?

A. I don't know how to circle that.

Q. Okay. So you're referring to --

A. Somewhere here at the beginning -- so there's a light. So the white strip that goes from the side of the pump towards the ascending aorta, that's what it shows fairly clearly, but there's no -- nothing like this at all that would indicate the inflow cannula.

Q. If the inflow tube were inserted into the ventricle of the heart, would it be visible in this photograph?

MR. CAHILL: Object to form.

A. It's a speculative question. They show certain elements and not show other elements. I don't know what they would show, what they would not show.

A conceptual drawing here shows, I

think, just a configuration of main elements, which is they have a pump. They have an internal controller and an external component on the belt. That's the entirety of what this diagram shows.

I wouldn't go much beyond that at all.

BY MS. RAGHAVAN:

Q. No. I understand what you're saying.

I'm asking whether an inflow tube that is inserted into a ventricle of the heart would actually be visible in a drawing like this.

A. Well, again, this drawing, when I looked at the clean picture of this, shows some internal structures of the heart. So I would -- I would think that if they were to have that configuration in mind, they could have shown it.

Q. Where would it be if you were to -- if you were to attach the pump as it's shown in this photograph, where would you expect the inflow tube to be if it's inserted into the ventricle of the heart?

A. I don't -- I have to -- I mean, that's

something I did not consider as part of the report.

What I -- what I know is what it doesn't show, and that's what I'm saying. But where they can put it, they can put it in different places.

Q. In this photograph, where's the left ventricle of the heart?

A. Well, it's on the photograph, and then the left ventricle is sort of to the right of the -- of the heart. It's the right section of the heart.

Q. Okay. So you're referring to the bottom right, correct?

A. More like middle right.

Q. Can you -- again, can you just circle where you're looking?

A. Well, it's to the right side of the outflow graft.

Q. Are you declining to circle things or --

A. Well, circle things. I mean, I don't know. The left ventricle is probably here. (Witness indicating.)

Q. Can you just label that?
A. (Witness complying.) LV.
Q. You understand that Akamatsu says that the inflow conduit was inserted into the left ventricle, correct?
A. I don't know if I understand that. I think that Akamatsu -- I have to review the article. It says that they take blood from the left ventricle rather than from the atrium in their animal experiments. I don't think it says anything beyond that.
Q. So we're referring to the same thing, let me give you a copy of Akamatsu.
This is Exhibit 1006.
A. Okay.
Q. You said you believe the article says they take blood from the left ventricle rather than from the atrium in their animal experiments.
Do you know where in the article it says that?
A. I don't -- I have to -- I have to look for it -- through it again. Let me -- let me review this again. I'll tell you.

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(Witness reviews document.)

Yeah. Well, here they describe their ex vivo study on page 4 of the paper. They're talking about animal studies.

Q. Yes.

A. And so they say that "The device was evaluated for long-term durability and nonthrombogenicity in a chronic sheep left heart bypass model. Three sheep were anesthetized," blah, blah, blah. "The Dacron outflow graft was sutured to the descending aorta, and the inflow conduit was inserted into the left ventricle through a cuff sutured to the left ventricle apex."

So they have little bit of a variation on that theme by suturing the left ventricular -- by suturing a cuff to the LV and then inserting the left inflow -- what is it? -- inflow conduit. I'm not sure what the conduit is through that -- through that cuff.

So here.

Q. So do you agree then that that portion of Akamatsu discloses an inflow tube that can be inserted into a ventricle of the heart?

A. Well, it discloses a conduit. I'm not sure what the conduit is, and it's inserted with the help of the cuff that was sutured, but the location was at the apex of the heart.

Q. Is it your position that an inflow conduit used where the cuff is different from an inflow tube for purposes of the '356 claim?

A. Well, it actually may be because, first of all, anatomy of a sheep is different than that of a human, so it doesn't say anything about the position of the pump itself.

The conduit may be a graft -- the same as the outflow graft, which may be routed to a position of the pump that may be somewhere else.

The inflow tube refers to a direct line of sight, so to speak, from the centrifugal pump to the -- to the left ventricle.

So I'm not sure what that actually means beyond what I read.

Q. Doesn't an inflow conduit serve the same purpose?

A. Yes, but is it the same as an inflow tube for the -- from the patent point of view? I'm not sure.

Q. A cuff is just like a suture ring, correct?

A. No.

Q. What is a cuff?

A. A cuff is a -- sort of a cup-shaped graft material. So, in other words, they cover, like, a little -- they put the -- how should I describe this?

The graft is a fabric, so it's -- think of a circular piece of fabric, but the bottom is not flat but, like, you know, shaped as a -- as my hand. (Witness indicating.)

So they put this on the ventricle, and then they suture it to the ventricle. So now they have -- the apex actually is not -- is covered with the graft material.

And then they put the conduit through that graft material, and I can't really speculate much further as to what that conduit is. It may be a soft graft also which is sutured to the cuff.

It's not what, let's say, hardware would do in terms of placement. They do not have a cuff at all. They just go right through the apex.

So I don't know whether it's the same thing or not. It doesn't seem like it's the same thing.

Q. Wouldn't you need a cuff to attach an inflow tube as well?

A. Not necessarily.

Q. But it's one option?

A. I suppose so, but it depends on what they use as a conduit. If the conduit is rigid enough, you may not need a cuff. If the cuff is soft and like a Dacron graft type, then they might.

Q. Could the inflow conduit be a tube?

A. A conduit is something that carries blood flow, so in that sense, it's a tube.

Q. If you look at Figure 1 of Akamatsu closely, you can kind of see a projection or a lightly colored tube that is going into the area that you marked as "left ventricle."

Do you see that?

A. (Witness reviews document.)

I don't know what I see. I don't know what that is. I see some structures here. I tried to enlarge it to look at this. I don't know what to make of this.

Q. Okay. So in your opinion, that pump is not connected to the heart in any way?

MR. CAHILL: Objection to form.

A. No. The pump will have to have some way to get blood from the ventricle. I just don't know what I'm looking at.

It is unlikely that it's an inflow tube because it goes too high in the ventricle if it is. That it has some opening here on the side, I don't know what that is.

BY MS. RAGHAVAN:

Q. So when I asked you to draw the left ventricle, you said it started towards the middle, correct, of the heart in that diagram?

A. Well, no, the fact that -- well, what I'm saying is the left ventricle is here, right? And it's still here. (Witness

indicating.)

Because you said that the left ventricle was at the apex, and I said that it was not just at the apex. It's in the middle of the heart, more towards the middle rather than towards the apex. That was my comment.

Q. Okay.

A. I still stand by my comment. I don't know what it shows. I don't think that the cartoon was intended to show every detail of that configuration.

It's just something that shows what they wanted to do at some point. That's why it's not only grainy, but it lacks any detail because they didn't think all those details through yet, which is why I call it aspirational.

Q. So Claim 1 of the '356 patent doesn't say anything about an apex, correct?

A. No, it doesn't.

Q. It generally requires the inflow tube to be inserted into a ventricle of the heart, correct?

A. Correct.

Q. And the apex of the heart is just one portion of the ventricle of the heart that you were showing me earlier?

A. That's correct.

Q. Okay. Let's turn to Paragraph 197 of your declaration.

A. Okay.

Q. This paragraph appears in the section related to limitation 1M of Claim 1 of the '356 patent.

Do you see that?

A. Yes.

Q. And here you're discussing partially the external control unit, correct?

A. Yes.

Q. Okay. In Paragraph 197, you start off by saying, "Akamatsu is silent regarding what this component is or what any of the other components are in Figure 1."

Do you see that?

A. And that refers to which component?

Q. I was going to ask you that.

A. Oh, I see.

Well, it refers to the component in

the previous sentence, which is the "Petitioner contends that Akamatsu 'teaches or suggests a controller (worn externally in Figure 1)' based on a marked-up version of Figure 1."

And in my next paragraph, I'm saying that it's not clear what that green box shows. That's what it is.

Q. Is it your opinion that it's impossible for the lime green components shown in the annotation of Figure 1 below Paragraph 196 to be an external controller?

A. Well, how do you define "an external controller"?

Q. What are you requiring the external controller to be as it is recited in the claims?

A. Well, a controller has the primary function of operating the device. Is it impossible for this lime green tube to show the main controller that operates the device? I believe so. I don't think that's an external controller -- that it is a controller that operates the device.

It may have some secondary functions here and there such as the -- I don't know --

(Stenographer clarification.)

A. Such as a percent depletion of the battery here and there, but I don't think that this is a controller.

BY MS. RAGHAVAN:

Q. Well, so if you look at the Limitation 1N that you have at the top of page 106 --

A. Yes.

Q. -- it says, "Connecting an external control unit to the heart assist pump device for regulating operation of the second magnetic device."

Do you see that?

A. Yes.

Q. Where does it say that the external control unit has to be the main controller?

A. Well, operating the second magnetic device is the main controller. That's what

the main controller does.

Q. Is that what regulating operation means?

A. Of course.

Q. So in your mind, this limitation says it's the main controller that is the only controller that's regulating operation of the device?

MR. CAHILL: Object to form.

A. It's not -- it may not be the only controller, but it's certainly the controller that's responsible for main performance issues associated with the -- with the pump.

BY MS. RAGHAVAN:

Q. So if -- let's say -- let's say the figure -- the schematic illustration of Akamatsu in Figure 1 shows an internal controller.

Is it possible for the lime green device or component to be an additional controller?

A. Well, again, it is possible for the lime green to show some additional information about the internal controller or the operation

of the device, but the key component that regulates -- that's responsible for the rotation of the rotor is certainly the internal control.

Q. Is it possible for a heart pump to have both an internal and an external controller?

A. It depends on the definition of what the controller is.

Q. Could the internal and external controller serve different functions?

MR. CAHILL: Object to form.

A. I have to think about this. My off-the-cuff answer is that the internal controller has the priority over the external controller.

BY MS. RAGHAVAN:

Q. And where are you seeing that requirement in the claims?

MR. CAHILL: Object to form.

A. In the language. The controller -- external controller unit for regulating operation of the second magnetic device to thereby magnetically drive the rotation,

that's a core function.
BY MS. RAGHAVAN:
Q. So what if the external controller regulates the operation of the internal controller?
Does that satisfy the claim limitation?
MR. CAHILL: Objection.
A. I did not consider that question.
BY MS. RAGHAVAN:
Q. Is it your opinion that the claim requires the external control unit to directly control the operation of the second magnetic device?
A. How do you define "directly"?
Q. I'm trying to understand how you're interpreting regulation -- regulating operation of the second magnetic device.
A. Any pump of that type would have a -- the main controller that makes it work. So if you were to have here -- for example, the main controller would be the internal implantable controller.
You may have some redundancy in some

secondary things for the external thing or some diagnostic or something, but the key -- if you take the lime green off, the patient will still live.

If you take the internal control out, then the patient will die. So that's the difference.

I think that, again, you see here that the controller is attached to the belt.

(Stenographer clarification.)

A. Belt. Is attached to the belt, and so is the -- one of the coils of the transmission system.

And the reason why it's done that way is so that the patient can take it off, for example, during showers, right? So the lime green controller can be removed and the patient would do fine whereas the internal controller cannot be removed. If it's removed, then the patient dies.

So, you know, by that definition, a controller that cannot be removed or

disconnected is the main controller.
BY MS. RAGHAVAN:
Q. So if there's an external controller that talks to the main controller that you're saying is the internal controller that then controls the internal operation of the pump, does that satisfy Limitation 1N of the claim?
A. I did not consider that question. The question is very clear here, and the language is clear.
You have to have a controller that operates the device which is external, and in this case, in my opinion, it is internal.
Q. Well, so the claim doesn't exclude the possibility of there being an additional internal control unit, correct?
MR. CAHILL: Object to form.
A. I'm not sure about that.
BY MS. RAGHAVAN:
Q. Does the claim require directly regulating operation of the second magnetic device by the external control unit?
A. We have to discuss what the word "directly" means.

Q. That's not something that you considered?

A. I read the claim. The claim says that external control unit is connecting -- connecting an external control unit to the heart assist pump device for regulating operation of the second magnetic device. So that's what I read, and that's what I interpreted.

Q. So you don't have an opinion one way or the other as to whether an external control unit that talks to an internal control unit within the heart assist pump device to then regulate the operation of the second magnetic device would satisfy limitation 1N of the '356 patent?

A. That is correct. I did not consider that as part of this.

Q. Let's turn to Paragraph 37 of your declaration.

In this paragraph, you appear to be talking about the term "magnetic coupling"; is that correct?

A. Yes.

Q. And also "magneto coupling"?
A. I don't see "magneto coupling" here.
Q. Are those different, in your view?
A. No. You asked me whether I talk about both of them, and I don't see the second one. And they are not different.
Q. But the claims say "magneto coupling," right?
A. I believe that's correct.
Q. Is it your opinion that a POSA would interpret "magneto coupling" to be the same thing as "magnetic coupling"?
A. Yes.
Q. You say at the end of Paragraph 37 that "As an example, the relied-upon Schima reference shows both rotating magnets and a stator that generates a rotating magnetic field, thereby showing different manners of achieving a magnetic coupling to drive a rotor."
Do you see that?
A. Yes, I do.
Q. And it's your opinion that the term "magnetic coupling" in the context of the '356

patent should not be limited to just rotating magnets, correct?

A. Correct.

Q. So in support of that opinion, you point to a disclosure in Schima that discloses both rotating magnets and a stator that generates a rotating magnetic field, correct?

A. Among other things, yes.

Q. So taking those statements together, you're not disputing that Schima discloses magneto coupling, correct?

A. I am not disputing that, no.

Q. But you also agree that Schima doesn't use the term "magneto coupling"?

A. I have to review Schima again for that reference, but I believe that's the -- that Schima broadly describes and discloses magnetic coupling.

Q. By providing examples?

A. Yes.

Q. Do you recall if the Schima reference used the term "magnetic coupling"

A. I don't remember what specific terms

they used, but there are some magnets there for sure.

Q. Let's turn to Paragraph 75 of your declaration. So here you're discussing the claim term "by the blood flowing."

Do you see that?

A. Yes.

Q. So, again, it's your opinion that Mr. Crosby's definition of the term "by the blood flowing" was too narrow; is that correct?

A. Correct.

Q. And so your opinion is that the term "by the blood flowing" in the context of the '356 patent should not be limited to just hydrodynamic bearings, correct?

A. That is correct.

Q. Similar to what we just talked about for a magnetic coupling, you say towards the end of paragraph that "Schima shows that it contemplates the use of either or both hydrodynamic and magnetic positioning of its rotor."

Do you see that?

A. Yes.
Q. So taking those opinions together, you're not disputing that Schima discloses the "by the blood flowing" limitation, correct?
A. I don't. Yes, I think that's correct.
Q. Let's turn to Paragraph 99 of your report.
A. Let me correct that. So what I -- what I think would be accurate to say about Schima is that they disclose a third-generation pump in the way that the -- that the rotor is spaced apart from the housing. That's what Schima discloses. By "blood flowing," I have to think about whether that particular limitation in the context of claim is disclosed or not. So I just want to be accurate about this.
Which paragraph are you talking about?
Q. Just staying with that for just a second, so you say that the term "by the blood flowing" should not be limited to hydrodynamic bearings, correct?
A. Yes.
Q. Would you agree that Schima's

disclosure of hydrodynamic bearings or magnetic positioning of its rotor are examples of "by the blood flowing"?

A. "By the blood flowing" is describing a spacing between the rotating member and the stationary member, and that spacing is filled by blood. So "by blood flowing" means that it's just filled by blood. That's how I understand it.

So Schima does disclose a design, which is a third-generation device, where the rotor is suspended within the housing, and therefore the space between the rotor and the housing is filled by blood.

Q. Got it.

We can turn back to Paragraph 99. So here you say that "Schima does not teach or suggest any practical implementation of its disclosed pump and instead discloses only details regarding the pump itself."

That's correct, right?

A. Just a minute. Let me understand the context here.

(Witness reviews document.)

Okay. Yes.

Q. So is it your opinion that the Schima device could not have been used as a heart assist device?

A. Schima discloses various uses, including that of pumping blood or, I believe, other sensitive liquids, something like that. So in that sense, it may be used as an LVAD, or it may be used for something else.

Q. So nothing in Schima precludes it from being used as a heart assist device?

A. Correct. Well, heart assist device, let's define "heart assist device." Is it my definition?

Q. Sure.

A. Yes.

Q. It's your definition.

A. Yes. Of course, yes.

Q. Were there other definitions of "heart assist device" that you considered?

A. Well, I mean, we talked about the Crosby definition versus my definition. So in my definition, it certainly can be used as a heart assist device. I'm not sure exactly

about the definition again of Crosby. I have to review the text. But in my -- in my opinion, it certainly can be.

Q. And does your definition also include extracorporeal pumps?

A. Yes.

Q. Can you take out Exhibit 1001 again, the '356 patent.

A. Okay.

Q. And let's turn to Figure 2.

A. Okay.

Q. So you told me a few minutes ago that the "by the blood flowing" limitation means that there's a gap between the rotor and its housing, correct?

A. Yes.

Q. And that it's not necessarily tied to any sort of bearing; is that correct?

A. Well, "any sort of bearing" is a broad term. So hydrodynamic bearings and magnetic bearings are certainly bearings. I would say it's not tied to -- when you have entirely -- when you have a rotor that is suspended within the housing, it means that there's nothing

mechanical or physical that touches it. Doesn't mean it doesn't have bearings.

Q. So "by the blood flowing" -- the "by the blood flowing" limitation can be met if the pump has a hydrodynamic bearing; is that correct?

A. Well, conceivably, yes.

Q. And it can also be met if the pump has a magnetic bearing, correct?

A. Correct.

Q. But it -- in your opinion, it cannot be met if there's a mechanical bearing?

A. Like, thrust bearings in the first embodiment of Wampler, that would be a limitation that would not satisfy that.

Q. So looking at Figure 2 of the '356 patent, can you explain how the rotor that's shown here is suspended such that there's a gap between the rotor and the housing?

A. Well, the housing has an outline here, and then the rotor has the first magnetic device that's attached to the rotor, and it's entirely not touched by anything else.

Q. But how is that maintained?

A. How is what maintained?
Q. How is the rotor maintained in that position?
MR. CAHILL: Objection. Outside the scope.
A. The patent says what it says, that the rotation of the rotor and the magnetic coupling is what maintains the rotor in that position.
BY MS. RAGHAVAN:
Q. So other than what's shown in Figure 2, there's no discussion of a hydrodynamic bearing that maintains a space between the rotor and its housing, correct?
MR. CAHILL: Objection to form.
A. I have to review what it actually says, but it's not really -- I mean, that picture is an exemplary picture. It doesn't impact me too much.
BY MS. RAGHAVAN:
Q. There's no other examples, as we discussed earlier, correct, in the '356 patent?
A. That's correct.

Q. Figure 2 shows two permanent magnets attracted to each other, correct?

A. I wouldn't limit it to that description. But it certainly shows the first and the second magnetic components.

Q. How does the -- the magnetic interaction between the two permanent magnets that are shown in this image prevent the rotor from contacting its housing?

MR. CAHILL: Objection. Outside the scope.

A. I didn't analyze that question.

MS. RAGHAVAN: Let's take a quick break. I'm going to see if I have any other questions, and we can come back and wrap up.

(Recess taken from 2:25 p.m. to 2:32 p.m.)

BY MS. RAGHAVAN:

Q. Could you pull out the patent again, so Exhibit 1001, just for a few quick questions.

Then turn back to Figure 2, please.

A. Okay.

Q. Looking at this diagram as -- from an engineering perspective, would you expect that the first magnetic device, Element 19, and the second magnetic device, Element 16, would exhibit an attractive or repulsive force towards each other?

MR. CAHILL: Objection. Outside the scope.

A. I did not consider it, but it doesn't have to be a binary choice.

BY MS. RAGHAVAN:

Q. What are the other options?

A. Well, they may have some magnets in some locations and some -- I mean, I wouldn't just -- starting the analysis, I wouldn't necessarily limit myself to these two choices, but I did not do the analysis on this question.

Q. What about the magnetic interaction between Element 16 and 19 in Figure 2 prevents the rotor from impinging on the bottom surface of the chamber, 14?

MR. CAHILL: Objection. Outside the scope.

A. Same answer.

BY MS. RAGHAVAN:

Q. Let's say it's a repulsive force, then. What prevents the conical section of the rotor from impinging on the housing in the upward direction?

MR. CAHILL: Objection.

A. Same --

MR. CAHILL: Outside the scope and complete hypothetical.

A. Same answer.

BY MS. RAGHAVAN:

Q. Is it your opinion that there has to be a bearing somewhere in Figure 2 for this device to be operational?

MR. CAHILL: Same objection.

A. I did not analyze that question as part of my report.

BY MS. RAGHAVAN:

Q. You analyzed the prior art references and considered whether they would be practically implantable, correct?

MR. CAHILL: Object to form.

A. It's a broad characterization. I say what I say in the report with regard to specific embodiments for pumps or configurations implying in a particular way. That's what I do.

BY MS. RAGHAVAN:

Q. You considered the practicality of whether the pumps can be used as shown in the schematics of the various prior art devices, correct?

MR. CAHILL: Object to form.

A. I considered different ways of implanting based on the available data that I looked at.

BY MS. RAGHAVAN:

Q. I mean, you reached the conclusion in some cases that some of the concepts that were disclosed in those prior art references were practically impossible, correct?

MR. CAHILL: Object to form.

A. Yes.

BY MS. RAGHAVAN:

Q. Did you do a similar analysis for the

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'356 patent or any of the related patents?

A. No, I did not.

Q. You didn't find that necessary to understand the claims?

A. I did not do that analysis, and I analyzed the claims, as they say.

Q. Is it your opinion that the example embodiment that's shown in Figure 2 meets the "by the blood flowing" limitation of Claim 1 of the '356 patent?

A. I didn't analyze that question either. I looked at the limitation with regard to the cited art.

Q. From an engineering perspective, looking at the schematic, what keeps the rotor stable in an axial direction?

MR. CAHILL: Objection. Outside the scope.

A. I did not analyze that question.

MS. RAGHAVAN: I don't have any further questions. Thank you for your time.

MR. CAHILL: No questions. Nothing for me.

(Off the record from 2:36 p.m. to 2:41 p.m.)

MS. RAGHAVAN: I am just going to mark the annotation that you made of the Akamatsu Figure 1 as part of Paragraph 176 of your declaration as a new exhibit. It's now marked Exhibit 1037.

(Exhibit No. 1037 marked for identification.)

BY MS. RAGHAVAN:

Q. If you want to, verify that this was, in fact, the annotation that you made to mark the left ventricle.

A. Yes.

MS. RAGHAVAN: Great. All right. That's all I have.

Thank you.

THE STENOGRAPHER: So just to confirm, both counsel would like a rough draft and expedited final for Monday?

MR. CAHILL: Yes.

MS. RAGHAVAN: Yes. Thank you.

(Deposition concluded at 2:42 p.m.)

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CERTIFICATION

I, DARLENE M. COPPOLA, a Notary Public, do hereby certify that BORIS LESCHINSKY, after having satisfactorily identifying himself, came before me on the 10th day of December, 2025, in Boston, Massachusetts, and was by me duly sworn to testify to the truth and nothing but the truth as to his knowledge touching and concerning the matters in controversy in this cause; that he was thereupon examined upon his oath and said examination reduced to writing by me; and that the statement is a true record of the testimony given by the witness, to the best of my knowledge and ability.

I further certify that I am not a relative or employee of counsel/attorney for any of the parties, nor a relative or employee of such parties, nor am I financially interested in the outcome of the action.

WITNESS MY HAND THIS 14th day of December, 2025.

Darlene M. Coppola

DARLENE M. COPPOLA
NOTARY PUBLIC
REGISTERED MERIT REPORTER
CERTIFIED REALTIME REPORTER

My commission expires:
November 2, 2029

PATENT AND TRIAL APPEAL BOARD

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ABBOTT LABORATORIES,

Petitioner

vs. NO. IPR202500096 (PTAB)

MIRACOR MEDICAL SA,

Patent Owner

****

I, BORIS LESCHINSKY, say that I have read the foregoing deposition and hereby declare under penalty of perjury the foregoing is true and correct: (as prepared) (as corrected on errata.)

Executed this _____ day of _____, 2025, at _____, _____.

_____

BORIS LESCHINSKY

CORRECTION PAGE

DEPONENT: BORIS LESCHINSKY

DATE TAKEN: DECEMBER 10, 2025

CASE: ABBOTT LABORATORIES

VS. MIRACOR MEDICAL SA

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