1 PATENT AND TRIAL APPEAL BOARD
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4 **********
5 ABBOTT LABORATORIES,
6 Petitioner
7 vs. NO. IPR202500096 (PTAB)
8 MIRACOR MEDICAL SA,
9 Patent Owner
10 **********
11
12
13 DEPOSITION OF: BORIS LESCHINSKY
14 BARNES & THORNBURG LLP
15 One Marina Park
16 Boston, Massachusetts
17 December 10, 2025 9:09 a.m.
18
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20
21
22 Darlene M. Coppola
23 Registered Merit Reporter
24 Certified Realtime Reporter

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1 P R O C E E D I N G
2
3 (Commencing at 9:09 a.m.)
4
5 BORIS LESCHINSKY,
6 a witness called for examination by
7 counsel for the Petitioner, having been
8 satisfactorily identified by the production of
9 his driver's license and being first duly
10 sworn by the Notary Public, was examined and
11 testified as follows:
12
13 THE STENOGRAPHER: Thank you.
14 You may proceed.
15
16 DIRECT EXAMINATION
17 BY MS. RAGHAVAN:
18 Q. Good morning, Mr. Leschinsky.
19 A. Good morning.
20 Q. My name is Saranya Raghavan. I am
21 counsel for petitioner in the IPRs that I
22 believe you submitted a declaration for.
23 Nice to meet you.
24 A. Nice to meet you too.

1 Q. Could you please state your name for
2 the record.
3 A. Yes. My name is Boris Leschinsky.
4 Q. A few moments ago, you just took an
5 oath to tell the truth today, correct?
6 A. Yes.
7 Q. Is there any reason why you would not
8 be able to offer truthful, complete, and
9 accurate testimony today?
10 A. No.
11 Q. Have you been deposed before?
12 A. Yes.
13 Q. How many times?
14 A. Four, six.
15 Q. Four or six?
16 A. Four to six.
17 Q. You don't recall?
18 A. Not really.
19 Q. When were those four to six
20 depositions?
21 A. In the last five years.
22 Q. Were they in IPR proceedings?
23 A. No.
24 Q. Were they in district court

1 proceedings?
2 A. I believe so, yeah.
3 Q. Were they in patent litigations?
4 A. Some were.
5 Q. What were the other ones?
6 A. Product liability.
7 Q. So I understand that you've been
8 deposed a few times before, but just so that
9 we're on the same page, I just want to go
10 through some general rules for the deposition
11 today.
12 Just to make our lives easier and life
13 easier for our court reporter, who is taking
14 down everything that all of us say today in
15 the room, it's very important that you answer
16 my questions with words as opposed to gestures
17 or head nods and so on; is that fair?
18 A. Understood.
19 Q. It's also important that we don't
20 interrupt each other so we have a clean
21 record. So I will wait until you finish your
22 answers to ask my next question, and I would
23 appreciate it if you let me finish my
24 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

1 Miracor, the patent owner, as a technical
2 expert in these proceedings; is that
3 correct?
4 A. It is.
5 Q. And you submitted a declaration in six
6 IPRs that were filed by the petitioner,
7 Abbott, against six Miracor patents; is that
8 your understanding?
9 A. That is correct.
10 Q. And you understand that the six
11 Miracor patents at issue in those six IPRs are
12 related patents, correct?
13 A. Yes.
14 Q. They're all from the same patent
15 family?
16 A. I believe so.
17 Q. Just for efficiency sake today, I will
18 be referring to your declaration in
19 IPR 2025-00096, which relates to the '356
20 patent, and asking you questions based on that
21 declaration as a representative declaration;
22 is that fair?
23 A. That's fine.
24 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.

1 THE WITNESS: I'm sorry. Yes.
2 MR. CAHILL: I'll object to the
3 form for that last question.
4 BY MS. RAGHAVAN:
5 Q. What, if anything, did you do to
6 prepare for today's deposition?
7 A. I reviewed my reports.
8 Q. You reviewed all six declarations?
9 A. Yes, I did.
10 Q. What else did you do to prepare?
11 A. I reviewed citations, materials that
12 were discussed in these -- in these reports.
13 Q. Anything else?
14 A. No.
15 Q. Did you meet with your counsel?
16 A. I did.
17 Q. Who was the counsel you met with?
18 A. These two gentlemen here.
19 Q. Anybody else?
20 A. Todd was on the phone at some point,
21 so -- but it was a remote connection.
22 Q. By "Todd," you mean Todd Vare?
23 A. Yes.
24 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.

1 Let me know when you're there.
2 A. Yes.
3 Q. You say here that you're being
4 compensated at your usual consulting rate.
5 Do you see that?
6 A. Yes.
7 Q. What is your usual consulting rate?
8 THE WITNESS: Should I disclose?
9 MR. CAHILL: Yes.
10 A. $400 an hour.
11 BY MS. RAGHAVAN:
12 Q. Okay. Let's turn to Paragraph 33 of
13 your declaration.
14 It's your opinion that Mr. Crosby's
15 definition of an LVAD is too narrow; is that
16 correct?
17 A. Yes.
18 Q. What does LVAD stand for?
19 A. The definition is left ventricular
20 assist device.
21 Q. In your opinion, the definition of
22 LVAD should include intra-aortic balloons?
23 A. Yes.
24 Q. In your opinion, the definition of

1 LVAD should include direct cardiac compression
2 devices?
3 A. Yes, it is.
4 Q. In your opinion, the definition of
5 LVAD should include aortic counterpulsation
6 devices?
7 A. Yes.
8 Q. In your opinion, the definition of
9 LVAD should also include an inflow cannula
10 placed in the left atrium rather than the left
11 ventricle; is that correct?
12 A. Yes.
13 Q. You told me earlier that LVAD stands
14 for left ventricular assist device, correct?
15 A. Yes.
16 Q. That expansion of LVAD doesn't include
17 the word "atrium" or variations of the word
18 "atrium," correct?
19 A. Just a second. Can you clarify? What
20 do you mean by "expansion"?
21 Q. Any variations -- or sorry.
22 By "expansion," I meant the expansion
23 of the acronym "LVAD," left ventricular assist
24 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.

1 Q. In Paragraphs 4 through 9 of your
2 declaration, you cover your education and
3 experience through 2009; is that accurate?
4 A. Which paragraphs?
5 Q. Paragraphs 4 through 9?
6 A. 4 through 9. Well, no, it's actually
7 not just limited to that period of time.
8 Paragraph 7 talks about my experience in 2009
9 to '13 and so on. So I think it covers --
10 these paragraphs together cover more than that
11 period of time.
12 Q. Any experience that you had prior to
13 the priority date of the patent, which is
14 2007, would have been summarized in
15 Paragraphs 4 through 9, correct?
16 MR. CAHILL: Object to form.
17 THE WITNESS: These paragraphs
18 do not separate my experience prior to and
19 after the filing date of the patent. They
20 summarize my experience overall.
21 BY MS. RAGHAVAN:
22 Q. But if I were to try to understand
23 what your experience was prior to the priority
24 date of the patent in 2007, I would look to

1 Paragraphs 4 through 9, correct?
2 A. Well, no. Some of them talk about in
3 the later period, so I don't know which
4 period -- but I would say probably 4 through 6
5 is more accurate because they go through 2009.
6 Q. Fair enough.
7 Let's look specifically at
8 Paragraph 5.
9 A. Yes.
10 Q. In this paragraph, you are talking
11 about your master's degree in mechanical
12 engineering from Moscow State Technical
13 University, which you received in 1987; is
14 that correct?
15 A. Yes.
16 Q. And the remainder of this paragraph is
17 discussing work that you did while earning
18 your master's degree?
19 A. No. It was afterwards.
20 Q. So the remainder of this paragraph is
21 talking about your experience out of college
22 after you earned your master's degree?
23 A. Correct.
24 Q. And roughly what time frame were you

1 performing those activities?
2 A. So I finished my education in 1997.
3 Then I was recruited by the Scientific
4 Institute, where I worked through 1990. And
5 then I left Moscow, and I came here, and I
6 started working at Datascope in 1990. And so
7 from that point on, I worked at Datascope on
8 various projects.
9 Q. So in the third sentence of
10 Paragraph 3, you say, "While at the Scientific
11 Institute, I developed new concepts for
12 centrifugal blood pumps."
13 Do you see that?
14 A. Well, it's Paragraph 5, yes.
15 Q. Sorry. Yes, Paragraph 5.
16 A. Yes.
17 Q. What new concepts did you develop for
18 centrifugal blood pumps?
19 A. I had applied for, I believe, five
20 Russian patents describing various innovations
21 that I came up with, and that was the result
22 of my actually couple of last years in college
23 and work at the Scientific Institute. So I
24 was closely interested in centrifugal blood

1 pumps at the time, and I was devising
2 different concepts how to make them better.
3 Q. What concepts specifically did you
4 devise?
5 A. Well, one of them had an idea of soft
6 blades versus the rigid blades that usually --
7 that these devices usually have.
8 Another concept had an idea of seeping
9 blood-compatible fluid through the surfaces of
10 the device such that there is no direct
11 contact between blood and the plastic of these
12 devices.
13 There's different concepts.
14 Q. And to the extent that you came up
15 with any new concepts, they were summarized in
16 the Russian patents --
17 A. That is correct.
18 Q. -- that you mentioned?
19 And you did this work between 1987 and
20 1990, correct?
21 A. '85. I was doing this when I was in
22 college, yeah, in 1990.
23 Your work on centrifugal blood
24 pumps was for extracorporeal devices; is that

1 right?
2 A. I didn't really separate them at the
3 time into --
4
5 (Stenographer clarification.)
6
7 A. I did not separate into extracorporeal
8 and implantable devices as far as I recall, so
9 they might have been applied to either one.
10 The tests that we did were primarily with
11 bench tests, so we didn't really proceed too
12 far to human implantation.
13 BY MS. RAGHAVAN:
14 Q. So is it fair to say that sometimes
15 centrifugal blood pumps could be used for
16 extracorporeal applications and as implantable
17 devices?
18 A. That's a broad statement. I would say
19 conceptually, whenever the new idea is
20 developed, it's developed for, like, a broad
21 idea of the centrifugal blood pump, and then
22 it finds its way into a specific application
23 at some later time.
24 Q. So at least for the devices that you

1 were developing, you believe they were
2 applicable for both extracorporeal
3 applications and as implantable pumps,
4 correct?
5 A. I don't remember. It's been a long
6 time.
7 What I do remember is that we didn't
8 really separate initially where it will go.
9 It was just looking at the ideas whether they
10 were practical or not.
11 Q. Do you think that's a common
12 philosophy in the industry?
13 A. I can't say. I can't tell. That's
14 what we did at the time. What other people
15 do, I don't know.
16 Q. The blood pumps you were testing, you
17 tested them on artificial heart pumps,
18 correct -- or artificial hearts, correct?
19 A. I didn't quite understand the
20 question.
21 Q. I'll rephrase.
22 The blood pumps that you were
23 designing were tested on artificial hearts,
24 correct?

1 A. Again, I don't understand the
2 question.
3 The heart pumps that we were
4 developing were used as a substitute for a
5 natural heart, so in that sense, they were,
6 broadly speaking, artificial hearts. So --
7 but we were not testing one pump on another
8 pump, if that's what you mean. That's why I
9 don't understand what you're asking me about.
10 Q. Did you ever implant any of the
11 centrifugal blood pumps that you designed?
12 A. No.
13 Q. Other than the patents that you filed,
14 were people in the field aware of the concepts
15 that you developed for centrifugal blood
16 pumps?
17 A. We published a paper or two.
18 Q. Why were you interested in developing
19 centrifugal blood pumps at that time?
20 A. Well, the laboratory that I worked at
21 already had a significant project on the total
22 artificial heart which was a device similar to
23 the Jarvik device, and so I was looking at
24 alternative ways to assist the heart, and

1 centrifugal blood pumps would constitute one
2 of these alternatives, so I was interested in
3 that.
4 Q. Do you know if others were interested
5 in centrifugal blood pump designs at the time
6 as well?
7 A. Like worldwide? Or -- I don't quite
8 understand the question.
9 Q. Yes --
10 A. My laboratory or like broader? Can
11 you specify what you're looking for?
12 Q. Sure. Let's start with in your
13 laboratory.
14 Were others interested in the designs
15 that you were coming up with for centrifugal
16 blood pumps?
17 A. My boss was interested in this, yes.
18 He supported the project.
19 Q. Did you know of others worldwide
20 outside your laboratory who were also working
21 on designs for centrifugal blood pumps at the
22 time?
23 A. Oh, yeah, many laboratories in
24 different places around the world were

1 developing these devices.
2 Q. Why do you think they were interested
3 in developing centrifugal blood pumps at that
4 time?
5 A. Well, it was a -- and it still is a
6 promising technology that can provide
7 significant clinical benefits.
8 Q. Can you turn to Paragraph 6 of your
9 declaration?
10 A. Yes.
11 Q. In this paragraph, you reference the
12 percutaneous heart assist PHP project,
13 right?
14 A. Yes.
15 Q. This is an intravascular heart pump;
16 is that right?
17 A. Yes.
18 Q. It's inserted percutaneously, as the
19 name suggests, correct?
20 A. Yes.
21 Q. Under your definition of LVAD, this is
22 an alternative LVAD configuration, correct?
23 A. That's one of the LVADs that
24 would fall into this -- into that broad

1 category, my definition. I wouldn't call it
2 alternative. It's one of.
3 Q. Would the PHP device be considered an
4 LVAD under Mr. Crosby's definition of an LVAD?
5 A. I don't know.
6 Q. But it is an LVAD under your broad
7 definition that you're proposing?
8 A. Yes.
9 Q. The PHP is a balloon pump; is that
10 correct?
11 A. No.
12 Q. What kind of pump is it?
13 A. It's a catheter pump. It is designed
14 to be inserted in a small compressed diameter
15 state, and when it's inside, it expands to
16 increase its size, and then it operates by
17 rotation of the impeller, and then when it's
18 done, it goes back to a small size to be
19 removed.
20 Q. So you wouldn't describe that
21 expansion process as a balloon?
22 A. No.
23 Q. How does that device impact the
24 pumping function of the heart?

1 A. Well, it provides what's called
2 unloading, which is it assumes a portion of
3 the blood flow that the left heart usually
4 expels into the aorta. So for hearts that
5 have impaired left ventricle function, it
6 would assist in that process, which is why I
7 believe it's -- it can be called a left
8 ventricular assist device.
9 Q. Let's look at Paragraph 7 of your
10 declaration.
11 This paragraph talks about work you
12 did from 2009 to 2013, correct?
13 A. Yes.
14 Q. And this is after the priority date of
15 the patents that we're discussing?
16 A. Apparently.
17 Q. From 2009 to 2013, you were just --
18 you were part of a team developing devices for
19 treating brain aneurysms; is that correct?
20 A. That is correct.
21 Q. You were not working on any cardiac
22 assist devices at that time?
23 A. That is correct.
24 Q. Let's look at Paragraph 8 next.

1 So in 2009, you also cofounded
2 LifeCuff Technologies; is that right?
3 A. Yes.
4 Q. When did you start at CorInnova?
5 A. Well, it says 2013. That is when I
6 actually formally joined CorInnova, but I
7 worked as a consultant before then.
8 Q. What years did you work as a
9 consultant for CorInnova?
10 A. Probably in the previous couple of
11 years, so 2011 to '13. I'm generalizing here.
12 Q. So as you say in Paragraph 9, "The
13 CorInnova device is a minimally invasive
14 nonblood-contacting direct cardiac compression
15 cardiac assist device"; is that correct?
16 A. That is correct.
17 Q. Can we shorten that to say that it's a
18 direct cardiac compression device?
19 A. Yes.
20 Q. It's not a blood pump, correct?
21 A. It is not a blood pump.
22 Q. Would the CorInnova device be
23 considered an LVAD under Mr. Crosby's
24 definition of an LVAD?

1 A. I'm not sure how to answer that
2 question.
3 Q. But you thought that Mr. Crosby's
4 definition was too narrow, correct?
5 A. Yes.
6 Q. But you haven't considered whether the
7 CorInnova device would have been considered an
8 LVAD under his definition?
9 A. I say what I say, which is the concept
10 of left ventricular assist device. I see it
11 as a functional definition, not a narrow
12 definition that's related -- that only
13 describes blood pumps.
14 For example, CorInnova device also
15 assists the heart, and in that sense, it
16 assists left ventricle, and for that reason, I
17 believe that it can be considered a left
18 ventricular assist device.
19 Q. I understand your definition of an
20 LVAD, but I'm asking you a different question,
21 which is whether the CorInnova device would be
22 considered an LVAD under Mr. Crosby's
23 definition of an LVAD.
24 A. You can ask Mr. Crosby.

1 Q. Do you recall, sitting here today,
2 that Mr. Crosby had a different definition of
3 an LVAD?
4 A. Well, I say in my report that it was a
5 narrow definition, and I expanded this to
6 include compensation devices and the direct
7 cardiac compression devices, so I don't
8 remember exactly the detail of his definition,
9 which is why I'm now hesitant to answer that
10 question.
11 But since I included these examples,
12 which he did not, I assume that under his more
13 narrow definition, it would not -- it would
14 not include these devices.
15 Q. So you needed to propose a broader
16 definition of LVAD in order to include these
17 other devices that you worked on, correct?
18 MR. CAHILL: Object. Object to
19 form.
20 A. The report says what it says.
21 BY MS. RAGHAVAN:
22 Q. You started working on this CorInnova
23 device in 2013, correct?
24 A. I formally joined the company in 2013,

1 correct.
2 Q. When did you first start working on
3 the CorInnova device?
4 A. As I mentioned before, I believe I
5 consulted for the company for a couple of
6 years before that here and there, but it was
7 not a full-time engagement.
8 Q. At the time you were consulting, were
9 you working on designs for the device?
10 A. I suppose so. I don't remember
11 exactly what I did.
12 Q. You would agree, though, that your
13 work on the CorInnova device was after the
14 priority date of the challenged patents?
15 MR. CAHILL: Object to form.
16 A. Yes, I would agree with that.
17 BY MS. RAGHAVAN:
18 Q. Let's look at the last sentence of
19 Paragraph 9 of your declaration. You state
20 here that "The device is positioned in the
21 pericardial space immediately surrounding the
22 heart and through this work I have developed
23 expertise related to delivering cardiac assist
24 devices to this space that is relevant to this

1 proceeding."
2 Do you see that?
3 A. Yes.
4 Q. By "this space," you're referring to
5 the pericardial space; is that right?
6 A. Yes, and also the area around the apex
7 of the heart, which is important in this case.
8 Q. But prior to 2013, you did not have
9 any experience relating to implanting devices
10 in the pericardial space or at the apex of the
11 heart?
12 MR. CAHILL: Object to form.
13 A. I wouldn't characterize it that way.
14 I mean, I was aware of these -- of these
15 devices and how they're implanted. I did not
16 have personal experience putting them in.
17 I never had personal experience
18 putting them in, but I understand how it
19 works, and so this work in particular was
20 instrumental in better understanding of what
21 the pericardial tissue is and how it's used
22 and how the procedure is performed usually,
23 what the mechanical properties of the
24 pericardium are, so I knew them in general,

1 but this work obviously gave me a better
2 understanding.
3 BY MS. RAGHAVAN:
4 Q. In 2013, that was the first time you
5 have direct experience with devices that were
6 implanted or designed to be implanted in the
7 pericardial space, correct?
8 A. No, that's not correct because my work
9 in the Russian institute and since then work
10 at DataScope. I was aware of these procedures
11 before then.
12 Q. So you're aware of other devices that
13 could have been implanted in the pericardial
14 space earlier than 2013?
15 A. Oh, yes.
16 Q. Were they blood pumps?
17 A. Some were. Some weren't.
18 An early example of a direct cardio
19 compression device is an Anstadt cup, Anstadt,
20 A-n-s-d-a-d [sic] -- d-t at the end, Anstadt
21 cup, which was in development since the '60s.
22 So it was well understood that it can
23 be done.
24 Q. You said Anstadt?

1 A. Anstadt. Let me just write it down so
2 I can spell it properly.
3 A-n-s-t-a-d-t, A-n-s-t-a-d-t.
4 Q. And you said this is a direct
5 compression device?
6 A. Correct, direct -- early direct cardio
7 compression device.
8 Q. Do you know how big this device was?
9 A. All of them are the same size, the
10 size of the heart. They surround the heart.
11 So I'm not sure. Big in terms of, like,
12 diameter or height or -- it's a cup, you know.
13 They come in different sizes, depending on the
14 size of the patient's heart.
15 Q. So whether a device is appropriate to
16 be placed in the pericardial space depends on
17 the patient and the size of the patient's
18 heart, correct?
19 A. I wouldn't say it that way. The
20 ability to place in the pericardial space
21 depends on the thickness of the device
22 primarily. Again, there's a difference
23 between LVADs that are implanted at the apex
24 versus direct cardiac compression devices that

1 go all the way around the heart. So we're
2 talking about different areas of the heart,
3 and so different requirements apply.
4 Q. But those requirements are determined
5 on a patient-by-patient basis. Would you
6 agree with that?
7 A. Well, there are generally -- I mean,
8 it depends on the ability of the device to
9 adapt to the size of the heart. Some adapt
10 better than others. But broadly speaking, the
11 size of the heart and the size of the patient
12 are certainly an important consideration.
13 Q. Prior to 2007, you never worked on an
14 LVAD that uses a centrifugal pump, correct?
15 A. Well, no, we just discussed the work
16 that I did at the -- in Moscow. That was --
17 that was that work.
18 Q. Was that an LVAD?
19 A. Yes, it could have been.
20 Q. Is that an LVAD under your definition
21 or under Mr. Crosby's definition?
22 A. Oh, I think it probably applies to
23 both, but it can also be used on the right
24 side. It would be RVAD. It can be used in

1 children. It can be used on both sides of the
2 heart. So there's flexibility there.
3 Q. And you said the device could have
4 been an extracorporeal device, or it could
5 have been an implantable device?
6 A. That is correct.
7 Q. Prior to 2007, did you work on an LVAD
8 that used magneto coupling?
9 A. We certainly used devices that used
10 magneto coupling in animal tests. It was an
11 extracorporeal device produced by Medicus
12 [sic]. BP-50 was the pump that we used
13 extensively as an extracorporeal device for
14 tests and actually in human clinical trials as
15 well.
16 Q. Was that an LAD?
17 A. I would say so, yes.
18 Q. Could you have implanted the
19 centrifugal blood pump that you developed when
20 you were in Moscow at the apex of the heart?
21 A. We didn't get that far. That -- the
22 answer to that question is it depends on the
23 size of the heart -- the size of the pump,
24 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

1 enough, then certainly.
2 Q. Does it also depend on the size of the
3 patient?
4 A. Yes, it does. Obviously for smaller
5 patients, for small women or children, it --
6 the space available is less. So that's true
7 now of any heart assist device. In fact, most
8 of them are applied in men rather than women
9 even today.
10 The heart rate failure -- the rate of
11 heart failure is about even between men and
12 women. However, men get three to one these
13 devices than women because -- in part, because
14 of the size consideration.
15 Q. So if we're talking about a larger
16 male patient, you can implant a larger pump,
17 correct?
18 A. Yes.
19 Q. Mr. Leschinsky, I'm going to hand you
20 a copy of the U.S. Patent 11,351,356. And
21 this was previously marked as Exhibit 1001.
22 A. Okay.
23 Q. You've reviewed this patent, correct?
24 A. Yes.

1 Q. This is the patent on -- this is one
2 of the patents on which you submitted a
3 declaration?
4 A. Correct.
5 Q. Let's look at Figures 1 and 2 of this
6 patent.
7 A. Yeah.
8 Q. This is a catheter-based
9 configuration, correct?
10 MR. CAHILL: Object to form.
11 A. This embodiment here that's
12 illustrated is a catheter pump, yes.
13 BY MS. RAGHAVAN:
14 Q. Is this an intra-aortic balloon
15 device?
16 A. I wouldn't call it an intra-aortic
17 balloon device in the classic counterpulsation
18 sense of the word, but it does have a balloon
19 that is inflated inside the aorta.
20 Q. Have you considered whether the device
21 shown in Figures 1 and 2 of the '356 patent
22 can be considered an LVAD under Mr. Crosby's
23 definition of an LVAD?
24 A. I don't know how to answer that

1 question. Again, I reviewed Mr. Crosby's
2 declaration at some point. I don't remember
3 exactly the wording of how he defines the
4 LVAD. All I say -- and I stand by this
5 statement that in my definition, other
6 devices, including this device, can be
7 considered an LVAD.
8 Q. So under your proposed definition for
9 an LVAD, the embodiment shown in Figures 1
10 and 2 of the '356 patent would be an LVAD,
11 correct?
12 A. Yes.
13 MS. RAGHAVAN: We're ready for
14 our first new exhibit of the day.
15
16 (Exhibit No. 1033 marked for
17 identification.)
18
19 BY MS. RAGHAVAN:
20 Q. This is an article you coauthored; is
21 that correct?
22 A. Yes, that is correct.
23 Q. You're discussing the CorInnova device
24 that you were talking about earlier, in this

1 article?
2 A. That is correct.
3 Q. I'm going to specifically refer you to
4 the last sentence on the first page. Let me
5 know when you've had a chance to read it.
6 A. (Witness reviews document.)
7 Yes.
8 Q. You see here that it mentions
9 mechanical cardiac assist devices; is that
10 right?
11 A. Uh-huh.
12 Q. Then it talks about intra-aortic
13 balloon pumps.
14 Do you see that?
15 A. Yes.
16 Q. And percutaneous catheter-based heart
17 pumps, correct?
18 A. Yes.
19 Q. Left ventricle assist devices.
20 Do you see that?
21 A. Yes.
22 Q. And so presumably, those are three
23 different categories or examples of devices
24 that would be considered mechanical cardiac

1 assist devices, correct?
2 A. Well, people use the word "left
3 ventricle assist device" differently in
4 different contexts. This one refers to 3,000
5 long-term implantable devices. So that's what
6 this sentence says.
7 However, I would still consider
8 intra-aortic balloon pumps and percutaneous
9 devices as left ventricle assist devices in
10 the functional definition of the word. In
11 other words, they all support left heart.
12 So this one should have said probably
13 implantable long-term or durable left
14 ventricle assist devices, but it's only a part
15 of it. I still say that, you know, other
16 devices should be considered as well in this
17 definition.
18 Q. But reading it here today, that's not
19 what it says, correct?
20 A. Well, the text says what it says.
21 Q. And you authored this article -- or
22 coauthored this article?
23 A. Yes.
24 MS. RAGHAVAN: We'll mark our

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

1 proceeding, in this PGR, was U.S. Patent
2 No. 10,926,069.
3 Do you see that?
4 A. Yes, I see that.
5 Q. Do you recall this patent?
6 A. No. I have to look at it again
7 frankly. It's been a while ago.
8 Q. If you could turn to Paragraph 32 of
9 Exhibit 1034, you start here with a summary of
10 the '069 patent, correct?
11 A. Yes, that's what the text says. But
12 it would be actually useful if you can give me
13 that patent to look at. Do you have it?
14 Q. I do have it. I can give it to you.
15 A. Okay.
16 MS. RAGHAVAN: Let's mark this
17 as Exhibit 1035.
18
19 (Exhibit No. 1035 marked for
20 identification.)
21
22 BY MS. RAGHAVAN:
23 Q. Exhibit 1035 is a copy of U.S. Patent
24 926,069 [sic].

1 Do you see that?
2 A. Yes.
3 Q. And this is the White Swell Medical
4 Limited patent that you opined on in Exhibit
5 1034; is that correct?
6 A. Yes.
7 Q. Would you agree that this is a
8 catheter device?
9 A. That seems to be the case, yes.
10 Again, it's been a while.
11 Q. If we go back to Paragraph 32 of your
12 declaration, Exhibit 1034, the first sentence
13 says, "The invention of the '069 patent
14 relates to an inventive treatment that helps
15 avoid the risk of developing acute heart
16 failure and compromised renal function in
17 certain patients such as those experiencing
18 edema."
19 Do you see that?
20 A. Yes.
21 Q. Is that your understanding of the '069
22 patent?
23 A. I believe so.
24 Q. Does the -- to your recollection does

1 the '069 patent relate to a catheter device
2 that includes sensors and a controller to
3 adjust the device?
4 MR. CAHILL: Object to the form.
5 A. I have to look more closely to recall
6 this, but it would not surprise me if it does.
7 MR. CAHILL: Object to form.
8 BY MS. RAGHAVAN:
9 Q. If you could look at Paragraph 33 of
10 your declaration -- excuse me -- of your
11 declaration in the PGR, which is Exhibit 1034,
12 you provide a few more details about the '069
13 patent.
14 Do you see that?
15 A. Yes.
16 Q. And we'll read through the rest of the
17 paragraph. It mentions that "This catheter
18 device has pressure sensors, and it also has a
19 control module that can include multiple
20 feedback loops to adjust the performance of
21 the system."
22 Do you see that?
23 A. Yes.
24 Q. So you would agree that the catheter

1 device generally includes sensors and a
2 control module, correct?
3 A. Catheter devices in general?
4 Q. No. The one that's described in the
5 '069 patent.
6 A. Oh, yeah, yeah. Yeah, uh-huh, yes.
7 Q. If we look at Paragraph 34 of Exhibit
8 1034, in the first sentence, it says, "The
9 '069 patent describes a catheter device that
10 would be placed in the superior vena cava"; is
11 that correct?
12 A. Yes, SVC.
13 Q. Where is the SVC?
14 A. In the second line of Paragraph 34,
15 superior vena cava.
16 Q. Where is that in the human body?
17 A. Oh, it's a part of the venous return
18 to the heart. It's above the heart, superior.
19 Q. Would you agree that the '069 patent
20 describes a catheter device that was meant to
21 support the heart and the associated
22 circulatory system?
23 MR. CAHILL: Object to form.
24 A. I have to think about this. It's not

1 really designed for -- I mean, it -- it
2 assists the heart in a -- in one way, but it's
3 not unloading the heart in the sense that left
4 ventricle assist devices do. So I wouldn't
5 call it an LVAD, if that's what you're asking.
6 BY MS. RAGHAVAN:
7 Q. Would you agree that it's a heart
8 assist device?
9 A. Probably in a broad sense, yes. It
10 helps patients with edema, so that's one of
11 the signs of a heart failure. So in that
12 sense, it does.
13 Q. But your testimony is that it's not an
14 LVAD; is that right?
15 A. I wouldn't call it an LVAD, no.
16 Q. What is the distinction you're making
17 between the device that's described in the
18 '069 patent and your definition of an LVAD?
19 A. Well, I have to think about this more.
20 I think that different systems that alleviate
21 heart failure symptoms can be called that --
22 that they are assisting the heart in
23 alleviating the symptoms. Now, an LVAD is a
24 more direct unloading of the heart or helping

1 the heart to pump blood.
2 Heart failure is a broad category of
3 different conditions, and they cause different
4 symptoms and different ailments throughout the
5 body. So anything that helps that will help
6 the heart as well indirectly. But an LVAD, in
7 my opinion, is something that actually
8 promotes blood pumping.
9 Q. So not all heart assist devices are
10 LVADs; is that correct?
11 A. Probably true if you extend that
12 logic.
13 Q. And generally an LVAD is a device that
14 helps the heart pump blood?
15 A. I would say so, yes.
16 Q. Let's go to Paragraph 36 of Exhibit
17 1034. In this declaration, you offered a
18 definition of a POSA.
19 Do you see that?
20 A. I do see that.
21 Q. And in the first portion of your
22 definition of a POSA, you say, "It could be an
23 MD or a bachelor's or a master's degree in
24 mechanical engineering, biomedical

1 engineering, or a similar field as well as two
2 or more years of work experience with
3 catheters or similar medical devices."
4 Do you see that?
5 A. I do see that.
6 Q. I'm going to refer you to the part
7 that says "catheter or similar medical
8 devices."
9 A. Uh-huh.
10 Q. What are you referring to when you say
11 "similar medical devices"?
12 A. Well, again, this was a number of
13 years ago, and this was in reference to this
14 particular patent. And the particular patent
15 here has a catheter with balloons that are
16 inflatable in the body. So there may be a
17 possibility of delivering balloons or
18 inflating them with catheters or with other
19 means, I suppose.
20 The definition here is that a person
21 would have two or more years of experience
22 developing these devices directly. For
23 example, anybody with a pharmaceutical
24 experience with not qualify.

1 Q. For this particular technology in the
2 '069 patent, you felt that two years of work
3 experience was sufficient; is that right?
4 A. Correct. In the field with these
5 particular devices.
6 Q. But that work experience didn't need
7 to be limited to catheters?
8 A. Well, it has to be related to similar
9 technologies.
10 Q. Which are still balloon-based
11 catheters, correct?
12 A. I have to look at it again, but
13 broadly speaking, you are correct.
14 Q. We saw earlier that the catheter
15 described in the '069 patent was meant to be
16 placed at the superior vena cava, correct?
17 A. Yes.
18 Q. Your definition of a POSA, though, did
19 not specifically require work experience with
20 a catheter that had to be placed at the
21 superior vena cava, correct?
22 A. That is correct. If a person has
23 experience with placing catheters and balloons
24 in other places than in the venous system or

1 the arterial system, that would still qualify.
2 Q. Why would that still qualify?
3 A. Well, a person who would understand
4 how to position a catheter in a blood vessel
5 would know sufficiently well what this whole
6 thing is all about.
7 Q. Going back to your declaration in this
8 particular IPR that we're discussing today,
9 you say that a POSA must have had five years
10 of experience designing and developing
11 implantable cardiac assist devices, correct?
12 A. Which portion are we referring to?
13 Q. We can turn back to your declaration
14 in this case.
15 I believe it's on page 38 in
16 Paragraph 57 of your declaration.
17 A. Yes.
18 Q. So you see here you say that "A POSA
19 would be a person with at least a bachelor's
20 degree in engineering" -- or -- sorry --
21 that's the definition that's offered by the
22 petitioner.
23 Do you see that?
24 A. Yes.

1 Q. And then in Paragraph 59, you offer
2 your definition of a POSA.
3 Do you see that?
4 A. (Witness reviews document.)
5 Yes.
6 Q. And in your definition, you're
7 requiring a POSA to have "at least five years
8 experience designing and developing
9 implantable cardiac assist devices in
10 particular."
11 Do you see that?
12 A. Yes.
13 Q. What is your basis for opining that a
14 POSA in this context needs at least five years
15 of work experience?
16 A. Well, it's not only years of
17 experience. It's experience in this
18 particular field. Implantable cardiac assist
19 devices are extraordinarily complex and
20 difficult to make and to design. So if a
21 person has five years of experience designing
22 another implant, I don't know, a knee
23 replacement prosthesis, that would not really
24 be relevant to this particular technology. So

1 you have to be in this field for a while to
2 understand all the nuances that are required
3 to appreciate the complexity and the
4 difficulty making these devices.
5 Q. So I believe that explains the cardiac
6 assist devices portion of your definition, but
7 if you could explain your basis for requiring
8 five years of experience designing and
9 developing specifically implantable cardiac
10 assist devices.
11 A. Right. What is it that you want me to
12 explain?
13 Q. Why would a POSA need to have specific
14 experience with implantable cardiac assist
15 devices in particular?
16 A. Well, again, that's what I said. It's
17 a -- making such a device is a very difficult
18 task, and so you need to be well experienced
19 to understand all the difficulties.
20 Q. Do you have that experience?
21 A. I believe I do.
22 Q. How so?
23 A. Well, I have 30-plus experience in
24 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.

1 Q. Even though those devices that you
2 were designing were not specifically meant for
3 implantable use, correct?
4 MR. CAHILL: Object to form.
5 A. Again, I would not necessarily limit
6 this to what they call durable left ventricle
7 assist devices. We have to define the terms a
8 little bit better here.
9 The experience that I think is
10 necessary is to design -- is the designing of
11 the circulatory assist devices. Implantable,
12 if you -- it certainly would be useful to have
13 implantable long-term durable LVAD experience.
14 But if a person has experience designing blood
15 pumps that are implanted in a way that they
16 are connected to the heart but the pumps
17 itself are extracorporeal, for example, that
18 would still be useful.
19 BY MS. RAGHAVAN:
20 Q. So your definition covers
21 extracorporeal use of a heart assist device as
22 well?
23 A. Yes.
24 Q. Is your definition of a POSA limited

1 to those who have work experience developing
2 and designing totally implantable cardiac
3 assist devices?
4 A. How do you define "totally
5 implantable"?
6 Q. As in every portion of the devices
7 must be implantable?
8 A. No, that's not -- that's a very --
9 that's -- it would be certainly nice, but it's
10 a more narrow definition. I would accept
11 people who develop extracorporeal devices.
12 Anything that pumps blood to assist the heart
13 would be useful.
14 Q. Let's go back to Paragraph 6 of your
15 declaration in this case, which, again, is the
16 patent owner's Exhibit 2015.
17 And I'm going to refer you back to the
18 portion of Paragraph 6 that talks about the
19 PHP project.
20 A. Okay.
21 Q. Is the PHP an axial flow catheter
22 pump?
23 A. Yes.
24 Q. Did the PHP use a drive shaft to drive

1 the rotor?
2 A. Yes.
3 Q. It didn't use magneto coupling to
4 drive the rotor, correct?
5 A. It did not.
6 Q. When designing the PHP device, why did
7 you choose to design an axial flow pump rather
8 than using a drive shaft that was controlled
9 by magneto coupling?
10 A. You mixed two technologies in one
11 question.
12 Q. Well, so let me break it up.
13 Why did you choose to design an axial
14 flow pump rather than a centrifugal flow pump,
15 for example?
16 A. That was the choice based on the
17 intended use.
18 Q. What was the intended use?
19 A. Well, the use was to -- you have to
20 thread it through the vessels, and so the
21 diameter was very limited. And an axial flow
22 pump in that sense wouldn't have been
23 advantageous.
24 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

1 shaft, turn the impeller.
2 Q. Because you were actually developing a
3 different portion of that device, correct?
4 A. The most difficult portion was to make
5 a product that would expand and collapse
6 properly. And so the turning, it was sort of
7 the convenient off-the-shelf tool that we
8 used. We did not develop it at the time
9 further than this.
10 We were trying to solve the most
11 difficult problem, which was how to make a
12 plastic impeller that would -- that would
13 collapse and expand properly and housing
14 around it. So we just had -- it's a bicycle
15 shaft basically that we used to power it and
16 see how it works.
17 Q. So in focusing on making the -- making
18 a plastic impeller, you mixed and matched
19 other portions of the system that would have
20 been required, but you were not specifically
21 focused on those other parts of the system,
22 correct?
23 A. At the time of the development, the
24 main objective was to show the feasibility of

1 the implantable portion which would expand and
2 collapse. And so that was the extent of the
3 project that we developed.
4 Q. But you knew that if that plastic
5 impeller were ever to be implantable or
6 implanted in a patient, you needed other parts
7 to be able to make that work?
8 A. Of course.
9 Q. How did you know where to look for
10 those our parts that would work with that
11 impeller?
12 A. It's a design choice.
13 Q. How so?
14 A. Well, you need to have something that
15 would make the impeller turn, and so a drive
16 shaft was a convenient way to do that. But I
17 would assume that it can propagate to clinical
18 prototype as well. It was not something
19 that's entirely prohibitive. So it was a
20 convenient way for us to start with this, but
21 there was no reason to change it afterwards.
22 Q. Would you have also needed some sort
23 of a controller to go with that -- those
24 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.

1 And so the controller would typically include
2 a battery of some sort that would sustain its
3 operation when the patient is being
4 transported, for example.
5 So we didn't design the controller to
6 a full extent. But the assumption was that it
7 would not be dissimilar to other devices on
8 the market.
9 Q. But you knew generally it needed to
10 have a controller?
11 A. Yes.
12 Q. And so when you were writing
13 publications that described the PHP device,
14 did you describe the controller that would be
15 used with the PHP device in great detail?
16 A. Well, I described the principles of
17 what the controller would do in significant
18 detail. Something that would define that
19 particular controller functionality would be
20 useful to describe. But I did not describe, I
21 don't know, the position of the display, for
22 example. Some of the details there were not
23 important at the time.
24 Q. Going back to your design choice of

1 using a drive shaft for the PHP device, was
2 there a reason you didn't use an electromagnet
3 to drive the motor?
4 A. Yes.
5 Q. What was that reason?
6 A. The electrical -- miniaturized
7 electrical motors that would use magnets were
8 used by our competitor, and they had patents
9 on them.
10 Q. So it was not a technical reason?
11 A. Well, among other things, it was a
12 technical reason also because it was difficult
13 to make a small device. But patents would
14 just -- I mean, they had so many patents on
15 this that we were not really trying to break
16 through the...
17 Q. Do you recall which competitor?
18 A. Abiomed.
19 (Stenographer clarification.)
20 A. Abiomed.
21 Q. A-b-i-o-m-e-d?
22 A. Yes. Some people say it "Abiomed."
23 Some people say it differently.
24 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.

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

1 Q. So you, as the inventor, were not
2 compensated in any way for the sale?
3 A. No.
4 Q. Did you think that was fair?
5 A. Yes, because I worked for the company.
6 Q. Let's turn to Paragraph 86 of your
7 declaration.
8 In this section, you're discussing the
9 Wampler prior art, correct?
10 A. Wampler, yes. Uh-huh.
11 Q. Wampler.
12 And in Paragraph 86 specifically, you
13 are discussing the rotor and magnets that are
14 disclosed in the Wampler device, correct?
15 A. Yes.
16 Q. And specifically the magnets are
17 referred to as the arcuate, permanent magnetic
18 segments.
19 Do you see that?
20 A. Oh, yes. Uh-huh.
21 Q. And below Paragraph 86, you have a
22 copy of Figure 13 from the Wampler reference.
23 Do you see that?
24 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

1 don't know how to answer that question.
2 Q. Sure, you can include the position
3 numbers.
4 A. Well, I mean, if you look at
5 Figure 13 --
6 Q. Sure.
7 A. -- you have a part that rotates, and
8 the part that is the housing is stationary.
9 So everything that rotates is a rotor.
10 Q. Okay. And then referring to Figure 13
11 specifically, you see that the permanent
12 magnets that we were referring to earlier are
13 labeled as Element 88.
14 Do you see that?
15 A. Yes.
16 Q. You'd agree that the magnetic
17 pieces, 88, are in the rotor, correct?
18 A. They're a part of the rotor, yes.
19 Q. They're embedded within each impeller
20 blade sector? That's what it says in the
21 Wampler reference?
22 A. Yes.
23 Q. You'd agree that the magnetic
24 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

1 necessarily.
2 Q. Well, how would you describe their
3 shape?
4 A. Well, they -- the patent describes
5 them as arcuate segments, so some of them -- I
6 mean, some shape here resembles a rectangle,
7 but they have -- they have this sort of
8 expanding shape from the center to the
9 periphery, which is not necessarily
10 rectangular.
11 Q. So it has some sort of an arc,
12 correct?
13 A. Yes.
14 Q. In addition to being somewhat
15 rectangular?
16 A. Yes.
17 Q. And you're saying it expands kind of
18 in a trapezoidal geometry as well?
19 A. Again, different surfaces of these
20 magnets have different shapes.
21 Q. And by "different surfaces," you're
22 talking about like the outer surface versus
23 the inner surface?
24 A. Well, if you cut out one of these

1 magnets from the rotor you would -- you would
2 have a surface that would be curved on the
3 outside, maybe curved on the inside. The
4 inside curve would be probably smaller than
5 the outside curve because of the expansion
6 from the center.
7 The side -- side walls probably would
8 be rectangular.
9 Q. Are those side walls touching the
10 rotor?
11 A. They are embedded in the rotor.
12 Q. So are they touching the rotor?
13 A. Well, they're inside the rotor. I'm
14 not sure how to define "touching."
15 Q. Well, if they're inside, are they
16 touching or no?
17 A. Well, I mean, when I touch it like a
18 piece of paper, then -- then -- then my hand
19 is one, you know, item, and then the piece of
20 paper is the other.
21 The magnets are inside. They're
22 embedded. So if you include the word, you
23 know, "touching" to mean embedded, then they
24 are.

1 I wouldn't necessarily call them
2 touching.
3 Q. Is it fair to say that the magnetic
4 pieces share at least one common side with the
5 rotor?
6 MR. CAHILL: Object to form.
7 A. How do you define that?
8 BY MS. RAGHAVAN:
9 Q. Are they in contact at at least one
10 side?
11 A. Well, they are embedded, so they
12 clearly are in contact with the rotor because
13 they're inside it.
14 Q. At least the inner surface of the
15 magnetic piece is in contact with the rotor,
16 correct?
17 A. Well, all sides of the -- of the
18 magnetic pieces are in contact with the
19 internal volume of the rotor, I suppose.
20 Q. Okay. Let's turn to Paragraph 191 of
21 your declaration.
22 A. Are we coming up on a break?
23 MS. RAGHAVAN: Yes. If you --
24 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.

1 Q. Would you agree that, as drawn, the
2 inner surface of the permanent magnet is
3 touching the impeller?
4 A. What do you call an inner surface?
5 Q. So I'll make it more general.
6 So is the permanent magnet touching
7 the impeller?
8 A. Well, it's the same answer as with the
9 previous one where the permanent magnet is
10 embedded in the impeller, so to that extent,
11 they're touching.
12 Q. Does the permanent magnet then share
13 at least one common side with the impeller?
14 A. I don't understand that question.
15 Q. The permanent magnet is resting within
16 the impeller, correct?
17 A. It's embedded within the impeller.
18 Q. Let's turn to Paragraph 77 and 78 of
19 your declaration.
20 These paragraphs are under a heading
21 titled "At a Position Axially Adjacent"
22 Do you see that?
23 A. Yes.
24 Q. And you understand that's one of the

1 claim terms?
2 A. Yes.
3 Q. In Paragraph 77, you quote from the
4 board's institution decision to say that "The
5 board has adopted a construction for the term
6 'at a position axially adjacent' to mean
7 adjacent to one another as measured along a
8 central axis."
9 Do you see that?
10 A. Yes.
11 Q. Is that the construction that you
12 applied in your analysis?
13 A. Yes.
14 Q. So let's take a look back at Paragraph
15 113 of your declaration, and this is your
16 analysis of limitation 1H for the Wampler
17 reference, correct?
18 A. Yes.
19 Q. And at the start of Paragraph 113, you
20 refer back to your Section VIII.C regarding
21 claim construction of the term "at a position
22 axially adjacent" which we just looked at,
23 correct?
24 A. Yes.

1 Q. Further down in Paragraph 113, you say
2 that you "do not believe a POSA would have
3 understood this term," so at a position
4 axially adjacent, "to include adjacency along
5 different axes or components that are embedded
6 within one another such that they overlap or
7 occupy the same space as measured along a
8 central axis."
9 Is that right?
10 A. That's what it says.
11 Q. You still -- is that still your
12 opinion?
13 A. Yes.
14 Q. And then you say that "The board has
15 adopted this construction in the institution
16 decision."
17 Do you see that?
18 A. Yes.
19 Q. But the board's construction that we
20 looked at that you quoted in Paragraph 77
21 doesn't expressly exclude elements that
22 overlap, correct?
23 A. Well, the text says what it says. I
24 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

1 that definition.
2 Q. The board's definition did not
3 expressly say anything about overlapping
4 elements, correct?
5 A. Well, the text is what the text is.
6 Q. And the same question as to elements
7 that occupy the same space.
8 The board's definition does not
9 expressly say anything about elements
10 occupying the same space?
11 A. The meaning is expressed I think quite
12 clearly, and my understanding of that meaning
13 is what I express here in this paragraph.
14 Q. When you say "quite clearly," where
15 are you extracting these --
16 A. Well --
17 Q. -- these additional requirements
18 from?
19 A. I'm sorry.
20 MR. CAHILL: Object to form.
21 A. The board's definition says that a
22 position axially adjacent means "adjacent to
23 one another as measured along a central axis,"
24 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?

1 A. Well, again, the report says what it
2 says.
3 Q. Did you consider any dictionary
4 definitions?
5 A. I did not.
6 Q. Is it possible that two POSAs would
7 interpret the board's meaning of "at a
8 position axially adjacent" differently?
9 MR. CAHILL: Object to form.
10 A. That's a speculative question. People
11 can think of, you know, all kinds of different
12 things, I suppose. I provided this definition
13 the way I understand a POSA would interpret
14 this.
15 BY MS. RAGHAVAN:
16 Q. And that's just based on your own
17 personal understanding, correct?
18 A. I agree with what the board says.
19 Q. But as for elements that are
20 overlapping or occupying the same space, you
21 believe such elements are not included within
22 the definition of "at a position axially
23 adjacent" based on your own personal
24 understanding, correct?

1 A. Well, adjacent to one another is next
2 to each over, not overlapping.
3 Q. And that's your personal
4 understanding?
5 A. That's my understanding, but that's my
6 understanding of what a POSA would understand.
7 Q. Let's turn to Paragraph 152 of your
8 declaration.
9 A. Yes.
10 Q. And specifically I'm going to refer
11 you to the table that starts on page 85 and
12 continues on page 86.
13 Do you see that?
14 A. Yes.
15 Q. The purpose of this table is to
16 compare different pumps to the size of the
17 HeartWare HVAD pump; is that right?
18 A. No. The purpose of this table is just
19 to list different devices, their relative
20 sizes and weights, and their position of
21 implantation to show which device goes
22 where.
23 Q. So in this table, you've listed the
24 weight and volume of different pumps; is that

1 correct?
2 A. Yes.
3 Q. And you've listed the location at
4 which you understand those pumps to be
5 implantable, correct?
6 A. Correct.
7 Q. And you list the year of publication
8 or approval of those pumps per your
9 understanding, correct?
10 A. Yes.
11 Q. When you say "approval," what are you
12 referring to?
13 A. FDA approval or any regulatory
14 approval.
15 Q. Is that limited to the United
16 States?
17 A. No, but I believe that the years
18 listed are referring to the United States.
19 Not all pumps were approved, so that's
20 why sometimes the numbers refer to publication
21 year and sometimes to the actual approval.
22 Q. Got it.
23 Throughout your declaration in this
24 case, you compare the purported size of the

1 various pumps cited in a prior art to the
2 purported size of the HeartWare HVAD pump; is
3 that correct?
4 A. Well, it's one point of comparison.
5 Again, I wouldn't characterize the table as
6 listing everything else versus HeartWare.
7 This is just a list of available
8 technologies to then compare them against each
9 other.
10 Q. Sure. But in other portions of the
11 declaration, you did compare the relative
12 sizes of the pumps in the prior art to the
13 HeartWare HVAD pump, correct?
14 A. That's true, yes.
15 Q. Is it your opinion that the HeartWare
16 HVAD pump is the maximum size of a pump that
17 can be implanted at the apex of the heart?
18 A. Well, there was another one. At least
19 the Wampler device was one of the devices.
20 There are two of them there described in the
21 patent.
22 The one that he later developed to a
23 prototype was intended for this implantation
24 as well.

1

2 (Stenographer clarification.)

3

4 A. For this implantation as well, meaning

5 at the apex of the heart.

6 It was a little larger but not that

7 much larger.

8 BY MS. RAGHAVAN:

9 Q. When you say he later developed it,

10 what are you referring to?

11 A. Well, the patent -- I don't remember

12 exactly the dates when the patent was

13 published, but then there was also

14 publications of actual development of

15 prototypes, and they refer -- the publication

16 that I reviewed was, I believe, published

17 after the patent was published or applied for.

18 And so that represents the

19 continuation of that effort chronologically,

20 and so that device that was already -- that

21 was in further development is one of the two

22 main prototype embodiments that were described

23 in the patent of Wampler.

24 Q. So based on that, a pump larger than

1 the HeartWare HVAD pump can be implanted at
2 the apex of the heart, correct?
3 A. A little large -- larger but not too
4 big. And, you know, the question's what's --
5 the whole point of that table is to show that
6 larger pumps cannot be implanted at the apex
7 of the heart whereas the smaller ones can.
8 So the point here is to show that both
9 the size and the weight of the pump are
10 important considerations when it comes to
11 attaching the device at the apex of the heart
12 to the heart itself. The heart can tolerate
13 smaller pumps, but cannot tolerate larger
14 pumps, and there's no space for larger pumps
15 in that location.
16 Q. And is that applicable to all
17 patients?
18 A. Well, again, a design of an LVAD is a
19 balance of conflicting requirements. Clearly
20 the smaller, the better, the lighter, the
21 better.
22 So the lighter and the smaller the
23 pump is, the broader the range of patients
24 that it can be implanted in. So broadly

1 speaking, the demarcation here is that a
2 couple of pumps that were small enough, which
3 is the Wampler prototype and HeartWare, are
4 suitable for implantation at the apex of the
5 heart whereas larger pumps that are listed
6 here are not.
7 Q. But to clarify, when you're saying
8 they're small enough, you're saying they're
9 small enough to be implanted at the apex of
10 the heart for a larger portion of patients?
11 A. For a sizeable portion of patients,
12 yes, to be practical and useful.
13 Q. But in your mind, is it possible for
14 there to be a patient for whom a larger device
15 can be implanted at the apex of the heart?
16 A. It's a speculative question. It
17 depends on the size of the patient. It
18 depends on the size of the pump.
19 Q. Do you have an opinion as to what the
20 maximum size of a pump can be that can be
21 implanted at the apex of any patient -- apex
22 of the heart of any patient?
23 A. It is hard to actually draw a straight
24 line because, again, a POSA would want to

1 develop a pump that would be useful for not
2 just the largest patients but for a reasonable
3 number of patients, for at least half of the
4 patients or more than half of the patients.
5 So in that sense, I think that the
6 Wampler device is at the -- is sort of at the
7 end of this line where the weight of the pump
8 is about 200 grams, so anything under 200
9 grams would probably be suitable for this.
10 And the same goes for volume and size because
11 there's only limited space between the apex of
12 the heart and the diaphragm.
13 Q. Separate from reading these prior art
14 references and devices that you've summarized
15 in this table in Paragraph 152, have you
16 independently done an analysis of the weight
17 and volume that -- of a pump that can be
18 implanted at the apex of the heart?
19 A. Well, the table represents that
20 analysis.
21 Q. But aside from this table, you have
22 not done a separate analysis, correct?
23 A. Prior to the separate --
24 Q. Yes.

1 A. -- to this whole declaration, no, I
2 have not.
3 Q. As part of this declaration, you have
4 not done that analysis either, correct?
5 A. Well, that table is that analysis.
6 Q. But separate from the table, you have
7 not conducted a different analysis that you
8 don't speak of in your declaration?
9 A. The analysis is here in the table.
10 I'm not sure how to answer that question
11 differently.
12 Q. When you said earlier that a POSA
13 would have wanted to design a pump that can be
14 implanted at the apex of the heart for a wide
15 range of patients, that's a commercial
16 consideration, correct?
17 A. Well, it's not just a commercial
18 consideration. It's a consideration for why
19 these devices are being developed in the first
20 place, which is to help people with heart
21 failure. So a POSA -- I mean, it takes ten
22 years or more to develop a product like this.
23 And so a POSA would understand that to develop
24 a pump that can be implanted in a particular

1 location for the largest, biggest man and not
2 for somebody else is sort of not very useful.
3 Q. So usability aside, would a POSA
4 understand that a larger pump could be
5 implantable at the apex of the heart of a
6 large male patient, for example?
7 A. To an extent. Again, I believe that
8 some of these pumps are still too large even
9 for that to happen.
10 Q. But you don't know what the maximum
11 size would be for such a pump to be implanted
12 in a large male patient?
13 A. Well, the consideration is not just
14 the size. The consideration for a larger pump
15 is twofold. One is the larger the pump, the
16 more risk there is to impede on the volume
17 that's available for the heart itself.
18 So as you grow the size of the pump,
19 there is less and less room that's left for
20 the heart. So you will sort of start to
21 impede on the movement and the free sort of
22 physiological expansion and contraction of the
23 heart itself. I don't know if I can draw a
24 line to say, you know, X number of ccs will

1 kill somebody or -- but at some point, it will
2 start to impede more and more. So it's a
3 little bit of a gray area right there, number
4 one.
5 And, number two, the same goes for the
6 weight. You are sort of hanging something
7 onto the heart when you implant it to the
8 apex, and the same consideration applies. The
9 larger it is, the more difficult it is for the
10 heart to move and not to notice there is a
11 brick attached to it. So it's a continuous
12 sort of process. It's not like before and
13 after.
14 Q. So there's no clear line as to what
15 weight or volume a pump needs to be after
16 which it becomes possible or impossible to
17 implant a particular pump at the apex of the
18 heart?
19 A. Well, again, we have to make a
20 judgment call here somehow, and clinical
21 experience shows that HeartWare clearly was
22 implanted successfully in a number of -- in a
23 large number of patients, so that's a yes.
24 Wampler is a little bit of a stretch

1 from that and never implanted, but I would
2 probably say it's a yes. But beyond that,
3 it's hard to say that it will be a yes without
4 significant clinical evidence.
5 Again, it depends. I mean, patients
6 come along a distribution curve also, so
7 it's -- plus it's not just the size. It's the
8 consideration of how strong the heart is,
9 how -- you know, how much assist is needed.
10 There's a whole bunch of factors here.
11 Medicine is not a precise science.
12 Q. So in your view, the Wampler prototype
13 and the HeartWare HVAD are examples of pumps
14 that can be implanted at the apex of the heart
15 of some patients?
16 A. Of a good enough, large enough number
17 of patients, yes.
18 Q. Referring back to the table here, you
19 have a row for HeartMate III and then
20 "clinical" in parentheses.
21 Do you see that?
22 A. Yes.
23 Q. What are you referring to when you say
24 "clinical" in parentheses?

1 A. Well, HeartMate III has been in
2 development for many years and up and until
3 about 2006 was the pump configuration that I
4 refer to as HeartMate III prototype.
5 And then after that, they redesigned
6 the pump significantly, made it significantly
7 smaller by certain innovations about the, you
8 know, design of the pump, and commercialized
9 that as a clinical version of HeartMate III.
10 So literature refers to HeartMate III
11 throughout an entirely, you know, sort of long
12 period of time, but these are two different
13 pumps.
14 So my demarcation here is to refer to
15 an earlier device as a prototype and to a
16 later device, which was significantly
17 different than the first device, as a clinical
18 device because both of them are called
19 HeartMate III as compared to HeartMate II,
20 which was a totally different pump altogether.
21 Q. So "clinical" refers to the commercial
22 embodiment of HeartMate III?
23 A. Correct.
24 Q. Are you aware that the patent owner,

1 Miracor, has asserted the challenged patents
2 that are at issue in these IPRs in district
3 court litigation as well?
4 A. I believe that was mentioned once, but
5 I don't know the details.
6 Q. Did you review or consider Miracor's
7 infringement contentions from the district
8 court litigation in preparing your opinion for
9 the IPRs?
10 A. No.
11 Q. Did you consider, for example, how
12 Miracor understands certain claim terms in
13 alleging infringement of the HeartMate III
14 product in district court litigation in
15 forming your opinion as to how those same
16 terms should be interpreted in the IPRs?
17 A. No.
18 Q. I'm going to hand you what we'll be
19 marking as Exhibit 1036.
20
21 (Exhibit No. 1036 marked for
22 identification.)
23
24 BY MS. RAGHAVAN:

1 Q. Sorry. I understand you're not
2 familiar with this document, correct?
3 A. (Witness reviews document.)
4 I don't think I am.
5 Q. So I will represent to you that this
6 is the publicly filed version of Miracor's
7 infringement chart for the '879 patent, which
8 is one of the other patents that you submitted
9 a declaration for.
10 A. Okay.
11 Q. Do you generally understand how
12 infringement claim charts work?
13 A. Generally.
14 Q. Do you understand this to be an
15 infringement chart?
16 A. It looks like it.
17 Q. Then you can see here that there are
18 limitations -- claim limitations from the '879
19 patent on the left side, correct?
20 A. It appears like it. Again, I have not
21 seen this before, so I -- I cannot go beyond
22 what the text says.
23 MR. CAHILL: I'm going to object
24 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

1 need to understand what the first chamber
2 versus the second or third or fifth chamber
3 is. I -- you're, you know, asking me to point
4 at small detail here that I don't understand
5 the entire context of.
6 Q. So you can't tell me where just the
7 rotor is in this clinical pump?
8 A. I can, but I need to study this more
9 closely, and I'm not comfortable doing it
10 right now.
11 Q. But you've expressed opinions in your
12 declaration about the HeartMate III clinical
13 pump, correct?
14 A. My opinions about the HeartMate
15 clinical pump are limited to the size and the
16 weight of the device.
17 Q. So you cannot -- you're declining to
18 identify where the magnetically driven rotor
19 is in this diagram?
20 A. At this point, yes.
21 Q. Can you turn to page 9 of this
22 document. And I'm going to refer you
23 specifically to the box with the text with the
24 rectangle around it.

1 Do you see that? It starts with "The
2 rotor is fully supported by magnetic
3 levitation."
4 A. Oh, yes, uh-huh.
5 Q. Then towards the middle of that text,
6 it says -- starts saying, "By measuring the
7 position of a permanent magnet in the rotor
8 and appropriately controlling the current and
9 the drive and levitation coils, the radial
10 position and rotational speed of the rotor is
11 actively controlled."
12 Do you see that sentence?
13 A. Yes, I do.
14 Q. Is it your understanding that the
15 permanent magnet in the rotor of the
16 HeartMate III clinical pump is embedded within
17 the rotor?
18 MR. CAHILL: Objection. Outside
19 the scope and misleading.
20 A. You're asking me to comment on a
21 document that I have not seen before. I have
22 to study this. I can come to a certain
23 conclusion, but I cannot do it right now.
24 BY MS. RAGHAVAN:

1 Q. Are you aware of how the permanent
2 magnet in the HeartMate III clinical pump is
3 configured within the rotor of the
4 HeartMate III clinical pump?
5 A. Not in great detail.
6 Q. Did you consider how the HeartMate III
7 clinical pump is designed, separate from its
8 weight and volume, in coming to a conclusion
9 as to how you understand the claims as part of
10 your declaration in the IPRs?
11 A. In broad terms.
12 Q. How so?
13 A. Well, I understand they have magnets.
14 They have magnetic suspension of some sort.
15 They have a way to rotate the rotor, and it
16 pumps blood. I didn't go much beyond that.
17 Q. So you didn't understand that the
18 permanent magnet was embedded within the rotor
19 of the HeartMate III clinical pump?
20 MR. CAHILL: Same objections.
21 A. Again, we're talking about specific
22 definitions here, which I did not analyze
23 closely to confirm or agree or not agree with
24 that statement. I have to do more work on

1 that.
2 BY MS. RAGHAVAN:
3 Q. Within the diagrams of the HeartMate
4 III clinical pump that we looked at, are you
5 able to identify where the permanent magnet
6 is?
7 A. Again, I'm sure I can. I'm not
8 comfortable just pointing out to a particular,
9 you know, component on a small diagram with
10 many details. I have to understand what's
11 what more closely.
12 Q. So you haven't done that analysis as
13 part of arriving at your opinions that you
14 presented in your declaration?
15 A. My analysis was limited to a broad
16 understanding of what that pump is and its
17 size and weight. That's the extent of what I
18 looked at.
19 Q. You're saying that if you were to try
20 to identify the permanent magnet within the
21 HeartMate III clinical pump in this diagram,
22 you would have to do that analysis sitting
23 here today?
24 A. I cannot do that sitting here today,

1 but I can do that.
2 Q. You haven't done that?
3 A. I have not done it.
4 Q. You can set that document aside.
5 Let's go back to your declaration,
6 which is Exhibit 2015.
7 I'm going to turn you to your table of
8 contents, which is on the second page of the
9 document.
10 Your declaration, starting with
11 Ground 10, is structured so your analysis is
12 organized by the grounds that are alleged by
13 the petitioner, correct?
14 A. Yes.
15 Q. So you address Ground 1 first,
16 followed by Ground 2, then Ground 3, then
17 Ground 4; is that correct?
18 A. Yes.
19 Q. Does your -- does the table of
20 contents accurately present that you only
21 express opinions that Wampler fails to
22 disclose claim limitations 1A, 1B, 1H, 1M, 1N
23 and 1O?
24 A. Repeat the question again. Wampler

1 what?
2 Q. Sure. So based on the table of
3 contents --
4 A. Yes.
5 Q. -- your declaration only expresses
6 opinions that Wampler fails to disclose the
7 claim limitations listed here, so 1A, 1B, 1H,
8 1M, 1N, and 1O?
9 A. Yes.
10 Q. Nowhere in your report do you dispute
11 that Wampler discloses the remaining
12 limitations and claims that are challenged by
13 the petitioner, correct?
14 A. I don't talk about this, so I talk
15 about what I talk about.
16 Q. So I'll refer you to Ground 2.
17 Similarly, you only express opinions that
18 Bourque 2001, in view of Wampler, fails to
19 disclose Claim Limitations 1C, and then
20 dependent Claims 5 and 7?
21 A. Correct.
22 Q. And nowhere in your report do you
23 dispute that Bourque 2001, in view of Wampler,
24 discloses the remaining limitations and

1 claims?
2 A. The report is silent on that.
3 Q. Let's turn to Ground 3. For Ground 3,
4 you only express opinions that Akamatsu fails
5 to disclose Claim Limitations 1A, 1H, 1N, and
6 1O; is that correct?
7 A. That's what the report says.
8 Q. Then nowhere in your report do you
9 dispute that Akamatsu discloses the remaining
10 limitations and claims, correct?
11 A. The report is silent on the other
12 limitations.
13 Q. And turning to Ground 4, you only
14 express opinions that Schima, in view of
15 Akamatsu, fails to disclose Claim Limitations
16 1A, 1N, 1O, and then dependent Claims 5 and 7;
17 is that right?
18 A. Correct.
19 Q. Nowhere in your report do you dispute
20 that Schima discloses the remaining
21 limitations and claims, correct?
22 A. I do not discuss other limitations.
23
24 (Stenographer clarification.)

1

2 A. I do not discuss other limitations in
3 the report.
4 BY MS. RAGHAVAN:
5 Q. So with that, let's turn to
6 Paragraph 87 of your declaration.
7 So in Paragraph 87, you say, "Wampler
8 discloses different embodiments of blood
9 pumps."
10 Do you see that?
11 A. Yes.
12 Q. Okay. And you say, "A first
13 embodiment is shown in Figures 1 through 8,"
14 yes?
15 A. Yes.
16 Q. And then you say, "Alternative
17 embodiments are shown in Figures 11
18 through 20," correct?
19 A. Yes.
20 Q. The embodiment that's shown in
21 Figures 1 through 8, that uses mechanical
22 thrust bearings; is that correct?
23 A. Correct.
24 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?

1 MR. CAHILL: Objection.
2 A. That is correct.
3 MR. CAHILL: Object to form.
4 BY MS. RAGHAVAN:
5 Q. In your opinion, where would a POSA
6 understand that the embodiment of Figures 11
7 through 13 should be implanted?
8 A. Well, the fact it doesn't say where
9 they are to be implanted. But based on the
10 size and the relative components that are
11 here, I would think that the only position
12 that it can be implanted is in the
13 preperitoneal pocket.
14 Q. You would agree that the patent
15 doesn't explicitly say that about Figures 11
16 through 13, correct?
17 A. It doesn't.
18 Q. As a POSA, as a general matter, would
19 you agree that when you're reading a patent or
20 another publication, you would review all of
21 the teachings together?
22 MR. CAHILL: Object to form.
23 A. Broadly speaking, that's correct.
24 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?

1 A. The patent describes a placement for
2 the embodiment that it does, and it doesn't
3 say anything else, so it's silent on that.
4 So I think that it would be not
5 feasible to implant other devices in the same
6 position because of what I described in the
7 report what I believe a POSA would understand
8 as well. And it's indirectly confirmed by the
9 fact that that pump was never developed
10 further other than the paper exercise.
11 Q. Let's turn to Paragraph 101 of your
12 declaration.
13 This is part of your analysis of
14 Ground 1, correct?
15 A. Correct.
16 Q. So here you're continuing to analyze
17 the Wampler reference?
18 A. Yes.
19 Q. At the bottom of Paragraph 101, you
20 have two side-by-side figures from Wampler,
21 namely Figure 5 and Figure 13.
22 Do you see that?
23 A. Yes.
24 Q. And they have various annotations that

1 were added by the petitioner?
2 A. Correct.
3 Q. Okay. If the embodiment that's shown
4 in Figure 13 were inserted into the apex of
5 the heart as shown in Figure 5, would you
6 agree that the Impeller 74 would be positioned
7 outside the ventricle of the heart?
8 MR. CAHILL: Object to form.
9 A. (Witness reviews document.)
10 74 refers to impeller; is that
11 correct?
12 BY MS. RAGHAVAN:
13 Q. Yes.
14 A. I don't -- I need to look at this.
15 But the entire part that is pink, which is
16 what you call the impeller, I suppose, would
17 be outside the heart. That's correct.
18 Q. I'm going to hand you a copy of the
19 Wampler reference, which was Exhibit 1008.
20 A. Okay.
21 Q. If you could, turn to Paragraph 18 of
22 Wampler.
23 And, in particular, I'm going to refer
24 you to the sentence that says, "Torque drive

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

1 interaction.
2 BY MS. RAGHAVAN:
3 Q. So magnetic interaction is an example
4 of magneto coupling?
5 A. Yes.
6 Q. In describing this magnetic
7 interaction, Wampler is only referring to the
8 Impeller 74 and not to the Rotor 17,
9 correct?
10 A. I don't see any reference to one and
11 not the other.
12 Q. Well, you see that it says "impeller,"
13 correct?
14 A. Well, it talks about impeller blades.
15 Q. Well, in the second sentence, it says
16 "impeller," correct?
17 A. Yes.
18 Q. It doesn't say "rotor," correct?
19 A. Well, impeller is part of the rotor.
20 Q. But it doesn't say "rotor," correct?
21 A. The text says what it says.
22 Q. So would you agree that the
23 Impeller 74 of Figure 13 is what is being used
24 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

1 spindle certainly applies acceleration to the
2 blood because it rotates, and the blood that
3 comes in does not rotate. So it makes a --
4 makes the blood into -- into -- you know,
5 imparts some rotational movement on the blood
6 just by drag.
7 Clearly the impeller itself is the one
8 that imparts centrifugal force and forces the
9 flow of blood to turn and then to go towards
10 the outlet.
11
12 (Stenographer clarification.)
13
14 A. Towards the outlet.
15 THE STENOGRAPHER: If you could,
16 just keep your voice up just a bit.
17 BY MS. RAGHAVAN:
18 Q. And you would agree that Wampler
19 discloses a centrifugal pump, correct?
20 A. Of course.
21 Q. So is it your position that
22 Element 18, which is the shaft of Figure 13,
23 contributes to imparting acceleration to the
24 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

1 the second embodiment.
2 So there are some parts that overlap,
3 which is why it's one patent, but there are
4 other parts that are significantly
5 different.
6 BY MS. RAGHAVAN:
7 Q. You agreed earlier that Figures 11
8 through 13, the alternative embodiment, don't
9 use mechanical thrust bearing, correct?
10 A. Correct.
11 Q. They use hydrodynamic bearings
12 instead?
13 A. Well, they use magnetic bearing and
14 magnetic suspension and hydrodynamic bearings.
15 Q. So would you agree that when the pump
16 is working in -- when it's in motion, that the
17 rotor of Figures 11 through 13 is entirely
18 spaced apart from its housing?
19 A. Yes, which is not the case in the
20 first embodiment. That's the point of these
21 two paragraphs.
22 Q. So let's turn to Paragraph 122 of your
23 declaration.
24 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?

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

1 controller. One way is to incorporate within
2 the, you know, pump. You know, I -- it's a
3 speculative answer here because there's
4 nothing in the patent that describes that.
5 Q. So you would agree that the
6 descriptions corresponding to Figures 11
7 through 13 don't specifically prohibit using
8 an external controller, correct?
9 A. It doesn't say anything about it.
10 Q. Regardless of whether the embodiment
11 of Figures 11 through 13 uses an internal
12 controller or an external controller, where
13 would that pump get power from?
14 A. There are different ways to provide
15 electricity. It may be an implantable
16 battery. It may be supplemented by external
17 battery. It may be with coil transmission
18 through the skin, maybe with cable
19 transmission through the skin. There are
20 different ways of doing this.
21 Q. Were all those options known in the
22 art before 2007?
23 A. Well, known in the art conceptually.
24 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

1 the pump shown in Figures 11 through 13 would
2 need?
3 A. There is no way to tell just looking
4 at the figures.
5 Q. Can you provide a range?
6 A. I -- probably more than 20 watts and
7 less than, I don't know, 200. I mean, it's a
8 broad range.
9 Q. Is that specific to the embodiments of
10 Figures 11 through 13? Or would you -- would
11 you attribute the same range to the embodiment
12 of Figure 5?
13 A. I don't know. I have to think about
14 this a little more. I didn't -- I gave you an
15 off-the-cuff answer here, but it's really -- I
16 need to think about it more.
17 One thing that is probably true about
18 the embodiment, the second embodiment, is that
19 since it has electrical coils, it will
20 probably use more power than the first one
21 because it needs also power to suspend and to
22 support the rotor.
23 But how much power? It's a very
24 difficult question to answer.

1 Q. Can we look at Paragraph 80 of the
2 Wampler reference?
3 MS. RAGHAVAN: It's Exhibit 1008
4 for the record.
5 A. (Witness reviews document.)
6 Okay.
7 BY MS. RAGHAVAN:
8 Q. Okay. I'm going to refer you to the
9 second sentence of Paragraph 80, which says,
10 "Referring to Figures 11, 11A, 12, 13, and 14,
11 the Blood Pump 11 prime shown therein, is
12 similar to many respects to Blood Pump 11
13 illustrated in Figures 1 through 8."
14 Do you see that?
15 A. Yes.
16 Q. Did you consider that statement in
17 forming your opinion that the two embodiments
18 were disjoined?
19 MR. CAHILL: Object to form.
20 A. Well, it says what it says, and I
21 agree with what it says. It's similar. For
22 example, the spindle is similar. We talked
23 about this.
24 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?

1 A. Examples -- I mean, it describes what
2 it describes, so it has this particular
3 example. So in that sense, it does -- that is
4 correct.
5 Q. So the only example that the '356
6 patent provides is of a catheter-based device,
7 correct?
8 MR. CAHILL: Object to form.
9 A. That is an example of a particular
10 configuration.
11 BY MS. RAGHAVAN:
12 Q. But that's the only example
13 configuration it provides?
14 A. It says what it says.
15 Q. Let's turn to Paragraph 96 of your
16 report next.
17 If we go to the end of Paragraph 96,
18 the last sentence, you say here that "The
19 first device, the HeartWare HVAD, that was
20 clinically implanted in the pericardial space
21 years after the publication of Akamatsu (and
22 the priority date of '356 patent)."
23 Do you see that?
24 A. Uh-huh, yes.

1 Q. What do you mean by "clinically
2 implanted"?
3 A. Well, HeartWare was a commercially
4 available device for a number of years, and so
5 it went through conventional clinical studies
6 when it was implanted in human patients after,
7 I suppose, some animal trials, and then it was
8 commercialized and was sold to be implanted in
9 patients with heart failure.
10 Q. Do you know whether the inlet tube of
11 Akamatsu was placed within the apex of the
12 heart?
13 A. I don't.
14 Q. You don't know?
15 A. I don't know.
16 Q. Is there a difference between the
17 inlet tube being placed at the apex of the
18 heart and the pump being placed in the
19 pericardial space?
20 A. Well, it goes one way but not the
21 other. In other words, if the pump is in the
22 pericardial space, the likelihood is that the
23 inlet tube will be placed in the apex of the
24 heart because it's quite close to it. That's

1 the whole point of putting it there.
2 But if the inlet tube is placed in the
3 apex or anywhere else in the heart, it doesn't
4 mean that the pump is there, so it can be
5 extended somewhere else.
6 Q. So the two are not necessarily
7 synonymous, right?
8 A. Well, it can be one way but not the
9 other.
10 Q. Got it.
11 So let's turn to Paragraph 150 Of your
12 report next -- sorry -- of your declaration.
13 Towards the end of this paragraph, you
14 say, "This means Wampler only proposed an
15 unachievable concept of such a pump and
16 placement." And then it goes on to say that
17 "It took over ten years from the publication
18 of Wampler (many more from its priority date)
19 and five years after the priority date of the
20 '356 patent before an LVAD was actually made
21 small enough to be implanted at the apex of
22 the heart."
23 Do you see that?
24 A. I see the text. Let me review the

1 entire paragraph.
2 Q. Sure.
3 A. Just one second, please.
4 Q. Take your time.
5 A. (Witness reviews document.)
6 Yes, I understand.
7 Q. Okay. When you say "such a pump and
8 placement," what is the placement you're
9 referring to?
10 A. A pump that would be small enough to
11 be implanted at the apex of the heart.
12 Q. So are you saying a pump that would be
13 small enough to be placed within the
14 pericardial space?
15 A. We say that, within the pericardial
16 space. I think what we really need to say is
17 at the apex of the heart because the
18 pericardium is sort of cut open at that point.
19 So pericardial space better -- is
20 better defined as the space around the entire
21 heart. So clearly that's not part of what
22 we're talking about here.
23 So we're not closing the pericardium
24 around the pump. They're just cutting it open

1 to have access to the heart. So I just want
2 to be accurate here.
3 So in order to position that pump and
4 to have an inflow cannula in the apex of the
5 left ventricle, it has to be small enough to
6 fit in that space even though the pericardium
7 may not be completely surrounding that pump.
8 Pericardial space refers to space at
9 the apex of the heart. I think that would be
10 a more accurate way to describe that.
11 Q. But the claim only requires that an
12 inflow tube of the heart assist pump device is
13 inserted into a ventricle of the heart,
14 right?
15 MR. CAHILL: Object to form.
16 A. A claim -- claim what? Claim 1 of the
17 '356 patent?
18 BY MS. RAGHAVAN:
19 Q. Yes. So if you look at Claim 1 of the
20 '356 patent and look at the first limitation
21 after the preamble.
22 A. (Witness reviews document.)
23 Well, it's listed this way, but it's
24 not the only thing that the claim requires.

1 The claim requires a number of different
2 limitations.
3 Q. Sure. But as for placement
4 specifically, it says, "An inflow tube of the
5 heart assist pump device is inserted into a
6 ventricle of the heart," correct?
7 A. Well, it does. It does say that, but
8 that's not the only thing that's required with
9 an inflow tube. I think there is some axial
10 alignment somewhere else.
11 The inflow tube is mentioned somewhere
12 else here, right?
13 Q. Sure. I understand that there are
14 other requirements for the inflow tube, but as
15 for just placement alone, it just says it's
16 inserted into a ventricle of the heart,
17 correct?
18 A. For the placement, yes, that's
19 correct, but you would not place it anywhere
20 else, along the side wall of the ventricle,
21 for example. That would not be physical --
22 physically useful.
23 Q. The claim, for example, doesn't say
24 that the heart assist pump device needs to be

1 placed in the pericardial space?
2 A. Well, the claim says what it says.
3 Q. But it doesn't say "pericardial
4 space," correct?
5 A. It has limitations that it lists,
6 which is the suction end -- suction end of the
7 inflow tube on the heart assist pump is
8 inserted in the ventricle -- into a ventricle
9 of the heart. That's the -- that's what it
10 says.
11 Q. That's what it says about placement,
12 correct?
13 A. Well, again, it's not the only
14 limitation for the inflow tube, but in terms
15 of placing it, it says that it has to go into
16 the -- into the left ventricle of the heart.
17 Q. The other limitations that you're
18 referring to, you're talking about, like,
19 alignment of the various elements --
20 A. Right.
21 Q. -- of the pump, correct?
22 A. Correct.
23 Q. But I just want to focus in on the
24 limitations that relate to placement of the

1 devices.
2 A. Yes.
3 Q. As for placement, what does the claim
4 require?
5 A. Well, the placement requires that the
6 device is delivered to the heart so that a
7 suction end of an inflow tube of the heart
8 assist pump device is inserted into a
9 ventricle of the heart.
10 Q. Okay. Let's go back to Paragraph 150
11 of your declaration.
12 A. Yeah.
13 Q. You say here that you believed
14 Wampler's concept was unachievable, correct?
15 A. Well, the second embodiment.
16 Q. Okay. So you're saying the second
17 embodiment of Wampler describes an
18 unachievable concept, in your view?
19 A. Correct.
20 Q. Is that accurate?
21 A. Correct.
22 Q. Are you disputing that Wampler
23 disclosed the concepts of such a pump and
24 placement at the apex of the heart?

1 MR. CAHILL: Object to form.
2 A. As any patents strive to do, they
3 describe all possible combinations and
4 variations of the invention, right?
5 And then rarely all of them are
6 practical and actually used. So I believe
7 that Wampler discloses to be complete, and I
8 don't know what you make of this configuration
9 in 11 through 15 as to how it's placed and
10 what -- Wampler is silent about this. It was
11 never developed into anything.
12 So I don't know what to make of it
13 beyond what the pictures show, which they
14 don't show that placement of the pump at the
15 apex of the heart. So I don't know what to
16 make of it.
17 BY MS. RAGHAVAN:
18 Q. Okay. So still staying in the same
19 paragraph, you say it took five years after
20 the priority date of the '356 patent for the
21 HVAD to be actually made small enough to be
22 implanted at the apex of the heart, right?
23 A. That's what I said.
24 Q. Why -- explain the phrase "actually

1 made."
2 A. Well, it's one thing to show a picture
3 or a cartoon in an article or in a patent, and
4 the other one is to actually make a prototype
5 of the device or actually a clinical version,
6 clinical prototype of the device that would be
7 useful to be implanted in a human.
8 Q. Is that your understanding of what is
9 required to show obviousness of a claim?
10 MR. CAHILL: Objection.
11 A. I'm not commenting on the obviousness.
12 I'm just commenting on -- I'm explaining what
13 I mean by this text.
14 BY MS. RAGHAVAN:
15 Q. When you say this event happened five
16 years after the priority date of the '356
17 patent, is it correct that you're referring to
18 the 2012 U.S. FDA approval date for the
19 HeartWare HVAD pump?
20 A. Yes, that's correct.
21 Q. Okay. And then earlier in the same
22 paragraph, you said, "This pump received FDA
23 approval for such implantation in 2012, years
24 after the priority date of the '356 patent,"

1 correct?
2 A. I say that, yes.
3 Q. And then you cite two exhibits in
4 support of that sentence?
5 A. Yes.
6 Q. So I'd like to take a look at those
7 two exhibits.
8 The first one you cite is Exhibit
9 2003.
10 A. (Witness reviews document.)
11 Q. You reviewed this article, correct?
12 A. Yes.
13 Q. If you could, turn to page 729 of this
14 article, which is what you cited in your
15 declaration at Paragraph 150.
16 Let me know when you're there.
17 A. (Witness reviews document.)
18 Yes, I'm here.
19 Q. And is it correct that you're
20 referring to the paragraph that says, "Initial
21 clinical trials of the HeartWare LVAD began,"
22 that paragraph?
23 A. Yes, uh-huh.
24 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

1 works and it -- it's not -- it's not very
2 clear at what point -- I mean, I need --
3 certainly FDA approval would mean that the
4 device is workable because it's approved by
5 the FDA, so it's a good, practical, safe, and
6 effective device, right? So that certainly
7 would be one measure by which a POSA would
8 understand that the disclosure of something is
9 sort of -- you know, it works.
10 But I have to think about at what
11 point a POSA would actually consider something
12 viable or not viable. From a sketch to the
13 FDA approval, there's a lot of steps in
14 between. I didn't consider that question
15 carefully, but I can, I suppose.
16 BY MS. RAGHAVAN:
17 Q. So you would agree that there are at
18 least some circumstances in which a POSA would
19 not necessarily need to wait until the FDA
20 approval date to consider a disclosure in a
21 patent to be a viable disclosure?
22 MR. CAHILL: Objection. Outside
23 the scope. Object to form.
24 A. I have to think about how to answer

1 that question more. I can't really -- I
2 wouldn't speculate off the cuff.
3 BY MS. RAGHAVAN:
4 Q. But you're relying on the 2012 FDA
5 approval date, correct?
6 A. Well, FDA approval date will certainly
7 be a good indication for a POSA that the
8 device is viable, you know, commercial, safe,
9 and effective product because FDA said so.
10 That would be a strong indication of this.
11 Q. But prior to obtaining an FDA
12 approval, you understand that devices go
13 through clinical trials, correct?
14 A. Yes.
15 Q. If you can actually turn back to
16 Exhibit 2003 and stay at Paragraph 729, I have
17 a few further questions for you.
18 A. Okay.
19 Q. So same paragraph we were talking
20 about earlier refers to initial clinical
21 trials of the HeartWare LVAD, correct?
22 A. Yes.
23 Q. Did you consider the date of those
24 initial clinical trials in forming your

1 opinions for this IPR?
2 A. No, I did not.
3 Q. Are you aware of the date at which the
4 initial clinical trials started?
5 A. What relevance does it have as to when
6 the trial started?
7 Q. You don't see a relevance of that, do
8 you?
9 MR. CAHILL: Objection.
10 A. I don't know. I have to think about
11 this. I -- I didn't consider that as part of
12 my report.
13 BY MS. RAGHAVAN:
14 Q. Do you see that the article says that
15 "The initial clinical trials of the HeartWare
16 LVAD is as a bridge-to-heart transplant showed
17 patients 30-day and one-year survival rates
18 were 99 and 86 percent, respectively"?
19 A. Yes.
20 Q. Those are pretty high rates, right?
21 A. Well, I suppose they were high enough
22 for the FDA to approve it.
23 Q. So if you saw those numbers as a POSA,
24 would you consider the device that achieves

1 such rates to be a viable device?
2 A. Again, I have to consider -- it goes
3 back to the same question as to at what point
4 the POSA would understand something is good.
5 And I -- I just can't speculate and tell you
6 exactly after the clinical trial, at the
7 beginning of the clinical trial, before the
8 clinical trial, after an animal study.
9 At the end of day, even though the FDA
10 approved the device -- by the way, it came off
11 the market even years afterwards. So it was
12 not -- as it turned out, it was not good
13 enough. So it's a question that requires more
14 consideration.
15 Q. But the HeartWare LVAD device that
16 you're now saying was not good enough formed
17 the basis of your understanding of the size
18 and volume of pump that would be appropriate
19 to be placed in the pericardial space,
20 correct?
21 A. Oh, absolutely.
22 MR. CAHILL: Object to form.
23 BY MS. RAGHAVAN:
24 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

1 device to be sold. It's an approval for the
2 study to start. So they have to have some
3 basic safety measures, I suppose, that need to
4 be demonstrated.
5 Q. Are you aware that to get approval for
6 an IDE, there has to be a reasonable
7 expectation that the disclosed device will
8 work?
9 MR. CAHILL: Objection. Outside
10 the scope.
11 A. Broadly speaking, that is a -- that
12 sounds right.
13 BY MS. RAGHAVAN:
14 Q. But you didn't consider the date of
15 the IDE submission, correct?
16 A. I did not look at the date of the IDE
17 submission.
18 Q. You did not look at the date of the
19 initial clinical trials, correct?
20 A. We covered that ground already. As I
21 said before, the -- I had to draw a line
22 somewhere. So the FDA approval was a good
23 enough indication for me that the device was
24 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.

1 Q. And the fact that the patients' 30-day
2 and one-year survival rates were high much
3 earlier than that 2012 date, you didn't factor
4 that into your analysis?
5 MR. CAHILL: Object to form.
6 A. The report says what it says.
7 BY MS. RAGHAVAN:
8 Q. Let's take a look at the second
9 article that you cite on Paragraph 150, and
10 then after that, maybe it's time for a break.
11 This is the Symalla article, and it's
12 Exhibit 2020.
13 A. (Witness reviews document.)
14 Q. You cite page S-258 of this article,
15 right?
16 A. Yes.
17 Q. Can you turn to that page, please.
18 A. Uh-huh.
19 Q. And I believe you cited the paragraph
20 that starts with "a third generation of
21 LVADs," et cetera, correct?
22 A. Okay.
23 Q. Is that accurate?
24 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

1 what made it possible to implant it at the
2 apex, which is the main point of that
3 paragraph.
4 Q. Do you see that in the Symalla
5 article, Exhibit 2020, it says, "The HVAD was
6 initially evaluated as a BTT device in a
7 European pivotal trial"?
8 A. Yes.
9 Q. And "BTT" stands for bridge to
10 transplant, correct?
11 A. That is correct.
12 Q. And it goes on to say that that trial
13 enrolled 50 patients who received a HVAD as a
14 BTT, correct.
15 A. Where -- oh, yes, on the second page,
16 yes, or second column.
17 Q. It also says towards the end of that
18 long paragraph that "An important finding in
19 the HVAD trial was the decreased incidence of
20 pump thrombosis, and then the HVAD received
21 European CE mark for BTT in 2009 and FDA
22 approval for BTT in 2012."
23 Do you see that?
24 A. Yes.

1 Q. And you rely on the 2012 date for FDA
2 approval, correct?
3 A. Yes.
4 Q. Do you cite the 2009 European CE mark
5 date at all in your declaration?
6 A. I don't.
7 Q. Do you rely at all on the European
8 pivotal trial that's described in the Symalla
9 article you cite?
10 A. It may be considered to be reasonable
11 to have a CE mark as well as FDA approval. So
12 it may be considered that 2009 would be a more
13 appropriate date than 2012. I will give you
14 that.
15 But again, the point of this article
16 was that it still took years afterwards one
17 way or another. And the main -- the main
18 issue here is the size and the weight, not
19 when it was approved. I don't see any
20 relevance as to whether it was approved in one
21 jurisdiction in one year and the other
22 jurisdiction in the other. I cite this as an
23 example that it took years afterward.
24 So the key thing, the key finding that

1 is confirmed by both articles and is what I
2 say here, which is the size and weight of the
3 device is the primary factor that impacts its
4 ability to be implanted at the apex of the
5 heart.
6 Q. Is there any indication from this
7 article or from your other understanding that
8 the size of the HeartWare HVAD was changed
9 from its initial design to it receiving its
10 European CE mark in 2009?
11 MR. CAHILL: Objection. Outside
12 the scope. Objection to form.
13 A. I did not consider that level of
14 detail.
15 BY MS. RAGHAVAN:
16 Q. Is there any indication from this
17 article or otherwise in your personal
18 understanding that there was any change in the
19 size of the HeartWare HVAD pump from the time
20 it received its European CE mark to the time
21 it received USA FDA approval?
22 MR. CAHILL: Same objection.
23 A. I do not know if there is a difference
24 or not.

1 MS. RAGHAVAN: We can set that
2 aside.
3 Do you want to take a break now or...
4 MR. ROLLER: They say lunch is
5 here, so it might be a good time.
6 MS. RAGHAVAN: Let's break,
7 then.
8
9 (Recess taken from 12:36 p.m.
10 to 1:19 p.m.)
11
12 BY MS. RAGHAVAN:
13 Q. Mr. Leschinsky, welcome back from
14 lunch.
15 A. Thank you.
16 Q. Just some general questions for you.
17 Both the Bourque 2001 and Wampler
18 references describe third-generation LVADs,
19 correct?
20 A. Bourque, yes. And then Wampler --
21 well, there are two different embodiments in
22 Wampler. I would consider them differently.
23 The first embodiment is, I would consider,
24 second generation. The third embodiment would

1 be a third generation.
2 Q. Okay. Both Bourque 2001 and Wampler
3 describe implantable LVADs, correct?
4 A. They intend to go inside the body, so
5 in that sense, they're implantable, yes.
6 Q. Both Bourque 2001 and Wampler describe
7 LVADs using magnetic coupling to drive
8 centrifugal -- drive a centrifugal blood pump,
9 correct?
10 A. Well, Wampler, again, there are two
11 different embodiments there. But both
12 embodiments use magnetic torque generation, if
13 you will, to cause the rotation of the rotor.
14 So in that sense, they are similar to Bourque.
15 Q. So I think I heard you agree that they
16 both use magneto coupling to drive the rotor,
17 correct?
18 A. That would be correct.
19 Q. They both use magneto coupling to
20 suspend the rotor?
21 A. "Both" meaning Bourque and Wampler?
22 Q. Correct.
23 A. Well, Bourque, yes, but not both
24 embodiments in Wampler. Only one embodiment,

1 and the second one is suspended.
2 Q. So Bourque 2001 and the second
3 embodiment of Wampler both use magneto
4 coupling to suspend the rotor?
5 A. In both cases, the rotor is suspended
6 by more than just the magneto coupling.
7 Q. Okay. Do they both at least use
8 magneto coupling to suspend the rotor?
9 A. Yeah, that's probably fair.
10 Q. Do both Bourque 2001 and Wampler
11 describe a puck- or disc-shaped elements of
12 the pump -- of the pump? Sorry.
13 A. The only -- of the three pumps, which
14 is the Bourque and the two embodiments of
15 Wampler, I would say that the first embodiment
16 of Wampler is the only disc shape that I can
17 think of. I wouldn't describe others as disc
18 shape, at least the portion that's outside the
19 heart.
20 Q. Do you agree that both Bourque 2001
21 and Wampler sought to improve on some of the
22 drawbacks with second-generation devices?
23 A. Well, the same caveat applies to
24 Wampler: two different embodiments, two

1 different generations.
2 So, broadly speaking, the third
3 generation, which is a full suspension of the
4 rotor, that seek to improve on the second
5 generation, which has thrust bearings, by
6 eliminating them and -- and making the pump
7 safer.
8 Q. And what about for Bourque?
9 A. That's broadly true for all
10 third-generation devices.
11 Q. Would you agree that both Bourque 2001
12 and Wampler aim to reduce thrombosis?
13 A. It's an overarching sort of objective
14 of any pump to not have thrombosis. Reduced
15 thrombosis questions is from what to what. So
16 minimizing thrombosis would probably be a
17 better way to say it.
18 So every -- every design of every
19 blood pump seeks to minimize thrombosis.
20 Q. Is it your opinion that in order for a
21 POSA to combine teachings from different prior
22 art references relating to heart pumps, those
23 pumps must be both implantable and of the same
24 size or volume?

1 A. It's a broad question that needs to be
2 broken down to specifics as to what is common
3 and what is not common.
4 Certain elements may be transferable
5 from one device to another, and certain
6 elements may not be.
7 Q. So just focusing in on the size of the
8 pump, is it your opinion that teachings from
9 two prior art references are not combinable if
10 they talk about pumps of different sizes?
11 A. The same answer. Depends on the
12 specifics.
13 Q. You would agree that before the
14 priority date of the challenged patents, a
15 POSA was generally motivated to make LVAD
16 devices smaller, yes?
17 A. Generally.
18 Q. You would agree that second-generation
19 LVADs are generally smaller than
20 first-generation LVADs?
21 A. Broadly speaking, that's correct.
22 Q. And you would agree that
23 third-generation LVADs are generally smaller
24 than first- and second-generation LVADs?

1 A. On that, I would not necessarily agree
2 with. I think that the third generation would
3 be smaller than the first generation. But in
4 terms of the second generation, that's not
5 clear to me that it would be universally
6 smaller.
7 Q. Can you think of some examples of
8 second-generation devices that are smaller
9 than third-generation LVADs devices?
10 A. Yes. HeartMate II was not necessarily
11 that much different from Bourque Prototype 3.
12 Different shape, but the volume and the weight
13 was probably comparable.
14 Q. The large size of first-generation
15 devices was one factor that was associated
16 with infection rates, correct?
17 MR. CAHILL: Objection. Outside
18 the scope.
19 A. I don't know how to answer that
20 question accurately because, again, we're
21 broadly combining a number of different
22 devices that would be considered first
23 generation, and some had more infection rates
24 than others. So I -- you know, it's not a

1 definitive enough question to -- that I can
2 answer yes or no.
3 BY MS. RAGHAVAN:
4 Q. So let's look at Paragraph 34 of your
5 declaration.
6 A. Yes.
7 Q. You do agree here that size may have
8 been one factor at play?
9 A. Well, as I said before, there is a
10 number of different factors. Size may be one
11 factor. But infection rate is a complicated
12 issue that has to do with the devices, with
13 the implantation technique, with following
14 clinical progression of the patient, the
15 patient's condition. There are many different
16 factors.
17 Q. And size is one of them?
18 A. It may be one of them.
19 Q. Would a POSA have been motivated to
20 make LVAD devices smaller to hope to minimize
21 the risk of infection?
22 A. I wouldn't see it that way
23 necessarily. Generally speaking, smaller is
24 better. Safer is better. Less intrusive is

1 better. So I think the motivation is not
2 necessarily infection but the ability to
3 implant these devices in broader range of
4 patients and with less trauma.
5 Q. What are some motivations for a POSA
6 to design an LVAD device to be smaller?
7 A. Well, that's what I said. To provide
8 assistance to a broader range of patients and
9 to minimize the extent of surgery that is
10 required.
11 Q. So, for example, a POSA may have been
12 motivated to make LVADs that were smaller to
13 treat smaller patients, correct?
14 A. That would be one factor. Again,
15 there is not a single factor that is at the
16 core of optimization when a POSA would be --
17 would design a blood pump.
18 A blood pump has to satisfy a long
19 list of contradicting requirements. And the
20 ability to implant it and actually explant it
21 afterwards would be one of those requirements.
22 But also the device has to be safe. It has to
23 minimize thrombosis, or it has to provide
24 adequate output. It has to do all kinds of

1 things.
2 So size would be one of the factors
3 that certainly, given everything else the
4 same, nobody will try to design a larger pump.
5 But again, I wouldn't think that size is one
6 critical thing that is more important than
7 other requirements.
8 Q. Do you think that placement at the
9 apex of the heart minimizes the extent of
10 surgery compared to placement in the
11 preperitoneal pocket?
12 A. It may.
13 Q. What are the factors that play into
14 that?
15 A. Well, it depends on the size of the
16 incision, for example.
17 Generally speaking, if you have a
18 small pump that is implantable at the apex,
19 you can go through a particular location
20 between the ribs and implant the entire thing
21 without much of a -- cutting the chest open.
22 First-generation devices require open chest to
23 put them in. So that certainly would be
24 minimizing the extent of damage and then

1 postoperation recovery. So that's certainly
2 one factor. Again, it's one of many.
3 Q. So size is just one factor to keep in
4 mind when it comes to placement in designing
5 pumps generally?
6 A. Size is one factor in designing the
7 pumps generally. Location is another factor.
8 And so small enough size allows for certain
9 locations that larger sizes do not.
10 Q. And again, that's a patient-by-patient
11 consideration, correct?
12 A. Well, I mean, they generally separate
13 adults from children, for example, right? So
14 clearly a small child has a different anatomy
15 available for placement for a pump than a
16 large adult.
17 So among adults, one -- a POSA would
18 want to, you know, minimize the size as one of
19 the factors that would allow for easier
20 placement, but that does not mean that they
21 would sacrifice safety, for example, or
22 thrombogenicity of the pump. It's a balancing
23 act.
24 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.)

1 A. Nonstarter configuration.
2 BY MS. RAGHAVAN:
3 Q. I don't think I'm understanding --
4 A. Nonstarter.
5 Q. Nonstarter?
6 A. Yeah.
7 Q. Why?
8 A. Well, many -- a POSA would want to
9 devise -- to design a device that would be
10 practical and would consider implantation
11 technique, for example, as to how to put it
12 in.
13 If you have a large enough size of the
14 pump such as Bourque and you put an
15 intraventricular inflow cannula such as
16 Wampler, how would you put it in? It would
17 not fit in the place next to the apex of the
18 heart, so it would not be implantable like the
19 first embodiment of Wampler.
20 And at the same time, if you remove
21 the elbow, it would also not be implantable in
22 the way Bourque actually implanted his device
23 in the pocket below the diaphragm.
24 So I don't know what you would

1 actually do with this thing once you -- even
2 if you design it.
3 Q. In either situation, though, with or
4 without the elbow, the inflow tube goes into
5 the apex of the heart, correct?
6 A. Well, the device has to take blood
7 from somewhere, so -- from somewhere. It may
8 take blood from the left atrium or the left
9 ventricle.
10 In case of Bourque, there was a
11 connector that goes inside the heart, inside
12 the apex of the upper left ventricle. So in
13 that sense, that statement is correct.
14 Q. Prior to 2007, it was known in the art
15 to have a centrifugal LVAD without an elbow,
16 correct?
17 A. I don't know if it was known in the
18 art. Meaning that it would be implanted at
19 the apex?
20 Q. I'm not asking about the apex. I'm
21 just asking you about whether it was known in
22 the art prior to 2006 to have a centrifugal
23 LVAD without an elbow.
24 A. Well, we need to clarify what that

1 means. "Without an elbow" means that there
2 was a straight tube that goes into the -- into
3 the -- so no elbow means straight, right? So
4 the inlet tube has to be straight.
5 So the inlet tube is usually pointing
6 at the center of the centrifugal pump. So if
7 you have a straight tube -- again, if we're
8 talking about Bourque plus Wampler, for
9 example, if it's a big enough thing, I don't
10 know how you implant that. So in that sense,
11 no, it was not commonly known because it would
12 be a nonsensical configuration.
13 So by definition, to be useful, it has
14 to be small enough and then have the inflow
15 tube that would go into the ventricle of the
16 heart by the apex. So I don't know if it was
17 actually known before.
18 I mean, HeartWare had some probably
19 initial tests around that time -- I don't know
20 before or after -- so that would be probably
21 one example. But I can't think of any --
22 certainly not commercially available LVADs
23 that would have that feature.
24 Q. The Wampler reference doesn't have an

1 elbow, correct?
2 A. Well, the first embodiment does not.
3 The second embodiment, I don't know how you
4 would implant that. So again, it doesn't
5 really say much.
6 Q. Even with the second embodiment, as
7 you said, the pump would have to have an
8 inflow tube, correct?
9 A. Well, any pump would have an inflow
10 tube.
11 Q. And is it possible that the inflow
12 tube could be one without an elbow?
13 A. Possible.
14 Well, again, a POSA would design
15 something with a clinical application in mind.
16 So I know that the drawing shows that -- that
17 similar spindle in the front of both
18 embodiments, but I don't know how you would
19 actually implant that device. And it doesn't
20 say -- the patent itself doesn't really
21 discuss it either. So it's not something that
22 I would necessarily think a POSA would take
23 as a -- as a guidance.
24 Q. When you say the patent itself doesn't

1 disclose that, you're just talking about
2 Figures 11 through 13 --
3 A. Yes.
4 Q. -- specifically, right?
5 A. Yes.
6 Q. Because it does disclose that for the
7 first embodiment?
8 A. Correct.
9 Q. Akamatsu also describes and shows a
10 centrifugal LVAD that doesn't have an elbow in
11 the inflow tube, correct?
12 A. Well, Akamatsu article describes a
13 number of different configurations of the
14 pump, and it doesn't really specify one way or
15 another how they're implanted.
16 The aspirational figure that we're all
17 talking about doesn't show what the inflow of
18 the pump look like. It's a grainy picture
19 that is, again, a schematical representation
20 of the fact that the pump will be positioned
21 somewhere near the heart. That's all I can
22 tell you.
23 It doesn't really say -- it doesn't
24 show clearly the inflow cannula. It doesn't

1 show clearly the position of the pump. The
2 pump itself is -- at least the embodiments
3 that were discussed are the versions -- the
4 configurations were large and would not fit in
5 the apex of the heart. So I don't know what
6 to make of that.
7 Q. Are you familiar with the VentrAssist
8 pump?
9 A. Yes.
10 Q. Is that a centrifugal LVAD without an
11 elbow at the inflow tube?
12 A. I have to look at the -- there was
13 some publication that I believe I looked at.
14 I would like to look at this again just to see
15 what it is.
16 Q. Are you aware of any other pumps that
17 were disclosed prior to 2007 that did not have
18 an elbow at the inflow tube?
19 A. Nothing comes to mind.
20 Q. So let's take a look at Paragraph 176
21 of your declaration and talk about Akamatsu.
22 A. Okay.
23 Q. This is the figure you were referring
24 to earlier, right? Figure 1 is of Akamatsu?

1 A. Yes.
2 Q. In this figure, do you agree that it
3 shows an inflow tube that is inserted into a
4 ventricle of the heart?
5 A. No, I do not.
6 Q. Where else would it be inserted?
7 A. Well, now we're speculating. It
8 doesn't show anything. And so several factors
9 tell me that it may not be even possible to
10 put it this way because of the size of the
11 pump that is disclosed, and the figure doesn't
12 show the inflow cannula at all.
13 I know that you showed it in green
14 here. Nothing in the article points me in
15 that direction.
16 Q. So I understand that you don't believe
17 it's possible, but I'm just asking what is
18 shown in the image?
19 So setting aside the fact that you
20 don't think it's practical -- practically
21 possible, does this image show an inflow tube
22 that's inserted into a ventricle?
23 A. It doesn't.
24 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

1 think, just a configuration of main elements,
2 which is they have a pump. They have an
3 internal controller and an external component
4 on the belt. That's the entirety of what this
5 diagram shows.
6 I wouldn't go much beyond that at all.
7 BY MS. RAGHAVAN:
8 Q. No. I understand what you're saying.
9 I'm asking whether an inflow tube that
10 is inserted into a ventricle of the heart
11 would actually be visible in a drawing like
12 this.
13 A. Well, again, this drawing, when I
14 looked at the clean picture of this, shows
15 some internal structures of the heart. So I
16 would -- I would think that if they were to
17 have that configuration in mind, they could
18 have shown it.
19 Q. Where would it be if you were to -- if
20 you were to attach the pump as it's shown in
21 this photograph, where would you expect the
22 inflow tube to be if it's inserted into the
23 ventricle of the heart?
24 A. I don't -- I have to -- I mean, that's

1 something I did not consider as part of the
2 report.
3 What I -- what I know is what it
4 doesn't show, and that's what I'm saying. But
5 where they can put it, they can put it in
6 different places.
7 Q. In this photograph, where's the left
8 ventricle of the heart?
9 A. Well, it's on the photograph, and then
10 the left ventricle is sort of to the right of
11 the -- of the heart. It's the right section
12 of the heart.
13 Q. Okay. So you're referring to the
14 bottom right, correct?
15 A. More like middle right.
16 Q. Can you -- again, can you just circle
17 where you're looking?
18 A. Well, it's to the right side of the
19 outflow graft.
20 Q. Are you declining to circle things
21 or --
22 A. Well, circle things. I mean, I don't
23 know. The left ventricle is probably here.
24 (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.

1 (Witness reviews document.)
2 Yeah. Well, here they describe their
3 ex vivo study on page 4 of the paper. They're
4 talking about animal studies.
5 Q. Yes.
6 A. And so they say that "The device was
7 evaluated for long-term durability and
8 nonthrombogenicity in a chronic sheep left
9 heart bypass model. Three sheep were
10 anesthetized," blah, blah, blah. "The Dacron
11 outflow graft was sutured to the descending
12 aorta, and the inflow conduit was inserted
13 into the left ventricle through a cuff sutured
14 to the left ventricle apex."
15 So they have little bit of a variation
16 on that theme by suturing the left ventricular
17 -- by suturing a cuff to the LV and then
18 inserting the left inflow -- what is it? --
19 inflow conduit. I'm not sure what the conduit
20 is through that -- through that cuff.
21 So here.
22 Q. So do you agree then that that portion
23 of Akamatsu discloses an inflow tube that can
24 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.

1 It's not what, let's say, hardware
2 would do in terms of placement. They do not
3 have a cuff at all. They just go right
4 through the apex.
5 So I don't know whether it's the same
6 thing or not. It doesn't seem like it's the
7 same thing.
8 Q. Wouldn't you need a cuff to attach an
9 inflow tube as well?
10 A. Not necessarily.
11 Q. But it's one option?
12 A. I suppose so, but it depends on what
13 they use as a conduit. If the conduit is
14 rigid enough, you may not need a cuff. If the
15 cuff is soft and like a Dacron graft type,
16 then they might.
17 Q. Could the inflow conduit be a tube?
18 A. A conduit is something that carries
19 blood flow, so in that sense, it's a tube.
20 Q. If you look at Figure 1 of Akamatsu
21 closely, you can kind of see a projection or a
22 lightly colored tube that is going into the
23 area that you marked as "left ventricle."
24 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

1 indicating.)
2 Because you said that the left
3 ventricle was at the apex, and I said that it
4 was not just at the apex. It's in the middle
5 of the heart, more towards the middle rather
6 than towards the apex. That was my comment.
7 Q. Okay.
8 A. I still stand by my comment. I don't
9 know what it shows. I don't think that the
10 cartoon was intended to show every detail of
11 that configuration.
12 It's just something that shows what
13 they wanted to do at some point. That's why
14 it's not only grainy, but it lacks any detail
15 because they didn't think all those details
16 through yet, which is why I call it
17 aspirational.
18 Q. So Claim 1 of the '356 patent doesn't
19 say anything about an apex, correct?
20 A. No, it doesn't.
21 Q. It generally requires the inflow tube
22 to be inserted into a ventricle of the heart,
23 correct?
24 A. Correct.

1 Q. And the apex of the heart is just one
2 portion of the ventricle of the heart that you
3 were showing me earlier?
4 A. That's correct.
5 Q. Okay. Let's turn to Paragraph 197 of
6 your declaration.
7 A. Okay.
8 Q. This paragraph appears in the section
9 related to limitation 1M of Claim 1 of the
10 '356 patent.
11 Do you see that?
12 A. Yes.
13 Q. And here you're discussing partially
14 the external control unit, correct?
15 A. Yes.
16 Q. Okay. In Paragraph 197, you start off
17 by saying, "Akamatsu is silent regarding what
18 this component is or what any of the other
19 components are in Figure 1."
20 Do you see that?
21 A. And that refers to which component?
22 Q. I was going to ask you that.
23 A. Oh, I see.
24 Well, it refers to the component in

1 the previous sentence, which is the
2 "Petitioner contends that Akamatsu 'teaches or
3 suggests a controller (worn externally in
4 Figure 1)' based on a marked-up version of
5 Figure 1."
6 And in my next paragraph, I'm saying
7 that it's not clear what that green box shows.
8 That's what it is.
9 Q. Is it your opinion that it's
10 impossible for the lime green components shown
11 in the annotation of Figure 1 below Paragraph
12 196 to be an external controller?
13 A. Well, how do you define "an external
14 controller"?
15 Q. What are you requiring the external
16 controller to be as it is recited in the
17 claims?
18 A. Well, a controller has the primary
19 function of operating the device. Is it
20 impossible for this lime green tube to show
21 the main controller that operates the device?
22 I believe so. I don't think that's an
23 external controller -- that it is a controller
24 that operates the device.

1 It may have some secondary
2 functions here and there such as the -- I
3 don't know --
4
5 (Stenographer clarification.)
6
7 A. Such as a percent depletion of the
8 battery here and there, but I don't think that
9 this is a controller.
10 BY MS. RAGHAVAN:
11 Q. Well, so if you look at the
12 Limitation 1N that you have at the top of
13 page 106 --
14 A. Yes.
15 Q. -- it says, "Connecting an external
16 control unit to the heart assist pump device
17 for regulating operation of the second
18 magnetic device."
19 Do you see that?
20 A. Yes.
21 Q. Where does it say that the external
22 control unit has to be the main controller?
23 A. Well, operating the second magnetic
24 device is the main controller. That's what

1 the main controller does.
2 Q. Is that what regulating operation
3 means?
4 A. Of course.
5 Q. So in your mind, this limitation says
6 it's the main controller that is the only
7 controller that's regulating operation of the
8 device?
9 MR. CAHILL: Object to form.
10 A. It's not -- it may not be the only
11 controller, but it's certainly the controller
12 that's responsible for main performance issues
13 associated with the -- with the pump.
14 BY MS. RAGHAVAN:
15 Q. So if -- let's say -- let's say the
16 figure -- the schematic illustration of
17 Akamatsu in Figure 1 shows an internal
18 controller.
19 Is it possible for the lime green
20 device or component to be an additional
21 controller?
22 A. Well, again, it is possible for the
23 lime green to show some additional information
24 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,

1 that's a core function.
2 BY MS. RAGHAVAN:
3 Q. So what if the external controller
4 regulates the operation of the internal
5 controller?
6 Does that satisfy the claim
7 limitation?
8 MR. CAHILL: Objection.
9 A. I did not consider that question.
10 BY MS. RAGHAVAN:
11 Q. Is it your opinion that the claim
12 requires the external control unit to directly
13 control the operation of the second magnetic
14 device?
15 A. How do you define "directly"?
16 Q. I'm trying to understand how you're
17 interpreting regulation -- regulating
18 operation of the second magnetic device.
19 A. Any pump of that type would have a --
20 the main controller that makes it work. So if
21 you were to have here -- for example, the main
22 controller would be the internal implantable
23 controller.
24 You may have some redundancy in some

1 secondary things for the external thing or
2 some diagnostic or something, but the key --
3 if you take the lime green off, the patient
4 will still live.
5 If you take the internal control out,
6 then the patient will die. So that's the
7 difference.
8 I think that, again, you see here that
9 the controller is attached to the belt.
10
11 (Stenographer clarification.)
12
13 A. Belt. Is attached to the belt, and so
14 is the -- one of the coils of the transmission
15 system.
16 And the reason why it's done that way
17 is so that the patient can take it off, for
18 example, during showers, right? So the lime
19 green controller can be removed and the
20 patient would do fine whereas the internal
21 controller cannot be removed. If it's
22 removed, then the patient dies.
23 So, you know, by that definition, a
24 controller that cannot be removed or

1 disconnected is the main controller.
2 BY MS. RAGHAVAN:
3 Q. So if there's an external controller
4 that talks to the main controller that you're
5 saying is the internal controller that then
6 controls the internal operation of the pump,
7 does that satisfy Limitation 1N of the claim?
8 A. I did not consider that question. The
9 question is very clear here, and the language
10 is clear.
11 You have to have a controller that
12 operates the device which is external, and in
13 this case, in my opinion, it is internal.
14 Q. Well, so the claim doesn't exclude the
15 possibility of there being an additional
16 internal control unit, correct?
17 MR. CAHILL: Object to form.
18 A. I'm not sure about that.
19 BY MS. RAGHAVAN:
20 Q. Does the claim require directly
21 regulating operation of the second magnetic
22 device by the external control unit?
23 A. We have to discuss what the word
24 "directly" means.

1 Q. That's not something that you
2 considered?
3 A. I read the claim. The claim says that
4 external control unit is connecting --
5 connecting an external control unit to the
6 heart assist pump device for regulating
7 operation of the second magnetic device. So
8 that's what I read, and that's what I
9 interpreted.
10 Q. So you don't have an opinion one way
11 or the other as to whether an external control
12 unit that talks to an internal control unit
13 within the heart assist pump device to then
14 regulate the operation of the second magnetic
15 device would satisfy limitation 1N of the '356
16 patent?
17 A. That is correct. I did not consider
18 that as part of this.
19 Q. Let's turn to Paragraph 37 of your
20 declaration.
21 In this paragraph, you appear to be
22 talking about the term "magnetic coupling"; is
23 that correct?
24 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

1 patent should not be limited to just rotating
2 magnets, correct?
3 A. Correct.
4 Q. So in support of that opinion, you
5 point to a disclosure in Schima that discloses
6 both rotating magnets and a stator that
7 generates a rotating magnetic field,
8 correct?
9 A. Among other things, yes.
10 Q. So taking those statements together,
11 you're not disputing that Schima discloses
12 magneto coupling, correct?
13 A. I am not disputing that, no.
14 Q. But you also agree that Schima doesn't
15 use the term "magneto coupling"?
16 A. I have to review Schima again for that
17 reference, but I believe that's the -- that
18 Schima broadly describes and discloses
19 magnetic coupling.
20 Q. By providing examples?
21 A. Yes.
22 Q. Do you recall if the Schima reference
23 used the term "magnetic coupling"
24 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

1 disclosure of hydrodynamic bearings or
2 magnetic positioning of its rotor are examples
3 of "by the blood flowing"?
4 A. "By the blood flowing" is describing a
5 spacing between the rotating member and the
6 stationary member, and that spacing is filled
7 by blood. So "by blood flowing" means that
8 it's just filled by blood. That's how I
9 understand it.
10 So Schima does disclose a design,
11 which is a third-generation device, where the
12 rotor is suspended within the housing, and
13 therefore the space between the rotor and the
14 housing is filled by blood.
15 Q. Got it.
16 We can turn back to Paragraph 99. So
17 here you say that "Schima does not teach or
18 suggest any practical implementation of its
19 disclosed pump and instead discloses only
20 details regarding the pump itself."
21 That's correct, right?
22 A. Just a minute. Let me understand the
23 context here.
24 (Witness reviews document.)

1 Okay. Yes.
2 Q. So is it your opinion that the Schima
3 device could not have been used as a heart
4 assist device?
5 A. Schima discloses various uses,
6 including that of pumping blood or, I believe,
7 other sensitive liquids, something like that.
8 So in that sense, it may be used as an LVAD,
9 or it may be used for something else.
10 Q. So nothing in Schima precludes it from
11 being used as a heart assist device?
12 A. Correct. Well, heart assist device,
13 let's define "heart assist device." Is it my
14 definition?
15 Q. Sure.
16 A. Yes.
17 Q. It's your definition.
18 A. Yes. Of course, yes.
19 Q. Were there other definitions of "heart
20 assist device" that you considered?
21 A. Well, I mean, we talked about the
22 Crosby definition versus my definition. So in
23 my definition, it certainly can be used as a
24 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

1 mechanical or physical that touches it.
2 Doesn't mean it doesn't have bearings.
3 Q. So "by the blood flowing" -- the "by
4 the blood flowing" limitation can be met if
5 the pump has a hydrodynamic bearing; is that
6 correct?
7 A. Well, conceivably, yes.
8 Q. And it can also be met if the pump has
9 a magnetic bearing, correct?
10 A. Correct.
11 Q. But it -- in your opinion, it cannot
12 be met if there's a mechanical bearing?
13 A. Like, thrust bearings in the first
14 embodiment of Wampler, that would be a
15 limitation that would not satisfy that.
16 Q. So looking at Figure 2 of the '356
17 patent, can you explain how the rotor that's
18 shown here is suspended such that there's a
19 gap between the rotor and the housing?
20 A. Well, the housing has an outline here,
21 and then the rotor has the first magnetic
22 device that's attached to the rotor, and it's
23 entirely not touched by anything else.
24 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.

1 Then turn back to Figure 2, please.
2 A. Okay.
3 Q. Looking at this diagram as -- from an
4 engineering perspective, would you expect that
5 the first magnetic device, Element 19, and the
6 second magnetic device, Element 16, would
7 exhibit an attractive or repulsive force
8 towards each other?
9 MR. CAHILL: Objection. Outside
10 the scope.
11 A. I did not consider it, but it doesn't
12 have to be a binary choice.
13 BY MS. RAGHAVAN:
14 Q. What are the other options?
15 A. Well, they may have some magnets in
16 some locations and some -- I mean, I wouldn't
17 just -- starting the analysis, I wouldn't
18 necessarily limit myself to these two choices,
19 but I did not do the analysis on this
20 question.
21 Q. What about the magnetic interaction
22 between Element 16 and 19 in Figure 2 prevents
23 the rotor from impinging on the bottom surface
24 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?

1 MR. CAHILL: Object to form.
2 A. It's a broad characterization. I say
3 what I say in the report with regard to
4 specific embodiments for pumps or
5 configurations implying in a particular way.
6 That's what I do.
7 BY MS. RAGHAVAN:
8 Q. You considered the practicality of
9 whether the pumps can be used as shown in the
10 schematics of the various prior art devices,
11 correct?
12 MR. CAHILL: Object to form.
13 A. I considered different ways of
14 implanting based on the available data that I
15 looked at.
16 BY MS. RAGHAVAN:
17 Q. I mean, you reached the conclusion in
18 some cases that some of the concepts that were
19 disclosed in those prior art references were
20 practically impossible, correct?
21 MR. CAHILL: Object to form.
22 A. Yes.
23 BY MS. RAGHAVAN:
24 Q. Did you do a similar analysis for the

'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.

1 MS. RAGHAVAN: Yes. Thank you.
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3 (Deposition concluded at 2:42 p.m.)
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1 CERTIFICATION

2 I, DARLENE M. COPPOLA, a Notary Public, do hereby
3 certify that BORIS LESCHINSKY, after having
4 satisfactorily identifying himself, came before me on
5 the 10th day of December, 2025, in Boston,
6 Massachusetts, and was by me duly sworn to testify to
7 the truth and nothing but the truth as to his
8 knowledge touching and concerning the matters in
9 controversy in this cause; that he was thereupon
10 examined upon his oath and said examination reduced to
11 writing by me; and that the statement is a true record
12 of the testimony given by the witness, to the best of
13 my knowledge and ability.
14 I further certify that I am not a relative or
15 employee of counsel/attorney for any of the parties,
16 nor a relative or employee of such parties, nor am I
17 financially interested in the outcome of the action.
18 WITNESS MY HAND THIS 14th day of December, 2025.
19
20 Darlene M. Coppola
21 DARLENE M. COPPOLA My commission expires:
22 NOTARY PUBLIC November 2, 2029
23 REGISTERED MERIT REPORTER
24 CERTIFIED REALTIME REPORTER

1 PATENT AND TRIAL APPEAL BOARD
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3
4 **********
5 ABBOTT LABORATORIES,
6 Petitioner
7 vs. NO. IPR202500096 (PTAB)
8 MIRACOR MEDICAL SA,
9 Patent Owner
10 **********
11
12 I, BORIS LESCHINSKY, say that I have read the
13 foregoing deposition and hereby declare under penalty
14 of perjury the foregoing is true
15 and correct: (as prepared) (as corrected on errata.)
16 Executed this _____ day of _____,
17 2025, at _____, _____.
18
19
20 _____
21 BORIS LESCHINSKY
22
23
24

1 CORRECTION PAGE

2 DEPONENT: BORIS LESCHINSKY

3 DATE TAKEN: DECEMBER 10, 2025

4 CASE: ABBOTT LABORATORIES

5 VS. MIRACOR MEDICAL SA

6 **********

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