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BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,	)	CASE NOS.
	)	IPR2025-00096
PLAINTIFF,	)	IPR2025-00112
	)	IPR2025-00113
V.	)	IPR2025-00114
	)	IPR2025-00115
MIRACOR MEDICAL SA,	)	IPR2025-00116
	)	
DEFENDANT.	)	MOBILE VIDEOCONFERENCE
	)	DEPOSITION OF
		ROBERT GALLEGOS, M.D.

MOBILE VIDEOCONFERENCE DEPOSITION OF ROBERT
GALLEGOS, M.D., taken remotely before Cheryl A. Rooney,
RPR, CRR, Online General Notary Public within and for
the State of Nebraska, beginning at 9:00 a.m., on
December 15, 2025.

APPEARANCES

(Appearing Remotely)
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(Appearing Remotely)
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Peter Crosby (Appearing Remotely)

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EXAMINATION

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EXHIBITS

EXHIBIT NO.	MARKED
Exhibit 1038 Article Re: HeartWare pump	94
Exhibit 1039 Article Re: Animal Models For Cardiac Research	136

REPORTER'S NOTE: All quotations from exhibits are reflected in the manner in which they were read in the record and do not necessarily reflect exact quotes from the source documents nor necessarily match the punctuation.

1 (Whereupon, the following proceedings
2 were had, to-wit:)

3 ROBERT GALLEGOS, M.D.,
4 having been first duly sworn,
5 was examined and testified as follows:

6 DIRECT EXAMINATION

7 BY MS. RAGHAVAN:

8 Q. Good morning, Dr. Gallegos.

9 A. Good morning.

10 Q. My name is Saranya Raghavan. I am an
11 attorney for petitioner, Abbott Laboratories in
12 this case. A few moments ago you took an oath
13 to tell the truth. Do you remember that?

14 A. Yes.

15 Q. Is there any reason why you would not
16 be able to offer truthful, complete, and
17 accurate testimony today?

18 A. Not to my knowledge, no.

19 Q. Have you been deposed before?

20 A. Yes.

21 Q. How many times?

22 A. Oh, a handful of times related
23 primarily to other patent -- cardiovascular
24 patent-related issues.

25 Q. Were those in patent litigations?

1 A. Yes.

2 Q. Would you say it was more than five
3 times?

4 A. I'd say it's probably around that
5 number, about five times.

6 Q. Okay. Approximately when were those
7 depositions?

8 A. Most recent one would have been this
9 year for a separate project involving a
10 cardiovascular implant not related to this
11 topic, and then vast majority of them would have
12 been probably within the last three years. But
13 I don't recall the exact dates of all of them,
14 no.

15 Q. Have you ever testified in another
16 proceeding against Abbott?

17 A. No.

18 Q. So just so that we are clear on the
19 ground rules for today, I'll go through them
20 again, although I understand that you've done
21 this a few times before. Just to make sure our
22 life is easier and the court reporter's life is
23 easier today, who is taking down everything that
24 everybody will be saying today, it is very
25 important that you answer my questions with

1 words instead of gestures or hand nods or any
2 other kind of nonverbal movement; is that fair?

3 A. Understood.

4 Q. This is especially important because
5 we are in a virtual setting today. So I'd
6 appreciate it if you kept your voice up, and if
7 for whatever reason you're not able to hear me
8 or if my voice becomes unclear, please do let me
9 know.

10 A. I understand.

11 THE WITNESS: This one will go to
12 the court reporter. If I start speaking too
13 fast, don't feel bashful; tell me to slow down.
14 Unfortunately as physicians we often speak too
15 fast. So if I'm going too fast, let me know.

16 THE COURT REPORTER: Thank you.

17 BY MS. RAGHAVAN:

18 Q. It's also important that we do not
19 interrupt each other. And to that end, please
20 make sure to wait until I finish my question
21 before you answer, and I will wait until you
22 finish your answer before I ask my next
23 question. Is that fair?

24 A. That's fair.

25 Q. If at any time you don't understand

1 one of my questions, please let me know and I
2 will try to rephrase it; is that fair?

3 A. That's fair.

4 Q. We'll try to take a break every hour,
5 hour and a half or so, but let me know if you
6 need an additional break or a break sooner than
7 that. Is that fair?

8 A. Yes.

9 Q. Generally, unless there's a question
10 pending, we can accommodate a break.

11 A. Understand.

12 Q. Your counsel may from time to time
13 object to some of my questions, but unless your
14 counsel instructs you specifically not to
15 answer, you must answer my question; do you
16 understand that?

17 A. I understand.

18 Q. Is there anyone else in the room with
19 you today?

20 A. Nobody.

21 Q. Do you have any printed notes or
22 materials with you today?

23 A. So the only thing I do have is a fresh
24 binder with all the exhibits just because again,
25 we're in the virtual environment. But my

1 counsel did send me a clean copy of all of the
2 exhibits that I've cited at least in my
3 documents so that I would have available to me
4 in case we had an issue. That's the only thing
5 I have.

6 MS. RAGHAVAN: So Counsel, for
7 the record, are these clean copies of the
8 exhibits, with no attorney annotations and
9 highlights, those kind of things?

10 MR. VARE: That is correct.

11 BY MS. RAGHAVAN:

12 Q. When you say "exhibits," can you
13 clarify whether they are just exhibits to your
14 declaration or do you have exhibits to the
15 entire proceeding so far?

16 A. I believe you should have a listing of
17 all of the exhibits, at least the ones that are
18 pertinent here. They're numbered, at least in
19 mine, 1 through -- I'm flipping it here, the
20 table of contents is about 30 citations that
21 these would include, the patents, my report,
22 that sort of thing, the documents in terms of
23 papers that are referred to in my report.

24 Q. Got it, okay. So you have a clean
25 copy of your declaration that you submitted in

1 these proceedings?

2 A. Yes.

3 Q. And then as far as the exhibits, just
4 in terms of the terminology, I believe the
5 exhibits here are marked either 1000 something
6 when they're on behalf of the petitioner, or
7 2000 something when they're on behalf of the
8 patent owner. So I want to make sure when I'm
9 referring to an exhibit number you know which
10 one to look at.

11 A. Yes. I have exhibits, that are, for
12 example, 1003 through Exhibit 1018, I believe,
13 and then Exhibits 2013 through Exhibit 2022.

14 Q. Okay, perfect. So I think to just
15 make things easier for you, if it's your
16 preference, as long as you have a printed copy
17 of an exhibit, I'm fine for you to refer to your
18 paper copy of the exhibit. Again, if it's
19 easier for you to look at electronically, I'm
20 fine for you to do that as well, but since these
21 are all premarked exhibits for the most part,
22 you can refer to your paper copy. There may be,
23 during the course of this deposition, some
24 documents that have not yet been introduced as
25 exhibits, and then we will look at those

1 electronically; is that fair?

2 A. That's fair. If I'm not sure which
3 one you're asking, I may ask you to put it up
4 electronically just so I can verify that what
5 I'm looking at in paper is corresponding what
6 you're asking me to look at it. But yes, I
7 prefer to look at it on paper, if I can, just
8 because the screens make it a little bit tough
9 sometimes to read.

10 Q. Absolutely. I have quite the
11 tessellation of windows going on right now, so I
12 can appreciate that, too.

13 A. Yes.

14 Q. Okay. So backing up a little bit,
15 Dr. Gallegos, you were retained by Miracor, the
16 patent owner in this case; correct?

17 A. Correct.

18 Q. And you were retained as a technical
19 expert in this proceeding?

20 A. Correct.

21 Q. You submitted a declaration in six
22 IPRs that were filed by Abbott against six
23 Miracor patents; is that correct?

24 A. That's correct.

25 Q. And it's my understanding that you

1 filed the same declaration in all six IPRs. Is
2 that your understanding?

3 A. That's correct.

4 Q. Do you understand that the six Miracor
5 patents that are at issue in the six IPRs are
6 related patents?

7 A. I understand.

8 MR. VARE: Object to form.

9 BY MS. RAGHAVAN:

10 Q. We'll start by introducing
11 Exhibit 2017 for the record. That is a copy of
12 your declaration in these proceedings.

13 A. Okay.

14 MR. VARE: Are you going to like
15 introduce it for the court reporter's benefit?

16 MS. RAGHAVAN: I am trying to but
17 it's saying it's already marked so I'm trying to
18 figure out why that is. Give me one second. So
19 I've now introduced Gallegos Exhibit 2017 as an
20 exhibit, premarked exhibit, and I understand,
21 Dr. Gallegos, that you have a printed copy of
22 your declaration as well.

23 THE WITNESS: I do. I actually
24 don't see anything coming through on Exhibit
25 Share, just to let you know.

1 MR. VARE: Sometimes you just
2 need to refresh it. It takes a few seconds.

3 THE WITNESS: There we go. Just
4 wanted to make sure everything was coming
5 across. Yes, it's coming across now.

6 MS. RAGHAVAN: Just for
7 propriety, if you could compare the cover page
8 of the electronic document to the paper copy of
9 the document you have in front of you to verify
10 that they are in fact the same.

11 THE WITNESS: Yes, the cover
12 sheet appears to be correct.

13 BY MS. RAGHAVAN:

14 Q. The declaration that you have in front
15 of you, it's 57 pages long; correct?

16 A. Yes.

17 Q. And on the very last page, on Page 57
18 of your declaration, that's your signature;
19 correct?

20 A. Yes, it is.

21 Q. Did you review the final copy of your
22 declaration before it was submitted to the PTAB?

23 A. Yes.

24 Q. And you signed this declaration on
25 September 30, 2025; correct?

1 A. Yes, as dated.

2 Q. Dr. Gallegos, you have an
3 undergraduate degree in biomedical engineering;
4 is that right?

5 A. That's correct.

6 Q. You've never practiced as an engineer,
7 though?

8 A. No. I've practiced as a --
9 essentially I've been a practicing physician. I
10 did additional training in engineering after my
11 undergraduate year. So I did a Ph.D., which
12 involved a fair number of graduate engineering
13 courses at the University of Minnesota as well.
14 And then over the course of my research years at
15 the university, I did extensive work in
16 cardiovascular research. That's what my Ph.D.
17 was really focused on.

18 Q. But you didn't hold a title as an
19 engineer at a company outside of your research?

20 A. That would be correct.

21 (Discussion was had off the record.)

22 BY MS. RAGHAVAN:

23 Q. Dr. Gallegos, you don't have any
24 experience designing or developing implantable
25 medical devices; is that right?

1 A. My experience with medical devices
2 comes in the arena of testing devices for FDA
3 approval to move along, particularly in the
4 animal, preclinical arena, as well as in the
5 postclinical, first human clinical phases, I've
6 been involved in multiple clinical trials with
7 medical devices. So I do have extensive
8 experience with the testing of medical devices,
9 both in the preclinical animal settings and in
10 the human settings.

11 Q. So your experience is with testing
12 implantable medical devices; is that fair?

13 MR. VARE: Objection; form.

14 THE WITNESS: As I said before,
15 my experience has been within the process of
16 devices that are being tested, both in the
17 animal setting and in the human clinical trial
18 settings.

19 BY MS. RAGHAVAN:

20 Q. But you don't have any experience with
21 designing implantable medical devices; is that
22 fair?

23 MR. VARE: Objection; form.

24 THE WITNESS: Again, the concept
25 of preclinical testing and postclinical testing

1 is all aimed at making sure that these devices
2 are safe. So yes, it still does impact the
3 design of medical devices. We have to be
4 integrated in terms of what the design changes
5 are when we're testing --

6 COURT REPORTER: (Requests
7 clarification.)

8 THE WITNESS: A little slower.
9 So I guess to the extent I can answer your
10 question, yes, I've been involved in the design
11 and development of these devices because the
12 testing phase does involve understanding what
13 the design changes are, what the factors are
14 that we're looking at. So I would disagree with
15 your statement that I don't have experience. I
16 do.

17 BY MS. RAGHAVAN:

18 Q. Which phase of the development cycle
19 of an implantable medical device do you usually
20 step in?

21 MR. VARE: Objection; form.

22 THE WITNESS: I think I've
23 already answered that question in the sense that
24 I've been involved in both preclinical animal
25 testing and in human testing. So in many of

1 those phases. But again, it would depend on the
2 specific medical device that you're talking
3 about in terms of where --

4 COURT REPORTER: (Requests
5 clarification.)

6 THE WITNESS: I would say it
7 depends on the specific device you're testing
8 for me to make a blanket statement that I always
9 answer at this phase only, or I'm always
10 involved. That would be inappropriate. It
11 depends on the specific device.

12 BY MS. RAGHAVAN:

13 Q. Are you an inventor on any implantable
14 medical devices?

15 A. I am not listed as -- if you're asking
16 me am I a patent holder? No, I don't hold any
17 current patent licenses myself, no. But I have
18 been involved in the patent process with devices
19 that not necessarily have gone all the way
20 through fruition. So I do have an understanding
21 of the patent process.

22 Q. When you say you've been part of the
23 patent process, what do you mean?

24 A. Well, depends, again, on the
25 particular patent that you're talking about in

1 certain cases. I was the originator of the
2 idea, and the University and its attorneys
3 basically were involved from the get-go in terms
4 of taking it from idea to filing for patent and
5 the like. So I was involved in every stage at
6 that point from idea all the way through the
7 point where we're essentially asking the
8 question, is this patentable or is there an
9 existing patent that would predate this. So
10 again, I understand the process from idea to
11 awarding of patent very well.

12 Q. Would your name be listed as a named
13 inventor on those patents?

14 A. Well, again, as I said before, I don't
15 have a patent that I hold so it would have been
16 listed. But again, since I don't have a patent
17 number to offer you, no, there wouldn't be a
18 patent to look at that has my name listed as the
19 inventor.

20 Q. You obtained your engineering
21 undergraduate degree in 1994; is that right?

22 A. Yes, from UC San Diego.

23 Q. And immediately after that you started
24 your medical school at the same university?

25 A. That would be correct.

1 Q. You're offering opinions in this
2 proceeding today as a cardiac surgeon; correct?

3 A. I guess I don't understand --

4 MR. VARE: Objection; form.

5 THE WITNESS: I don't understand
6 the question.

7 BY MS. RAGHAVAN:

8 Q. The opinions that you've offered in
9 your declaration are from the perspective of a
10 surgeon, not from the perspective of an
11 engineer; correct?

12 MR. VARE: Objection; form.

13 THE WITNESS: I would say, again,
14 if you read my report it states that I am giving
15 my opinions as a person of skill in the art in
16 looking at this particular topic as it pertains
17 to the patents in question. So if you, again,
18 look at the report and read the report, my
19 opinions are pretty clear in terms of my
20 positions in terms of my statements.

21 I don't know that you can ask me to
22 separate my skills in terms of which brain am I
23 using. Am I talking specifically about
24 engineering principles? If you can show me a
25 point in my report where I specifically talk

1 about engineering principles, I can tell you
2 that perspective. But again, for me to answer
3 your question, I'm both an engineer and a
4 surgeon. So it's difficult to say I'm turning
5 one part of my brain off, if you want to ask in
6 that sense.

7 BY MS. RAGHAVAN:

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

10 A. Well, first thing is, of course, I
11 reviewed all of the documents involved. That
12 would include the patents in question. I
13 reviewed my own report. Anything that my own
14 report referred to in terms of documentation I
15 of course reviewed as well.

16 I did have meetings with my counsel
17 with regards to the logistics of the -- of this
18 deposition in terms of, well, first going from
19 in-person to Zoom to the like.

20 Q. When you say your "counsel," who are
21 you referring to?

22 A. Well, the individuals that are
23 involved. Todd, who is currently on the screen,
24 is one of those individuals, and Mr. Roller
25 would be the other.

1 Q. Do you recall when those meetings were
2 with your counsel?

3 A. They would have been in the last two
4 days to talk about logistics in terms of how we
5 were going to accomplish this, given the weather
6 and the changes.

7 Q. How many meetings did you have with
8 your counsel?

9 A. I believe we had two Zoom meetings
10 that I can recall. We did have some other
11 verbal -- well, I should say communication via
12 text in terms of organizing those meetings but
13 nothing of context would have gone on in those
14 conversations.

15 Q. Approximately how long did you meet
16 with your counsel?

17 A. It, I believe, was probably no more
18 than three hours total. I don't recall the
19 exact amount of time. But roughly about three
20 hours, I would say.

21 Q. Have you reviewed Mr. Leschinsky's
22 declaration in preparing your own declaration?

23 A. No, I did not.

24 Q. Have you met with Mr. Leschinsky?

25 A. No, I have not. I have never met him,

1 spoken to him in any form, whether it be
2 electronic or otherwise.

3 Q. Are you aware that he was deposed last
4 week?

5 A. Counsel did mention it to me but
6 that's about it.

7 Q. Did you review the transcript from his
8 deposition?

9 A. No. I wasn't part of his deposition,
10 so no.

11 Q. Other than reviewing your declaration
12 and the materials cited within, and meeting with
13 your counsel regarding logistics, is there
14 anything else you did to prepare for today's
15 deposition?

16 A. I had a good breakfast. That's about
17 it. No.

18 Q. That's always helpful.

19 A. Yes. Extra coffee.

20 Q. Let's turn to Paragraph 2 of your
21 declaration.

22 A. Do you have a page number? That will
23 probably make it a little faster.

24 Q. It's Page 6.

25 A. Page 6. Thank you. I'm there.

1 Q. Okay. It says here that you're being
2 compensated for your work in this case at a rate
3 consistent with your clinical compensation. Do
4 you see that?

5 A. Yes, I do.

6 Q. What is your hourly rate for this
7 matter?

8 A. My hourly rate is \$600.

9 Q. Approximately how many hours did you
10 spend drafting your declaration?

11 A. To be honest, I don't recall that I
12 absolutely tracked the exact number of hours.
13 It was, you know -- I would only be able to give
14 you a best guesstimate. It was over 40 hours,
15 but I don't recall. Some of this involved
16 reading documents, allowing it to, again, sit in
17 your mind, come back, read, rereview documents.
18 Also included looking at other documents that
19 might have been referenced. So it would have
20 been over 40 hours but I don't recall the exact
21 number.

22 Q. In several places in your declaration
23 you use the acronym LVAD. You're aware of that
24 acronym?

25 A. Yes.

1 Q. LVAD stands for left ventricular
2 assist system; correct?

3 A. Assist device.

4 Q. Assist device.

5 A. But oftentimes those terms can be used
6 interchangeably, assist system versus device,
7 but yes.

8 Q. What is your definition of an LVAD?

9 MR. VARE: Objection; form.

10 THE WITNESS: Well, again, the
11 acronym itself specifically defines what a left
12 ventricular assist device is. It's a device
13 that assists the left ventricle in terms of its
14 function.

15 BY MS. RAGHAVAN:

16 Q. In your opinion is an intraaortic
17 balloon device an LVAD?

18 MR. VARE: Objection; form.

19 THE WITNESS: I guess could you
20 ask your question in a way that's a little bit
21 more explicit?

22 BY MS. RAGHAVAN:

23 Q. What do you not understand about the
24 question?

25 A. Sorry. Are you asking me can an

1 intraaortic balloon pump assist the left
2 ventricle in its function? The answer would be
3 yes, it can.

4 Q. So would you consider it to be an
5 LVAD?

6 A. I would consider it to be grouped in
7 the same category as other devices that are
8 considered to be left ventricular assist
9 devices, yes, because it does assist in the
10 function of the left ventricle.

11 Q. What is the distinction you're drawing
12 there among the group of devices that are
13 considered to be left ventricular assist
14 devices?

15 MR. VARE: Objection; form.

16 THE WITNESS: Well, I'll go back
17 to your original question you asked me in terms
18 of what does left ventricular assist device
19 mean. As I said before, it's a device that
20 assists in the function of the left ventricle.
21 So in the example that you asked me about,
22 intraaortic balloon pump, it would, again, go to
23 the understanding of how an intraaortic balloon
24 pump functions.

25 So a balloon pump basically improves

1 coronary perfusion. If you improve coronary
2 perfusion to the left ventricle, you will
3 improve left ventricular function. So it can be
4 grouped in the category of devices that would be
5 considered a left ventricular assist device.

6 Q. In your practice as a cardiac surgeon
7 would you understand an intraaortic balloon
8 device to be an LVAD?

9 MR. VARE: Objection; form.

10 THE WITNESS: I think I've
11 already answered that question. I would say
12 that if you're asking me can it be grouped and
13 considered a left ventricular assist device,
14 anybody who -- let me rephrase that.

15 A person of skill in the art would
16 understand that if I'm asked to assist in the
17 improvement of the function of the left
18 ventricle, yes, it does that function. Now,
19 again, everything is to a degree. In the same
20 sense that if you ask me would a transplant be
21 considered a left ventricular assist device,
22 well, if I'm replacing one left ventricle for
23 another in improving its function, then that in
24 general could be, again, considered as part of
25 devices that would be considered left

1 ventricular assist devices. So all of these
2 devices are grouped within that category.

3 If you want a more specific
4 definition, then you'd have to provide me that
5 specific definition so that I could get at what
6 you're trying to discern. But again, these
7 devices do assist the left ventricle in terms of
8 its function.

9 Q. Are you distinguishing between what is
10 traditionally known as an LVAD to a device that
11 has the same functionality as an LVAD?

12 MR. VARE: Objection; lacks
13 foundation.

14 THE WITNESS: Again, you asked me
15 what the definition of a left ventricular assist
16 device is; I have provided it. You asked me
17 whether an intraaortic balloon pump would
18 satisfy that definition. It can.

19 BY MS. RAGHAVAN:

20 Q. Well, I asked you a more
21 straightforward opinion. I asked you if in your
22 opinion is an intraaortic balloon device an
23 LVAD, but you told me that you would group these
24 devices together based on their functionality.
25 So I do not understand why you cannot answer my

1 question yes or no.

2 MR. VARE: Objection; misstates
3 his testimony. He answered the question yes.
4 His testimony speaks for itself. And you're now
5 being argumentative of the witness.

6 THE WITNESS: So I guess my
7 question back to you would be if I'm not
8 understanding your question, please restate your
9 whole question so that I can understand what
10 you're trying to ask me because to my
11 understanding, I have answered your question.
12 But to yours, it appears I haven't. So please,
13 if you want, restate the whole question and I'll
14 try to answer that question.

15 BY MS. RAGHAVAN:

16 Q. I'm trying to understand whether
17 there's a difference in your mind between a
18 device that is considered an LVAD and a device
19 that shares the same functionality as an LVAD.

20 MR. VARE: Objection. I'm not
21 sure that's even a question.

22 THE WITNESS: Yeah, I can
23 honestly say I'm not sure that I understand the
24 question, still.

25 MS. RAGHAVAN: Todd, if you could

1 stop coaching the witness during the deposition,
2 that would be great.

3 MR. VARE: Well, I'm not. Your
4 job is to ask questions.

5 MS. RAGHAVAN: I am asking
6 questions. But it would be great if you like
7 didn't interject at every question to put in
8 your speaking objections. But thank you.

9 MR. VARE: I am not putting in
10 speaking objections.

11 THE WITNESS: So again, I still
12 don't understand your question. So if you would
13 like to restate it, please do.

14 BY MS. RAGHAVAN:

15 Q. Is there a difference between a device
16 that increases cardiac output to the whole body
17 versus an intraaortic balloon pump that you said
18 increases perfusion?

19 A. Well, by definition, by improving
20 perfusion to the heart, the heart function will
21 improve, which would improve the cardiac
22 function to the whole body. So again, by
23 function and mechanism, an intraaortic balloon
24 pump is a left ventricular assist device. So
25 again, there are many different types of left

1 ventricular assist device, but in the broadest
2 of terms when you're telling me what is a left
3 ventricular assist device, all of those devices
4 can fall into that category. If you want a more
5 specific look at which type of left ventricular
6 assist device, because there are different types
7 of left ventricular assist devices, again, I can
8 consider that question. Can they be considered
9 in the same grouping as left ventricular assist
10 devices? Yes.

11 Q. What are the different types of left
12 ventricular assist devices?

13 A. Well, again, the simplest would be a
14 balloon pump, an Impella, a use of ECMO, the use
15 of permanently implanted left ventricular assist
16 devices, the use of temporary assist devices
17 that are pumps that are essentially blood pumps,
18 the heart-lung machine --

19 COURT REPORTER: (Requests
20 clarification.)

21 THE WITNESS: So as I said
22 before, everything from intraaortic balloon
23 pump, which will improve coronary perfusion.
24 Impella devices that will, again, improve left
25 ventricular function, improve coronary

1 perfusion. ECMO, which improves coronary
2 perfusion and heart function. Both temporary
3 and permanently implanted devices that could
4 improve coronary perfusion, as well as
5 heart-lung machine, which essentially again is
6 another type of blood pump. So all of these can
7 be considered as left ventricular assist
8 devices.

9 What I would exclude would be
10 medications, for example, that can be infused
11 that would improve cardiac function because that
12 is not necessarily a device. That would be a
13 pharmaceutical. So in that sense, that's
14 where -- if you want to say draw the line, these
15 are all devices that can improve cardiac
16 function, as opposed to pharmaceuticals that can
17 also improve cardiac function.

18 Q. Is there a basis for your
19 understanding that an LVAD includes these
20 various types of devices?

21 A. I would say about 30 years of training
22 and practice.

23 Q. Did you cite a dictionary definition,
24 for example, in your declaration as to what an
25 LVAD means?

1 A. I don't specifically recall. If you
2 know a place in my report that you can point to,
3 we can go through it more. But again, if you're
4 asking me my opinion of what LVAD stands for, I
5 have given you that opinion and I have given you
6 what my thoughts are in terms of what does it
7 mean. Well, a device that supports and improves
8 the function of the left ventricle.

9 Q. So under your definition is a direct
10 cardiac compression device an LVAD?

11 A. If it improves the function of the
12 left ventricle, yes, it could be also grouped in
13 that.

14 Q. Does it?

15 A. If it's applied correctly, it can.
16 Again, all devices, if they're not properly
17 used, may not improve the function of the left
18 ventricle. So again, if it's properly applied
19 and utilized, yes, it can.

20 Q. In your opinion is an aortic
21 counterpulsation device an LVAD?

22 A. Are you referring to an intraaortic
23 balloon pump?

24 Q. These are all devices that
25 Mr. Leschinsky pointed to, so I'm trying to

1 understand what the terminology is in terms of
2 how he's phrasing it. So do you have an
3 understanding of what an aortic counterpulsation
4 device is?

5 A. Well, I can only assume he is trying
6 to speak towards an intraaortic balloon pump,
7 which accomplishes that task. I'm not sure if
8 he's speaking to another device. I'm not sure
9 that I -- I haven't spoken to him, so I'm not
10 sure what terminology he is using. But for me
11 that would imply an intraaortic balloon pump, I
12 believe.

13 Q. Is your answer as to whether it would
14 be an LVAD would be the same as your answer that
15 you gave earlier for an intraaortic balloon
16 device; correct?

17 A. Assuming that we're both speaking of
18 the same sort of device, yes.

19 Q. In your opinion, is a catheter with an
20 inflow placed in the left atrium as opposed to
21 the left ventricle considered an LVAD?

22 MR. VARE: Objection; form.

23 THE WITNESS: Well, it depends on
24 what this catheter is attached to. The catheter
25 itself placed there with no -- if you want to

1 call it -- whether it be a pump of some form
2 that performs the function, a catheter alone
3 won't do it. So again, we can place catheters
4 in a lot of different places but for example, I
5 wouldn't consider, for example, a Swan-Ganz
6 catheter a left ventricular assist device. That
7 is a cannula that travels from the internal
8 jugular vein through the right atrium through
9 the right ventricle into the pulmonary artery.
10 It is a diagnostic tool, not necessarily an
11 assist device in the sense that it's not
12 providing any function.

13 So when it comes to the question about
14 a catheter in the left atrium versus a catheter
15 in the left ventricle, the presence of the
16 catheter alone doesn't necessarily, to me, imply
17 that it's performing the function of improving
18 the left ventricle. So what is that catheter
19 attached to.

20 Q. If a catheter is attached to a heart
21 pump and it has an inflow that's placed in the
22 left atrium rather than in the left ventricle,
23 would that be considered an LVAD?

24 MR. VARE: Objection --

25 THE WITNESS: That could be

1 considered part of a left ventricular assist
2 device because you would also need another --
3 again, if I'm removing blood from the left
4 atrium with a pump but not returning it to the
5 body, then no, it wouldn't be considered left
6 ventricular assist device because you have to
7 have both an inflow to the pump and an outflow
8 to the body.

9 So if it was in total that system,
10 then yes, I would say that a catheter inflow
11 coming from the left atrium can function as part
12 of a left ventricular assist device, yes.

13 BY MS. RAGHAVAN:

14 Q. Are you familiar with Abbott's
15 commercialized HeartMate 3 pump?

16 A. Yes.

17 Q. Have you ever implanted the HeartMate
18 3 in a human?

19 A. No. I was -- right at the time when I
20 left the field in terms of no longer implanting,
21 we were in the process of onboarding the
22 HeartMate 3 but I did not get a chance to
23 implant it. I had to go through the training,
24 but I did not clinically use the device.

25 Q. When you say "we," who are you

1 referring to?

2 A. Well, at the time I was working at The
3 Christ Hospital in Cincinnati, Ohio, so our
4 entire team would have been involved in the
5 trainings. So that would have included myself,
6 other implanting surgeons, our heart failure
7 cardiologist, our anesthesiologist, our
8 perfusionist, our VAD coordinators, our nursing
9 staff. So that's what I mean by "we."

10 Q. Have you ever implanted the HeartMate
11 3 in an animal?

12 A. No. That would have been the next
13 phase in the training just prior to human use.

14 Q. Got it. Would you consider the
15 HeartMate 3 to be a catheter device?

16 MR. VARE: Objection; form. I
17 would also say, Counsel, it's outside the scope
18 of the opinions in the declaration.

19 THE WITNESS: Yeah, to be
20 truthful, I don't really quite understand what
21 you mean in terms of a catheter, what portion of
22 the HeartMate 3 are you asking me about. But in
23 the end, it's not something that I
24 necessarily -- wasn't part of the scope of what
25 I was looking at in terms of evaluating the

1 HeartMate 3 in terms of its technical specs.
2 The last time I looked at the HeartMate 3 would
3 have been, you know, a decade ago, probably. So
4 I'm not sure that I really understand your
5 question.

6 BY MS. RAGHAVAN:

7 Q. Do you understand the term "catheter
8 device"?

9 MR. VARE: Objection; form.
10 Outside the scope.

11 THE WITNESS: If you're asking me
12 what a definition of a catheter, it can be a
13 tube made of different materials. But again, I
14 don't know -- I'm trying to understand
15 necessarily how you're equating the two
16 questions. I wouldn't consider it necessarily
17 -- again, I understand what a catheter is, yes,
18 but I don't understand your question.

19 BY MS. RAGHAVAN:

20 Q. Can catheter be anything that's shaped
21 as a tube, or is it something with a specific
22 purpose?

23 MR. VARE: Objection; form.
24 Outside the scope.

25 THE WITNESS: Yeah, again, out of

1 context, I don't know that I can answer that
2 question. There are many different types of
3 catheter. There are bladder catheters, there
4 are gastric catheters, there are cardiovascular
5 catheters. To make a broad statement about all
6 catheters, I don't know that that's an
7 appropriate -- that I can give you the
8 appropriate answer without the context. If you
9 want to point to something in my report that I
10 discuss catheters, we can discuss that. But
11 beyond that, I'm not sure that I expressed an
12 opinion about a catheter.

13 Q. Okay. Let's turn to Paragraph 4 of
14 your declaration.

15 A. Yes.

16 Q. Let me know when you're there.

17 A. I'm there.

18 Q. You say here that you've been
19 practicing full time in the field of cardiac
20 surgery since completing your fellowship
21 training in 2008. Do you see that?

22 A. Yes.

23 Q. So prior to 2008 you were still
24 training to be a cardiac surgeon; is that fair?

25 MR. VARE: Objection; form.

1 THE WITNESS: I think you have my
2 CV. You have my full educational background in
3 terms of how I functioned from undergraduate
4 through my current practice. So I mean, that's
5 accurate.

6 BY MS. RAGHAVAN:

7 Q. When was the first time you implanted
8 a cardiac assist device?

9 A. Would have been in my training as
10 early as probably 1999.

11 Q. Was that in an animal or a human
12 being?

13 A. I take it back. 1998. Sorry. Would
14 have been in human.

15 Q. What kind of cardiac assist device was
16 it?

17 A. At the time these were other Thoratec
18 devices, whether it be -- at that point it would
19 be something called a PVAD. It would have been
20 the original HeartMate XVE, all the way up
21 through HeartMate II and HeartWare.

22 Q. When did you first implant the
23 HeartMate II?

24 A. It would have been after it was FDA
25 approved, I believe. Actually, take that back.

1 At the University of Minnesota we were involved
2 in some of the early LVAD trials. So it
3 probably would have been before that. I don't
4 recall --

5 COURT REPORTER: (Requests
6 clarification.)

7 THE WITNESS: Sorry. It would
8 have been in the time that it was available for
9 study because at the University of Minnesota we
10 were part of many of the device approval studies
11 that involved humans. So I don't recall the
12 exact date. But it would have been after 1998.

13 BY MS. RAGHAVAN:

14 Q. When did you first implant the
15 HeartWare device?

16 A. That would have been -- I believe it's
17 referenced in my report, but if I remember
18 correctly it would have probably been somewhere
19 around 2013, but my report would be correct.

20 Q. Okay. When was the first time you
21 implanted a device that you would consider an
22 LVAD?

23 A. Again, I would say as early as 1998.

24 Q. And which device would you be
25 referring to?

1 A. That would have been everything from
2 a -- at the time we used intraaortic balloon
3 pumps. We used, as I mentioned before, many of
4 the Thoratec devices, including the XV. We did
5 use the ECMO at the time, as well, so would have
6 also been using ECMO. So it would have included
7 -- I don't recall exactly what year we would
8 have been -- we would have had CentriMag
9 available to us, but we also used CentriMag from
10 Thoratec quite a bit.

11 Q. This was your experience as a fellow;
12 correct?

13 MR. VARE: Objection --

14 THE WITNESS: It was in my
15 experience as early as when I was a general
16 surgery resident. So as I mentioned, I trained
17 at the University of Minnesota. We used many of
18 these devices. We spent a lot of time on the
19 cardiovascular services during my training as a
20 general surgery resident, which is why I chose
21 to go there, but then that continued as I was
22 training as a fellow at the Brigham and Women's
23 Hospital in Boston as well.

24 BY MS. RAGHAVAN:

25 Q. Do you generally agree with the

1 terminology that the first generation LVADs
2 refer to pulsatile devices?

3 MR. VARE: Objection; lacks
4 foundation.

5 THE WITNESS: If you're using
6 that term general, the terminology is in the
7 literature in terms of what people consider each
8 generation. Pulsatile-type devices would fall
9 into that class as being the first generation.
10 BY MS. RAGHAVAN:

11 Q. And second generation LVADs refer to
12 pumps with rotors that have mechanical bearings;
13 is that right?

14 MR. VARE: Objection; form.

15 THE WITNESS: I believe that that
16 would be what the literature would represent,
17 yes.

18 BY MS. RAGHAVAN:

19 Q. And third generation devices refer to
20 pumps that are magnetically levitated, or at
21 least devices that do not have mechanical
22 bearings; is that right?

23 MR. VARE: Objection; form.

24 THE WITNESS: I would state it's
25 referring to those that don't have mechanical

1 bearings, yes.

2 BY MS. RAGHAVAN:

3 Q. When was the first time you implanted
4 a third generation LVAD?

5 A. Well, again, I think you already asked
6 me that question when you asked the question of
7 when I implanted HeartWare. So would have been
8 around the time of 2013.

9 Q. Okay. And was that in a human or an
10 animal?

11 A. It would have been in both because
12 again, as part of our training it involved both.

13 Q. Besides the HeartWare, have you
14 implanted any other third generation LVADs?

15 A. We considered other third generation
16 LVADs, but no, HeartWare was the only one.

17 Q. Which other third generation LVADs do
18 you remember considering?

19 A. Well, you already asked me. Again, it
20 was the HeartMate 3.

21 Q. In your declaration you presented
22 opinions about how a POSA would have understood
23 certain prior art pumps; right?

24 A. Well, I presented a lot of opinions.
25 Which page or paragraph are you referring to?

1 Q. Well, so generally you have opinions
2 about how a POSA would understand the Bourque
3 2001 device; correct?

4 A. Well, again, I guess I would say my
5 report gives my opinions. So if you can point
6 to a page on that, I can tell you whether or not
7 that was my opinion or not. You're asking for a
8 generalization. I'm not sure -- I did speak to
9 what I think a POSA is and I did speak to what a
10 POSA would feel about these topics. But if
11 there's a specific question about that, you
12 know, I'd be happy to -- if you would point to
13 that page, we can talk about it. Otherwise, I
14 can't give you a generalization.

15 Q. So without looking at a paragraph in
16 your declaration, you can't tell me whether you
17 expressed an opinion about POSA's understanding
18 of the Bourque 2001 pump?

19 MR. VARE: Objection; asked and
20 answered.

21 THE WITNESS: There are a lot of
22 different pieces of information with respect to
23 that pump. I mean, which specific point are you
24 asking me about? And did I express an opinion
25 about that specific point or not? I don't know.

1 So I'm not necessarily going to tell you I
2 expressed an opinion about every word in that
3 document.

4 BY MS. RAGHAVAN:

5 Q. Okay. Let's turn to Paragraph 8 of
6 your declaration.

7 A. Yes.

8 Q. Okay. You start this paragraph with
9 saying that you served as a director of
10 mechanical circulatory support at The Christ
11 Hospital in Cincinnati; is that right?

12 A. That's what the document states, yes.

13 Q. When was this, approximately?

14 A. Again, you have a copy of my CV that
15 lists my time at Christ. I believe it was right
16 about in and around 2011.

17 Q. You mention here that there was a
18 major clinical trial focused on optimizing
19 placement of the HeartMate II device. Do you
20 see that?

21 A. Which line are you -- oh, yeah.

22 Q. Says, "Under my leadership, the
23 program became one of the few nontransplant
24 centers to participate in a major clinical trial
25 focused on optimizing placement of the HeartMate

1 II device."

2 Do you see that?

3 A. Yes, I see that.

4 Q. Is there a difference in your mind
5 between MCS and LVAD?

6 MR. VARE: Objection; form.

7 THE WITNESS: Mechanical
8 circulatory support is another terminology
9 talking about the specific use of mechanical
10 devices to improve circulatory support. So that
11 MCS would include not only left ventricular
12 assist devices but also right ventricular assist
13 devices, or a total artificial heart. So again,
14 LVAD would be a subset of mechanical circulatory
15 support. So mechanical circulatory support --
16 sorry, that's a mouthful, MCS -- is a -- would
17 be the broader category that LVAD would fall
18 under.

19 So to say that, for example, that all
20 LVADs are mechanical circulatory support would
21 be correct; but to say that all mechanical
22 circulatory support are LVADs would not.

23 Q. Understood. So going back to the
24 second sentence in Paragraph 8 you mentioned a
25 major clinical trial.

1 A. Yes.

2 Q. Is it your understanding that the
3 design for the HeartMate II pump was locked in
4 prior to that trial?

5 MR. VARE: Objection; form.

6 THE WITNESS: I guess if you're
7 asking me am I aware that the device was already
8 FDA approved for use at the time, yes.

9 BY MS. RAGHAVAN:

10 Q. As part of this clinical trial, you as
11 a cardiac surgeon were implanting the HeartMate
12 II device in patients; correct?

13 A. Yes.

14 Q. Did you consider the HeartMate II
15 device to be safe at the time you were
16 conducting this clinical trial?

17 MR. VARE: Objection; form.

18 THE WITNESS: Well, I would say
19 that a person of skill in the art would
20 understand that if a device is FDA approved,
21 it's gone through the regulatory process to be
22 demonstrated to be safe and, yes, I would have
23 considered it, as most persons of skill in the
24 art at the time would have considered it to be
25 safe.

1 Now, safe is a relative term. Doesn't
2 mean it's free of a hundred percent
3 complications. They can have complications
4 related to devices whether it's improper use or
5 other potential problems that can happen with
6 any device. So safe is a relative term.

7 BY MS. RAGHAVAN:

8 Q. When you say it was FDA approved, can
9 you expand upon that?

10 MR. VARE: Objection; form.

11 THE WITNESS: Well, in what
12 sense? Are you asking me to explain the concept
13 of how a device goes from idea through
14 preclinical trials to clinical trials to
15 postclinical surveillance?

16 BY MS. RAGHAVAN:

17 Q. I'll ask you a more specific question.
18 So the device was still in clinical trial at the
19 time that you were implanting the HeartMate II
20 at Christ Hospital; correct?

21 A. I would say that it was in
22 postclinical phase trial, yes.

23 Q. Okay. So what --

24 A. Meaning that we were trying to
25 understand can we improve the use of a device.

1 It's not necessarily related to the device
2 itself. It could be related to how the device
3 is being used. So there are many different
4 facets of how a device is followed after it's
5 initially approved for use in humans. We
6 continue to monitor all devices to make sure
7 that a problem that wasn't necessarily brought
8 up initially in the use couldn't come up later
9 in time that might result in the device being
10 pulled from the market. So all of the devices
11 typically are followed in the -- after FDA
12 approval for ongoing safety concerns and issues.

13 Q. Do you recall what level of regulatory
14 approval the HeartMate II device had received
15 prior to you beginning this clinical trial?

16 A. So the device was already approved for
17 use in humans, so it was approved for use. This
18 particular trial was focusing on a particular
19 issue that was noted within this device, which
20 is thrombosis. And we were, as a group, looking
21 at the question of is there an issue in terms of
22 how the implant is being performed that is
23 resulting in an increased risk of thrombosis.
24 Wasn't necessarily that we were going back to
25 reapprove the device; it was looking at what is

1 causing the increase in thrombosis rates that
2 we're seeing with the device.

3 Q. Are you familiar with the regulatory
4 submission called an IDE?

5 A. Yes.

6 Q. What is that?

7 A. Well, I don't remember the exact
8 acronym right now, Investigational Device
9 Exemption, I believe is what it stands for. But
10 it's not something I reviewed again right now to
11 remember the exact term. But I understand what
12 it is.

13 Q. If a device has received IDE approval,
14 would you as a cardiac surgeon consider it a
15 suitable device to implant?

16 MR. VARE: Objection; form.

17 THE WITNESS: Again, I think
18 you're asking me about all devices. It would
19 depend on the specific device and what the
20 situation was. If there are other devices that
21 we know are already proven to be safer, I might
22 not. If it's the only devices in the category,
23 we may not have a choice but to use the device.
24 But again, that's speaking in very broad terms.
25 BY MS. RAGHAVAN:

1 Q. Would you agree that it has to be a
2 patient-by-patient consideration?

3 MR. VARE: Objection; form.
4 Outside the scope.

5 THE WITNESS: Again, it would
6 depend on the very specific situation, the very
7 specific device, what situation that particular
8 patient is in, what's available to me on the
9 market, are there any other therapies. But in
10 general, when I speak to a patient about
11 treatment options, I'm going to go through and
12 list all of the available options, what we are
13 aware of in terms of the relative safety of
14 those options, and then ultimately it's a shared
15 decision between myself and the patient as a
16 practicing clinician. I would say that most
17 persons of skill in the art, particularly of
18 cardiac surgery, would give you the same answer.
19 It's not a broad stroke, yes, I'm going to do
20 this every situation.

21 BY MS. RAGHAVAN:

22 Q. Toward the end of Paragraph 8,
23 actually the last sentence of Paragraph 8, you
24 say, "This work not only advanced surgical
25 strategies for durable LVAD implantation but

1 also helped expand access to advanced heart
2 failure therapies for patients who are not
3 transplant candidates."

4 Do you see that?

5 A. Yes, I do.

6 Q. What factors go into determining that
7 a patient is unsuitable for a heart transplant
8 but is suitable for other advanced heart failure
9 therapies?

10 A. Well, that's a very broad discussion.
11 I don't know that it's in the scope of what we
12 talked about in my report necessarily. I mean,
13 I can spend the time here to talk to you about
14 the entire workup we would do to look at a
15 patient and ask whether they're a patient who is
16 acceptable for transplant or a patient who would
17 be acceptable for what we would consider
18 destination therapy using LVAD. But I don't
19 know that that's in -- I don't know the
20 relevance to this particular topic.

21 Q. Well, so, Doctor, I'm asking you about
22 the sentence that you wrote in Paragraph 8. So
23 what was the relevance of the sentence to the
24 discussion -- or the opinion that you presented
25 in Paragraph 8?

1 MR. VARE: Objection; form.

2 THE WITNESS: Well, again, the
3 relevance is that we are looking at using this
4 type of mechanical circulatory support for
5 destination patients. So if a patient is a
6 candidate for destination therapy and this
7 device thromboses early, that would impact their
8 long term outcomes. So that's what the
9 relevance is here.

10 Again, you talk about putting an LVAD
11 in. It's not just about putting it in; it's
12 making sure that this LVAD continues to work in
13 this particular patient for as long as it
14 possibly can. So it's very relevant to the
15 topic of mechanical circulatory support and
16 destination patients.

17 BY MS. RAGHAVAN:

18 Q. Let's turn to Paragraph 34 of your
19 declaration. You say here that you agree with
20 Mr. Leschinsky's proposed level of skill for a
21 POSA for the reasons he identified. Do you see
22 that?

23 A. Yes, I see that.

24 Q. Would you agree that as a cardiac
25 surgeon, your -- any experience that would be

1 dated prior to the date of the challenge patents
2 would be the most relevant to understanding the
3 field here at the time of the invention?

4 MR. VARE: Objection; form.

5 THE WITNESS: I don't think I
6 quite understand the question.

7 MS. RAGHAVAN: I'll rephrase.

8 BY MS. RAGHAVAN:

9 Q. So you're talking about in this
10 paragraph, in Paragraph 34, the experience that
11 would be most relevant to analyzing the prior
12 art in this case; correct?

13 A. I guess -- so I've read Paragraph 34.
14 Which part of Paragraph 34 are you asking me to
15 understand?

16 Q. So you're calling for a more tailored
17 level of experience for someone who would
18 classify themselves as a POSA?

19 A. I said that I agree with the statement
20 that somebody -- a person of skill in the art
21 should be related to the particular art that
22 we're discussing here. As I said before, there
23 are a lot of different people who have
24 experience with cardiac devices, but there are
25 many different types of cardiac devices that

1 don't necessarily relate to this concept.

2 So a -- for example, a cardiologist
3 who places stents in coronary arteries would
4 probably have no idea of what we're speaking of
5 with respect to this particular topic. Now,
6 they are certainly considered persons of skill
7 in the art of catheter-based treatments with
8 respect to coronary arteries, putting stents in,
9 but they would not necessarily be fully
10 knowledgeable about this particular topic.

11 So that's just one example of when I
12 say you should be a person of skill in the art,
13 well, it should be art relevant to this topic,
14 not simply -- you know, again, for example, a
15 person who is skilled in the art of critical
16 care using medications to treat the heart
17 doesn't necessarily have the skill in the art to
18 talk about this particular topic.

19 So I agree with Dr. -- Mr. Leschinsky,
20 I'm sorry, his opinion in terms of that yes, it
21 should be a -- it would be more appropriate to
22 be tailored to the specific topic at hand. A
23 person of skill in the art who doesn't have
24 skill in this particular art is not necessarily
25 a person that I would talk to.

1 Very much so if -- the counter example
2 would be if I need brain surgery, I'm not going
3 to go talk to my colleague, the cardiac surgeon.
4 And similarly, I don't think my brain surgeon
5 colleague would be talking to his partners if he
6 needed cardiac surgery.

7 Q. Would you agree that the relevant
8 experience here would be experience prior to
9 2007?

10 MR. VARE: Objection; form.

11 THE WITNESS: I think my opinions
12 are stated throughout that in terms of
13 understanding that you have to understand the
14 devices, the anatomy. Do I think that a person
15 of skill in the art today who understands it
16 today who wasn't necessarily doing things in
17 that time, that they wouldn't understand it?
18 No, I don't necessarily agree with that. I
19 think somebody with skill in the art can go back
20 and evaluate the technology at the time and
21 understand it. So that would be my general
22 statement.

23 I think if you have a more specific
24 question about it, I'd have to -- you'd have to
25 ask that question. But no, I don't know

1 necessarily that a person of skill in the art
2 who understands these technologies would have to
3 have had -- experienced it at the time. Can
4 they go back and review the literature and
5 understand it? Yes.

6 BY MS. RAGHAVAN:

7 Q. Let's turn to the table of contents of
8 your declaration.

9 A. Okay.

10 Q. It's on Page 2. In your declaration,
11 among your various opinions, you offer opinions
12 about the combinability of prior art references
13 raised in Abbott's IPR petition; correct?

14 MR. VARE: Objection; form.

15 THE WITNESS: Again, we're
16 looking at the table of contents. If you're
17 asking me, is there a statement listed that --
18 where I address certain papers in combinations,
19 they're listed in the table of contents, yes.

20 BY MS. RAGHAVAN:

21 Q. In particular, in Section 7 you have
22 an opinion that a POSA would not have combined
23 Bourque 2001 with Wampler as petitioner
24 contends; correct?

25 A. That would be the label on the table

1 of contents, yes.

2 Q. And in Section 8 you offer an opinion
3 that a POSA would not have combined Schima with
4 Akamatsu as petitioner contends; correct?

5 A. That's listed in the table of
6 contents; correct.

7 Q. In your declaration you do not express
8 an opinion about whether those individual prior
9 art references on their own disclose the claim
10 limitations of the challenge patents?

11 MR. VARE: Objection; form.

12 THE WITNESS: Well, I would say
13 in general my task at hand, if you read through
14 my declaration, I don't specifically address any
15 of the claim limitations because that's not what
16 I was asked to perform. So I don't believe that
17 you'll find in my reports any comments with
18 respect to claim limitations. So unless you can
19 point me to a page that you would like me to
20 discuss, I don't believe it's in the report.
21 That wasn't necessarily my task that I was asked
22 to evaluate.

23 BY MS. RAGHAVAN:

24 Q. So you didn't conduct a
25 limitation-by-limitation analysis of the claims

1 of the challenge patents?

2 A. Again, if you can point me to
3 someplace in my report where I discuss that, we
4 can discuss it. To my knowledge, I did not.

5 Q. Did you look at the claims of the
6 challenge patents?

7 A. Well, as I said at the beginning of
8 the conversation, I reviewed all of the patents
9 involved in the litigation; more from a sense of
10 understanding what was being asked in general.
11 But no, my job was not to go claim by claim and
12 ask whether one patent or another violated the
13 claims because that wasn't the task that I was
14 asked to accomplish. I was asked to review the
15 materials and give an opinion about whether
16 these combinations made things obvious or not as
17 it's listed in the paragraphs.

18 Q. Let's turn to Paragraph 29 of your
19 declaration. Starts on Page 14. I'll refer you
20 to the first sentence which says, "I understand
21 that to render a claim obvious the prior art
22 taken as a whole must enable a POSA to make and
23 use the claimed invention."

24 Do you see that?

25 A. Yes, I see that.

1 Q. What do you mean by "taken as a
2 whole?"

3 MR. VARE: Objection.

4 THE WITNESS: In the literal
5 terms. It has to be the prior art that is being
6 claimed to render it obvious. It has to be
7 present within the document.

8 BY MS. RAGHAVAN:

9 Q. Can you explain what you mean by
10 present in the document -- within the document,
11 sorry?

12 MR. VARE: Objection; asked and
13 answered.

14 THE WITNESS: I would say that's
15 a pretty obvious term. I mean, I can only read
16 the document. I didn't write the document. I
17 didn't speak to the person who wrote the
18 document. I can't understand what they might or
19 may not have intended if it's not in the written
20 word of the document.

21 BY MS. RAGHAVAN:

22 Q. And that's what you mean by "taken as
23 a whole?"

24 MR. VARE: Objection; form.

25 THE WITNESS: I believe I

1 answered that question, yes.

2 BY MS. RAGHAVAN:

3 Q. Let's turn to Paragraph 37.

4 MR. VARE: Counsel, we've been
5 going an hour. Maybe a short break?

6 MS. RAGHAVAN: Sounds fine.

7 THE WITNESS: Okay.

8 MR. VARE: So five minutes, does
9 that work with everybody?

10 (10:04 a.m. - Recess taken.)

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1 (At 10:15 a.m., with parties present
2 as before, the following proceedings were had,
3 to-wit:)

4 BY MS. RAGHAVAN:

5 Q. Dr. Gallegos, if you could turn back
6 to Paragraph 37 of your declaration.

7 A. Paragraph 37, yes.

8 Q. I'm looking specifically at the
9 sentence that flows between Page 18 into
10 Page 19. There you make a statement that, "A
11 POSA would have immediately realized that the
12 blood pump placements disclosed in Wampler and
13 Akamatsu were merely aspirational intentions
14 that were not practically achievable at the time
15 of the invention."

16 Do you see that statement?

17 A. Yes, I do.

18 Q. To break down that sentence, do you
19 agree that Wampler and Akamatsu both disclose
20 placing a blood pump at the apex of the heart?

21 MR. VARE: Objection; form.

22 THE WITNESS: Disclose in what
23 sense? I think my testimony in the sense of
24 what's written in my document states that as a
25 whole, a person of skill in the art would have

1 recognized that what Wampler and Akamatsu
2 discussed was insufficient.

3 BY MS. RAGHAVAN:

4 Q. So I'm trying to understand whether
5 your disagreement is with whether the placement
6 that's discussed in Wampler and Akamatsu was
7 practically achievable at the time of the
8 invention, or whether your disagreement is
9 whether it was disclosed at all in those
10 references.

11 MR. VARE: Objection; form.

12 THE WITNESS: As I state in my --

13 COURT REPORTER: (Requests
14 clarification.)

15 THE WITNESS: Apologies. I'm
16 trying to read my report as well. I apologize.

17 As I was saying, I believe my document
18 states that Wampler and Akamatsu were merely
19 aspirational intentions that were not
20 practically achievable at the time of the
21 invention. That's a pretty clear statement.
22 They were not achievable.

23 BY MS. RAGHAVAN:

24 Q. But are you disputing whether Wampler
25 and Akamatsu describe placing a blood pump at

1 the apex of the heart?

2 MR. VARE: Objection; form.

3 THE WITNESS: I don't believe
4 they described it sufficient to a person with
5 skill in the art to understand. It's
6 aspirational in the sense that yes, we could
7 place it there, but they did not disclose the
8 technique or the mechanism of how.

9 BY MS. RAGHAVAN:

10 Q. You say here that the aspirational
11 intentions that were disclosed in Wampler and
12 Akamatsu were not practically achievable at the
13 time of the invention; right?

14 A. That would be the sentence that's in
15 the report; correct. It clearly states Wampler
16 and Akamatsu were merely aspirational intentions
17 that were not practically achievable at the time
18 of the invention.

19 Q. What did you do to assess whether the
20 statement disclosed in Wampler and Akamatsu were
21 practically unachievable at the time of the
22 invention?

23 A. I guess I don't understand your
24 question. Are you asking me did I go back and
25 perform animal experiments? What's your

1 question?

2 Q. Sure. What did you do to arrive at
3 the opinion that the disclosures in these
4 references were just aspirational and not
5 practically achievable?

6 A. I read the documents, and as a person
7 of skill in the art would recognize these were
8 aspirational and not practically achievable
9 because as I mentioned, they do not give the
10 information as to how to do this.

11 Q. So your opinion is based on reading
12 those references alone; correct?

13 MR. VARE: Objection; form.

14 THE WITNESS: Again, as I stated,
15 a person of skill in the art would not only read
16 those references but would put it in context to
17 what is known at the time in terms of technology
18 and abilities. So it would be an opinion based
19 on all of that, not just reading the papers, but
20 it would have to include understanding what was
21 going on at the time in terms of devices that
22 could be implanted in the way you're describing.
23 BY MS. RAGHAVAN:

24 Q. And what was the additional context
25 that you referred to in arriving at your opinion

1 that the disclosures in Wampler and Akamatsu
2 were not practically achievable?

3 A. The following paragraphs. If you go
4 through and read each paragraph, it explains
5 each. I think my testimony is explained in each
6 of the following paragraphs, which I believe
7 you've had an opportunity to read. So again, if
8 there's a question about one of those
9 paragraphs, I guess I would direct you to that
10 so that you can ask me my opinion about what's
11 in the report.

12 Q. Do you have any personal experience
13 that would either confirm or deny whether the
14 pumps of Wampler and Akamatsu were implanted in
15 humans before the priority date?

16 A. I believe my testimony would be in the
17 report. If I stated I had experience with those
18 pumps, personal experience, I would have stated
19 it. I don't believe it's in my report.

20 Q. Did you review any other materials
21 besides what's cited in your declaration to
22 confirm whether the Wampler pumps had been
23 implanted in humans before the priority date?

24 A. I reviewed a lot of documents, a lot
25 of papers. The ones that were relevant that

1 would have disclosed it would have been
2 referenced. I'm not aware of any others.
3 However, that doesn't mean that there isn't
4 another. Simply saying I'm not aware of it.

5 Q. Did you review any other materials
6 besides what's cited in your declaration to
7 confirm whether the Akamatsu pump had been
8 implanted in humans before the priority date?

9 A. I would say it's the same answer.

10 Q. Besides reviewing these references and
11 the cited materials relating to these
12 references, are you independently familiar with
13 the Wampler pump?

14 MR. VARE: Objection; form.

15 THE WITNESS: I suppose if you're
16 asking me the question did I consult with
17 Thoratec in the design or development of that
18 pump, no, I did not consult with Thoratec, no.

19 BY MS. RAGHAVAN:

20 Q. Prior to drafting this declaration for
21 these IPR proceedings, were you familiar with
22 Dr. Wampler's work?

23 A. Well, as an individual who worked in
24 the field, I would say yes. But would I
25 specifically know it was his work? Not

1 necessarily. I guess I would say I've never met
2 Dr. Wampler, if he is a doctor. I'm not sure.

3 Q. Prior to drafting this declaration for
4 these IPR proceedings, were you familiar with
5 the work of Akamatsu?

6 A. Am I familiar with Dr. Akamatsu? No,
7 I wasn't necessarily familiar with his work by
8 name, no.

9 Q. Referring back to your sentence at the
10 end of Paragraph 37 that these disclosures in
11 Wampler and Akamatsu were not practically
12 achievable, is it your opinion that disclosures
13 in prior art references need to be practically
14 achievable in order to invalidate a point?

15 MR. VARE: Objection; form.

16 THE WITNESS: I'm not exactly
17 sure what your question is. I guess I would
18 start by saying I'm not an attorney. If I had a
19 question to that, I would speak to my attorney.
20 So I don't know that I can answer that question.
21 That sounds more like a legal question to me
22 than others. I gave my opinion as it's stated
23 in the report, but I'm not an attorney so I'm
24 not going to -- I can't say that I can answer
25 your question directly.

1 BY MS. RAGHAVAN:

2 Q. So you can't speak to how the
3 practical achievability of the disclosures in
4 Wampler and Akamatsu ties to the law in
5 obviousness; correct?

6 MR. VARE: Objection; form.

7 THE WITNESS: As I stated before,
8 I'm not an attorney. So do I understand the law
9 in its totality? No, because that's not my job.
10 I can give my opinion, and those opinions are
11 then looked at by people like yourself to
12 understand whether my opinion meets those
13 criteria or not.

14 BY MS. RAGHAVAN:

15 Q. In Section 4 of your declaration you
16 lay out the various legal standards that you
17 understood were applicable to the analysis you
18 performed in your declaration; correct?

19 A. On which page are you referring?

20 Q. I believe it starts on Page 10 and
21 then goes through Page 15.

22 A. Yes, I see.

23 Q. And within Section 4 you included a
24 section on obviousness; correct? That's
25 subsection D.

1 A. And what page are you referring to?

2 Q. Page 12 through 15.

3 A. Yes, I see that.

4 Q. And this is your understanding of the
5 law on obviousness as communicated to you by
6 counsel; correct?

7 A. Yes.

8 Q. Nowhere in this section do you see
9 anything about practical achievability; correct?

10 MR. VARE: Objection; form.

11 THE WITNESS: I would have to
12 read the entire section, if you want me to read
13 the entire section. I don't have it memorized.

14 BY MS. RAGHAVAN:

15 Q. Why don't you go through it and tell
16 me if you see anything about practical
17 achievability.

18 A. To the extent, again, Paragraph 27 I
19 believe would address your concern. It states
20 that I further understand that whether there is
21 a reasonable expectation of success in combining
22 references in particular ways relevant to the
23 analysis. So from my perspective, if it was
24 unlikely to achieve success, in other words, as
25 I stated in the other paragraphs, I believe that

1 would fall into that category.

2 Q. Let's turn to Paragraph 38 of your
3 report.

4 A. Yes.

5 Q. Here you say, "Indeed, as of the
6 priority date I was not aware of any implantable
7 left ventricular assist device LVAD blood pump
8 being placed at the apex of the heart."

9 Right?

10 A. Correct, it states that.

11 Q. You're not saying nobody had
12 positioned a LVAD at the apex of the heart by
13 the priority date; correct?

14 MR. VARE: Objection; form.

15 THE WITNESS: I think the
16 statement pretty clearly states that I'm not
17 aware of an implantable left ventricular assist
18 device blood pump that was being placed at the
19 apex of the heart, that's correct, not in the
20 manner that's described by what's being
21 suggested.

22 BY MS. RAGHAVAN:

23 Q. You're just saying that you personally
24 were not aware of an LVAD being positioned at
25 the apex of the heart by the priority date?

1 A. As of the use of the word "I" in A
2 sentence would suggest that, yes, that's
3 correct, because I stated that.

4 Q. And when you say you were not aware of
5 an LVAD positioned at the apex of the heart by
6 the priority date, when did you make that
7 assessment?

8 A. I'm sorry, I don't understand your
9 question. When did I make the assessment? My
10 report is dated. So I would tell you that the
11 report is finalized on the date that I signed
12 it. So this report was performed on that date,
13 as we mentioned before. I spent a lot of time
14 in between that coming to these conclusions. So
15 I don't know the exact date that I can say that
16 I came to this conclusion. But as of the
17 signing date it's reflective of what my opinion
18 is.

19 Q. At the time of writing your
20 declaration -- I am not asking when during the
21 duration that you were preparing your
22 declaration, but just generally as you were
23 preparing your declaration, did you try to
24 recollect whether prior to 2007 you were aware
25 of an LVAD being positioned at the apex of the

1 heart?

2 A. There's obvious ways that you can do
3 to look at that. What was being used at the
4 time by physicians like myself? I can go back
5 and look at my own records and see when I first
6 implanted, for example, the HeartWare device,
7 like you asked me when. I can go back and look
8 at my records and see when was I first aware.

9 But again, as of the priority date, I
10 was unaware of any other device that would be
11 explicitly implanted in the fashion at the apex
12 of the heart.

13 Q. Prior to 2007 you were a resident;
14 correct?

15 A. I would have been a resident and
16 fellow in cardiac surgery by that point. And I
17 guess I should clarify, you know, the primary
18 reason I chose to go to the University of
19 Minnesota is that this is the birth place of
20 cardiac surgery. So the concept of the first
21 heart-lung machine, which would be the first
22 left ventricular assist device used, was born
23 there.

24 So University of Minnesota has an
25 extensive experience with mechanical circulatory

1 support, which is why as a resident I was
2 exposed to this, which is why as a resident I
3 was involved with the implantation of left
4 ventricular assist devices of all different types.
5 It's why I have an exceptionally large volume of
6 experience with these devices all the way
7 through this period.

8 This continued when I went to the
9 Brigham and Women's Hospital, which at the time
10 was one of the preeminent heart hospitals in the
11 U.S. and if not the world. It would be the
12 Harvard Institution. So we were very familiar
13 with many of these devices, what was available,
14 what was being studied. So again, it comes with
15 a long, both personal experience of what was
16 going on at the time, and being aware of what
17 was going on at the time.

18 You know, again, when you ask me about
19 Wampler and Akamatsu, I can't tell you I didn't
20 read those papers back in those days because
21 these would have been papers of relevance that
22 we had been reading. Do I know them personally?
23 No. Do I recall which date I read these papers?
24 Not necessarily.

25 Q. Do you know whether the blood pump

1 that's disclosed in the challenged patents is
2 being disclosed as being implanted at the apex
3 of the heart?

4 MR. VARE: Objection; form.
5 Outside the scope.

6 THE WITNESS: I guess, again, if
7 you would point to a point in my report that we
8 can discuss that, I don't really know what your
9 question is trying to get at.

10 BY MS. RAGHAVAN:

11 Q. Is that an analysis you performed as
12 part of preparing your declaration?

13 MR. VARE: Outside the scope.

14 THE WITNESS: Again, that's such
15 a vague question, I don't really know what
16 you're -- I still don't understand your
17 question.

18 BY MS. RAGHAVAN:

19 Q. Did you evaluate the disclosures of
20 the challenge patents to determine where the
21 pump that's disclosed in those challenge patents
22 would be placed?

23 MR. VARE: The question is
24 outside the scope of his declaration.

25 THE WITNESS: I wasn't asked to

1 specifically evaluate the relevance of that
2 particular point-by-point patent claim, no.

3 BY MS. RAGHAVAN:

4 Q. Do you agree with your counsel's
5 objection that it was outside the scope of your
6 declaration?

7 A. I'm not an attorney so I can't even
8 begin to agree or disagree with one of you. So
9 all I'm stating is that it wasn't what I was
10 specifically asked to do. If you can point to a
11 place in my report that would address that, if I
12 discussed something relevant to that, then I can
13 go through those points. But again, I wasn't
14 asked to evaluate the claims point by point in
15 any way.

16 Q. Let's go to Paragraph 23 of your
17 declaration. And here you recite some of the --
18 here you recite your understanding of what an
19 obviousness analysis requires; correct?

20 A. Yes.

21 Q. And part of it, in your recitation
22 here says that it involves the general knowledge
23 in the art at that time. Do you see that?

24 A. Yes, I see that, Line 4 of
25 Paragraph 23.

1 Q. How did you evaluate the general
2 knowledge in the art at the time as relevant to
3 the opinions that you present in your
4 declaration?

5 A. That would have been a review of the
6 literature that was appropriate for that time
7 period, as well as my own knowledge as a person
8 of skill in the art.

9 Q. And where you found literature to be
10 relevant, you cited that literature in your
11 declaration; correct?

12 A. That would be appropriate, yes.

13 Q. Would you say that general knowledge
14 in the art at the time was limited to devices
15 that were approved for use by a regulatory body?

16 MR. VARE: Objection; form.

17 THE WITNESS: As I said before, I
18 reviewed the literature. So included in the
19 literature is other devices that aren't
20 necessarily approved by the regulatory body.
21 Would I have been very familiar with those that
22 were already approved and in use? Of course.
23 Would I have been familiar with those that were
24 in research and development? Potentially, if it
25 was published and it was publicly disclosed, I

1 would have been. And that's, again, using a
2 search of the literature at the time would have
3 brought up whatever was available to me as a
4 person of skill in the art.

5 If it was not published, there's no
6 way that I could have reviewed it or been aware
7 of it.

8 BY MS. RAGHAVAN:

9 Q. Would general knowledge in the art at
10 the time have included devices that were in
11 clinical trials?

12 A. Well, again, I would believe that
13 answer has already been answered, again, if it's
14 a device that's been disclosed in some way. If
15 it's in clinical trials it certainly would have
16 been disclosed.

17 Q. So you would agree that POSAs are
18 generally aware of devices that are in clinical
19 trials; correct?

20 A. In general I would say that most POSAs
21 would be aware of devices. Now, a person of
22 skill in the art, if they are not part of the
23 clinical trial may or may not be --

24 COURT REPORTER: (Requests
25 clarification.)

1 THE WITNESS: Let me rephrase
2 that so you can catch up with me. My thought
3 process was a person of skill in the art in
4 general should be aware of what is going on in
5 the field. If you're asking about a specific
6 knowledge of a device that's in clinical trial,
7 they may have different variations of level of
8 understanding of the device if they're directly
9 involved in the clinical trial or not.

10 So I would have to -- you know, again,
11 you'd have to ask each individual POSA at that
12 point, are you aware of this particular
13 information, and they would give you their
14 opinion if they were or were not.

15 BY MS. RAGHAVAN:

16 Q. In terms of your opinion that POSAs
17 were or were not aware of certain teachings in
18 the art at the time of the invention, did you
19 talk to anyone else who you would have
20 considered to be a POSA relevant to this case?

21 A. Relevant to this case? I would have
22 only discussed topics in general in terms of are
23 you aware of any material I should be reviewing.
24 But no, I didn't necessarily speak to anybody
25 else, no.

1 Q. When you were conducting clinical
2 trials for the HeartMate II at The Christ
3 Hospital, would you agree that other POSAs were
4 generally aware of the HeartMate II device?

5 MR. VARE: Objection; form.

6 THE WITNESS: I would say that
7 person of skill in the art who were implanting
8 the device, or who were beginning to consider
9 implanting the device, or were treating patients
10 with the device would have been aware of the
11 device, yes.

12 BY MS. RAGHAVAN:

13 Q. Let's turn to Paragraph 39 of your
14 declaration.

15 A. Okay.

16 Q. Towards the ends of this paragraph you
17 refer to the HeartWare HVAD. Do you see that?

18 A. Yes.

19 Q. And you say that it came years after
20 the 2007 priority date. Do you see that?

21 A. Yes.

22 Q. When you say the HeartWare HVAD came
23 years after, what specifically do you mean by
24 that?

25 A. Means that it was available for use

1 after the priority date of 2007.

2 Q. What do you mean by "available for
3 use"?

4 A. Available for use.

5 Q. By who?

6 A. By a person of skill in the art.

7 Q. Are you referring to the date by which
8 it was approved by the FDA?

9 A. I would tell you that again, from a
10 clinical perspective, it was not available to me
11 in 2007. It wasn't necessarily generally
12 considered a type of device that we were
13 available to use.

14 Q. So as a clinician, when does a device
15 become available to you for use?

16 A. Depends on where you're at in the
17 process. Again, there are those who are
18 involved in early trials. There are those who
19 are involved after it's FDA approved. I don't
20 recall exactly the specific date that I would
21 have been aware. It would definitely have been
22 before it was necessarily FDA approved, but it
23 wasn't available to me at the time.

24 Q. So just to clarify, in this paragraph
25 you say the HeartWare HVAD came years after the

1 2007 priority date. Are you referring to the
2 date it became available to you, or are you
3 referring to a different event?

4 A. I don't really understand your
5 question. I mean, in the context of the entire
6 paragraph, what I'm saying is that relative to
7 the available devices that could have been put
8 in this position, these devices were much too
9 large, even comparative to the HVAD that itself
10 came out, but that was available after 2007.

11 So all of these devices are much too
12 large in comparison to even the HVAD. That's
13 what it stated.

14 Q. But specifically what is your basis
15 for saying that the HeartWare HVAD came years
16 after the 2007 priority date?

17 MR. VARE: Objection; asked and
18 answered.

19 THE WITNESS: Plain English. It
20 says it came after 2007. That's it.

21 BY MS. RAGHAVAN:

22 Q. What does that mean "it came after?"
23 Like in regulatory terms what does that mean?

24 A. Well, in regulatory terms the FDA
25 approval was after 2007.

1 Q. Okay. Is that what you're relying on
2 to say that it came after the priority date?

3 MR. VARE: Objection --

4 THE WITNESS: I believe I've
5 already answered your question. It wasn't
6 available for us to -- this sort of technology,
7 this application of the device wasn't available
8 until after 2007. So I think I've answered your
9 question to the best of my ability.

10 BY MS. RAGHAVAN:

11 Q. And it would have only been available
12 to you as a cardiac surgeon after it was
13 approved by the FDA; correct?

14 MR. VARE: Objection; form.

15 THE WITNESS: I think I've
16 already answered your question repeatedly that
17 we have access to devices at different phases of
18 development. I'm not necessarily only saying at
19 FDA approval that it would have been available
20 to a person of skill in the art. But not every
21 person of skill in the art would have
22 necessarily had access to it.

23 BY MS. RAGHAVAN:

24 Q. So if a person of skill in the art
25 were conducting clinical trials relating to the

1 HeartWare HVAD, that person of ordinary skill in
2 the art did have access to that pump prior to
3 2012 when it was approved by the FDA; correct?

4 A. Well, at the time of the concept of
5 these -- of the priority date, the person of
6 skill in the art would not have had access to
7 the HVAD to use. I think I've answered your
8 question repeatedly in stating that the rest of
9 the paragraph is referring to the comparison of
10 the size of these disclosed pumps in the other
11 patents relative even to a device that was
12 available even much years after the priority
13 date of the patents. So technically speaking,
14 all of these devices are much too heavy, much
15 too large to have occupied a position in the
16 chest for implantation.

17 Q. We'll get to that, but I'm not asking
18 about that right now. I'm asking about what did
19 this --

20 A. That's what this paragraph is
21 referring to. So again, that's the context of
22 the paragraph. So in the context of the
23 paragraph, I'm answering the question.

24 Q. I'm asking you about the word choice
25 that you used specifically for this portion of

1 this paragraph.

2 A. And I'm trying to clarify to you that
3 individual words taken out of context mean very
4 little. So in general, in the context of the
5 entire paragraph, what it's talking to you about
6 is the size. And it also states that, by the
7 way, the HeartWare device was significantly
8 smaller.

9 So in the context, if you take it out
10 of context and ask me to talk about individual
11 words, it's nonsensical. I have to answer the
12 question with respect to the entire paragraph
13 and the paragraphs that both precede and follow
14 it for you to understand it. I am not going to
15 talk to you about individual words. It's the
16 whole concept. The word "to" may have many
17 different meanings. In the context of what I'm
18 talking about, that's what I'm going to answer
19 the question about, because that is my testimony
20 in terms of what I was speaking to.

21 Q. I assume you chose the words that you
22 put in your declaration; correct?

23 A. Yes, I did, but there are a lot of
24 different English words. Again, spoken in the
25 context of the paragraph, that's the meaning.

1 Q. Did you look up when the HVAD was
2 first implanted in humans?

3 A. At some point I certainly would have,
4 yes. But I don't recall specifically the date
5 at hand at this point. If you can point to a
6 point in my report that I discuss that, we can
7 talk about it. But the short answer is, yes, I
8 would have looked it up as part of my research
9 involved in this, as well as other things. I
10 was aware of it at the time when I was using the
11 HVAD. But today, this is a few decades in
12 between and a lot of devices in between. So
13 unlike the company who could probably give you
14 the whole history, no, I can't today without
15 looking it up.

16 Q. So when you say the HVAD came years
17 after the 2007 priority date, are you referring
18 to the date at which the HVAD was first
19 implanted in humans?

20 A. What I'm referring to in this
21 paragraph again is the type of -- the size of
22 the HVAD in comparison to the pumps in question
23 above. Because that's in the context of this
24 paragraph. And then if we go on to the next
25 paragraph, you know, again, you can read it.

1 This, again, was an unsuitable pump for the
2 reasons that were disclosed in my report.

3 So I don't really understand your
4 question beyond the fact that what I'm telling
5 you is that I'm going to give you the context of
6 what I was trying to say in the whole paragraph.
7 I'm not going to tell you that Page 20 is more
8 relevant than Page 22, because I don't know
9 what's on that.

10 In the same way that an individual
11 word, you have to ask me what is it relative to
12 the context of the paragraph that I'm
13 discussing. So I'm going to give you my opinion
14 in terms of the context of that paragraph, not
15 an individual word.

16 Q. Did you look up when the HVAD was
17 first implanted in humans at the apex of the
18 heart?

19 A. I believe, if you want to ask the
20 court reporter to re-read the testimony, she can
21 tell you that I've already answered that
22 question.

23 Q. Did you look up when the HVAD clinical
24 trials began?

25 A. Again, as I stated before, I would

1 have been aware at the time and I probably did
2 look it up, but I don't recall the specific
3 dates. If it's in my report, if I stated it,
4 you can point it to me and I can confirm whether
5 that's what I wrote or not. I don't recall
6 right now.

7 Q. Did you take into consideration the
8 clinical trials for the HeartWare HVAD in coming
9 to your opinion in Paragraph 39?

10 MR. VARE: Objection; form.

11 THE WITNESS: I don't really --
12 again, if it's in my report, we can discuss it.
13 I don't recall if there's a specific point in my
14 report that I state that or not. If you want to
15 point me to the paragraph and the page number,
16 we can discuss that. I reviewed a lot of
17 material. You know, again, looked at a lot of
18 different devices, a lot of different papers. I
19 can't recall the specifics. If there's
20 something in my report you want to question,
21 let's go to that page.

22 BY MS. RAGHAVAN:

23 Q. Let's go to Paragraph 39 of your
24 report.

25 MR. VARE: 39?

1 MS. RAGHAVAN: Yes.

2 THE WITNESS: That's where we've
3 been --

4 MS. RAGHAVAN: I was talking
5 about Paragraph 38, but I would like you to
6 refer to Paragraph 39.

7 MR. VARE: No, we were actually
8 talking about Paragraph 39.

9 MS. RAGHAVAN: Well, the witness
10 was talking about Paragraph 39; I was talking
11 about Paragraph 38.

12 MR. VARE: No, the witness was
13 talking about Paragraph 39.

14 THE WITNESS: No, you asked me
15 specifically about Paragraph 39.

16 BY MS. RAGHAVAN:

17 Q. Okay. Well, continue looking at
18 Paragraph 39.

19 A. Okay.

20 Q. Are you talking about the Bourque 2001
21 reference here?

22 A. I believe that's what it states in the
23 paragraph.

24 Q. Do you agree that a pump the size of
25 the Bourque 2001 device could have been

1 implantable in at least one patient at the apex
2 of the heart?

3 MR. VARE: Objection; form.

4 THE WITNESS: As I stated, I gave
5 my opinion that I don't believe a pump of this
6 size would be appropriate to be delivered to the
7 apex of the heart. So I don't agree with your
8 statement. I stated that I don't agree that
9 this would be an appropriate pump of this size
10 to put at the apex of the heart.

11 BY MS. RAGHAVAN:

12 Q. I'm trying to clarify whether that
13 opinion applies to all patients.

14 A. I believe you've asked and I've
15 answered. It's not appropriate to implant,
16 because of its size, at the apex of the heart.

17 Q. Would it be possible to implant the
18 Bourque 2001 device in an adult male patient of
19 a large size?

20 A. So what you're asking me to do, I
21 believe, is out of the scope, you're asking me
22 to go experiment on patients. So what I'm
23 telling you is a pump of that size, a person of
24 skill in the art would generally accept that
25 that was too large a pump to place at the apex

1 of the heart, and would not have chosen to do
2 that at the time of this disclosure.

3 So at the end of the day if you're
4 asking me to go back and do experiments, that
5 would take us way out of the scope of this
6 particular discovery. But again, a person of
7 skill in the art would not have taken a pump of
8 that size and put it at the apex of the heart.

9 Q. What is your basis for that
10 understanding?

11 A. The technical and feasibility of
12 placing a pump of that size in the chest.

13 Q. And what did you rely on to come to
14 that conclusion?

15 A. Based on the skill of the art at the
16 time, any person with skill in the art would
17 have known not to put a pump of that size in the
18 chest. The rest of it is discussed in the
19 subsequent paragraphs of my report. So if you
20 read my report, you'd understand my thinking as
21 a person of skill in the art.

22 Q. In terms of understanding what a
23 person of skill in the art would have known or
24 not known separate from your own personal
25 understanding, what did you rely upon?

1 MR. VARE: Objection; form.

2 THE WITNESS: I would refer you
3 to the subsequent paragraphs that explain in
4 detail what I relied upon. And I can read --

5 BY MS. RAGHAVAN:

6 Q. So anything that you relied upon --

7 A. I can re-read the whole report to you
8 if you'd like me to at this point in time, but
9 again --

10 Q. I've read your report, thank you. But
11 I'm trying to ask you questions relating to your
12 report that you're refusing to answer. So I
13 would like to ask the questions and I would like
14 you to answer those questions. So if we can
15 move forward that way, that would be great.

16 MR. VARE: So I'll just interject
17 an objection as argumentative, but I would also
18 just I think advise everyone to not speak over
19 each other for the benefit of the court
20 reporter.

21 THE WITNESS: Yes, I would
22 appreciate that because I was not done speaking
23 at the time. So you made me lose my train of
24 thought in terms of what I was speaking to. So
25 at the end of the day I will again state, my

1 report gives you the information in terms of
2 what I considered. If there is something
3 specific that you want me to discuss, I can do
4 that. If you're asking me to go back and
5 reconsider every element of this that wasn't in
6 my report, it's going to be difficult because it
7 would take me time to review any other question
8 you asked me that's not necessarily in this
9 report.

10 So again, if you have a question
11 specific to my report in terms of not
12 understanding the report or something else,
13 please refer me to that point. Otherwise, if
14 you're asking me to theorize or hypothesize
15 about something that I did not consider in this
16 report, it would be difficult for me to answer
17 at this time.

18 I pride myself as an expert in the
19 field, which means if you're going to ask me to
20 talk about a hypothetical, that would mean I
21 would have to go and review all of the material
22 related to that hypothetical, and I would not at
23 this point tell you that I feel comfortable
24 answering a question about a hypothetical that
25 wasn't already considered in my report.

1 So again, if there is something
2 specific in my report that you have a question
3 to, please direct me to that. Otherwise, if
4 you're asking me about hypotheticals, my answer
5 to you is I will not consider a hypothetical
6 because I cannot give you an answer as an expert
7 today without sufficient time to review and come
8 back with an answer. That would be way outside
9 of the scope of today.

10 BY MS. RAGHAVAN:

11 Q. Is that it? I don't want to
12 interrupt.

13 A. Yes.

14 Q. So in terms of the materials that you
15 relied on to form your understanding of what a
16 POSA would have understood at the time of the
17 invention, is it fair to say that the materials
18 you found relevant to forming and understanding
19 of what a POSA would have known at the time are
20 cited in your declaration?

21 MR. VARE: Objection; asked and
22 answered.

23 THE WITNESS: I would agree with
24 that statement; I've already answered that
25 question.

1 MS. RAGHAVAN: I'm going to
2 introduce a new document that I'm going to mark
3 as Exhibit 1038. This was not a document that
4 was cited in your declaration, so you'll have to
5 view it electronically. Let me know when you
6 have it up.

7 (Exhibit 1038 marked for
8 identification.)

9 THE WITNESS: I have it up. I'm
10 just reading it. Okay.

11 BY MS. RAGHAVAN:

12 Q. Let me know when you're ready.

13 A. I'm ready.

14 Q. Did you consider this article in
15 forming your opinions for this proceeding?

16 A. In what way?

17 Q. Did you consider it in any way?

18 A. I don't recall.

19 Q. Have you seen this article before?

20 A. I may have. This was a paper
21 published years ago. I couldn't tell you. I've
22 read thousands of papers in between.

23 Q. Are you familiar with the ASAIIO
24 journal?

25 A. Yes.

1 Q. And March of 2004 was before the
2 priority date of the patent; correct?

3 A. Yes.

4 Q. This article discusses the HeartWare
5 pump; correct?

6 A. It appears to, yes.

7 Q. And in particular it talks about a
8 miniaturized version of the HeartMate pump;
9 right?

10 A. Oh, if you could -- very hard to read,
11 it's so small. But if there's a specific line
12 you can ask me about -- I don't see it.

13 Q. It's just in the title, it says a
14 novel miniaturized passive maglev centrifugal --

15 A. That's discussing HeartWare. I don't
16 see anything that says HeartMate. I'm not sure
17 if I misheard you.

18 Q. Oh, sorry. It talks about a
19 miniaturized version of the HeartWare pump; is
20 that right?

21 A. That's the title, yes.

22 Q. Do you see where it says that
23 HeartWare -- it's the second sentence, I
24 believe, it says, "The HeartWare has developed a
25 miniaturized passively magnetically suspended

1 centrifugal VAD, which has a displaced volume of
2 50 CC and weighs 145 grams."

3 Do you see that?

4 A. I see that.

5 Q. Is this the size of the HeartWare HVAD
6 pump that you considered in forming your
7 opinions about the practical feasibility of the
8 pump?

9 A. Well, I can say that -- I can't say
10 necessarily, because this short abstract does
11 not give any illustrations, does not give any of
12 the technical specs beyond just the weight and
13 the displacement. So it could be. I don't
14 know.

15 Q. Okay. Let's take a look at
16 Paragraph 44 of your declaration.

17 A. But also here, this description is so
18 brief, it doesn't tell me exactly how this pump
19 is connected or where it's connected. Simply
20 that it's miniaturized.

21 Q. Let's take a look at Paragraph 44,
22 please.

23 A. I'm sorry, of my disclosure?

24 Q. Yes.

25 A. Okay.

1 Q. In Paragraph 44 you talk about
2 Wampler's disclosure of a pump that displaces
3 only 28 CC; correct?

4 A. That's what it states, yes.

5 Q. And Exhibit 1038, which we were just
6 looking at, describes a HeartWare pump that has
7 a displaced volume of 50 CCs; correct?

8 A. I'm sorry, I didn't hear the whole
9 question. Could you repeat it? I was in the
10 process of reading, so...

11 Q. In Exhibit 38 that we were just
12 looking at, it describes a HeartWare pump that
13 has a displaced volume of 50 CC; correct?

14 A. Yes, I can see that on the document.

15 Q. Okay. A pump that displaces a volume
16 of 50 CC is larger than a pump that displaces
17 only 28 CC; correct?

18 MR. VARE: Objection; form.

19 THE WITNESS: Are you asking
20 about a hypothetical pump? Yes, they would --
21 based on the numbers, would displace different
22 volumes.

23 BY MS. RAGHAVAN:

24 Q. In the middle section of Exhibit 1038
25 it describes the miniaturized HeartWare pump as

1 having a short integrated inflow cannula. Do
2 you see that?

3 A. Yes.

4 Q. It also says that the size of the
5 device coupled with the perpendicular
6 relationship of the outflow to the inflow allows
7 for intrapericardial pump placement and fast
8 implantation. Correct?

9 A. Yes.

10 Q. So would you agree that this article
11 discloses placing a pump with a displaced volume
12 of 50 CCs in the intrapericardial space?

13 MR. VARE: Object to form.

14 THE WITNESS: It does, but it
15 doesn't disclose how or where.

16 BY MS. RAGHAVAN:

17 Q. What do you mean by "where"?

18 A. It tells me it's put in the
19 intrapericardial pump, but it doesn't tell me
20 how that pump is connected to the heart. But I
21 will say that, again, this fits with my opinion
22 in that the very first sentence stating that for
23 it to be successful, it had to be a small size
24 and optimized to fit. Highly relevant -- all of
25 the topics here point to the same statement that

1 support my opinion that the accused product was
2 not of the appropriate size, was not configured
3 to be able to be placed in the intrapericardial
4 space. So just because this particular pump
5 might have been able to be placed there doesn't
6 necessarily mean that the pump as described by
7 Wampler could have been.

8 And furthermore, at the end of the day
9 as I said before, this is such a brief
10 disclosure, it doesn't tell me anything about
11 how this was to be accomplished. So as a person
12 of skill in the art, I would have had interest
13 in this but I would have needed more information
14 to understand how to accomplish this task.

15 Q. But you would agree that there was
16 other published literature about the HeartWare
17 pump, correct, from which you could have gleaned
18 that information?

19 MR. VARE: Objection; form.

20 THE WITNESS: Again, I told you I
21 didn't -- did a search of literature. What was
22 relevant to what I discussed is in my report. I
23 didn't say that there wasn't any other
24 literature available. And again, if you want me
25 to read every paper about HVAD, we can spend a

1 lot of time today reading every paper. But
2 again, I didn't say I didn't read it. I didn't
3 quote it because again, it wasn't necessarily
4 relevant. I should have maybe attributed this
5 particular one because it, again, supports my
6 belief, as most people of skill in the art would
7 have said, that in order for a device of this
8 type to be placed at the apex, it has to meet
9 the criteria, and Wampler's pump did not.

10 BY MS. RAGHAVAN:

11 Q. Is it your understanding that the
12 Wampler pump is different than the HeartWare
13 pump that's described in this article?

14 A. Well, if you're asking me if the
15 prototype HeartWare 3 is different than the
16 HVAD, yes, they are different. They are
17 different size; they're different weights.
18 Could they have been used in the same fashion?
19 As I already said in my opinion, no. I'm sorry,
20 I take it back. I'm confusing terms. The
21 Bourque pump. I misspoke. I understand your
22 confusion now.

23 Q. Okay. So I want to backtrack a little
24 bit just so that we are clear on what we're
25 talking about. You said prototype HeartWare 3.

1 By that you're referring to the Bourque 2001
2 prototype?

3 A. Yes, yes. I recognize by the confused
4 look you gave me I was mixing things there. I
5 apologize. What I meant to say was this
6 particular pump as it's described is
7 significantly different than the Bourque pump,
8 and it supports my other people of skill in the
9 art who would have said this size of pump may
10 have been possible, but the Bourque pump would
11 not have been; too large.

12 Q. So my question to you was, is it your
13 understanding that the Wampler pump is different
14 than the HeartWare miniaturized pump that's
15 described in this article?

16 A. Again, I apologize. I misspoke.
17 These are the pumps that we were talking about.
18 I was mixing Wampler with Bourque. And I
19 apologize --

20 COURT REPORTER: (Requests
21 clarification.)

22 THE WITNESS: I said I did mix
23 the two pumps, and I'm going to have to correct
24 myself. What I was stating in terms of the two
25 different pumps, I was misstating that the

1 Wampler pump and the Bourque pump were the same.
2 So that, I need to correct myself and say that I
3 was wrong. I'm speaking too fast.

4 BY MS. RAGHAVAN:

5 Q. This article, Exhibit 1038, also says
6 that the HeartWare HVAD as described in the size
7 that's provided in this article is suitable for
8 a large patient population. Do you see that?

9 A. Yes, and I apologize. Let me find out
10 what's barking here. Give me two seconds.

11 Q. Sure.

12 (Discussion was had off the record.)

13 BY MS. RAGHAVAN:

14 Q. I was asking you about the last
15 sentence of Exhibit 1038, and whether you agree
16 that the HeartWare VAD as described in this
17 article is suitable for a large patient
18 population.

19 MR. VARE: Objection; misstates
20 the sentence.

21 THE WITNESS: I would say that if
22 you read the entire statement, it says that the
23 HeartWare VAD promises to be an easily
24 implantable, highly reliable, long term
25 mechanical ventricular assist device suitable

1 for a large patient population. The word
2 "promises" would mean that even at the time the
3 author, Dr. Fraser, didn't necessarily conclude
4 that it was.

5 BY MS. RAGHAVAN:

6 Q. But you would agree that he's talking
7 about a HeartWare VAD pump that has a displaced
8 volume of 50 CCs; correct?

9 A. I would agree that the topic of the
10 article is related to that, yes.

11 Q. And that he's talking about a pump
12 that weighs 145 grams; correct?

13 A. It appears that's what it states in
14 the article.

15 Q. Just because there was some confusion
16 in the record earlier, I just want to make sure
17 that I understand your testimony on this point,
18 so I'll re-ask a question. Apologies if --

19 A. No, I understand completely.
20 Apologize for my mixing of names. After a
21 while, unfortunately, you know how it goes in
22 terms of mixing names, and I want to be as
23 accurate as possible as well. So please go
24 ahead.

25 Q. Yes. So to revisit that, do you agree

1 that the HeartWare HVAD is a Wampler pump?

2 MR. VARE: Objection; form.

3 THE WITNESS: Yes, it's a pump
4 that ultimately became known as HeartWare. But
5 not necessarily every Wampler pump is, you know,
6 the implanted HeartWare device.

7 MS. RAGHAVAN: Understood.

8 BY MS. RAGHAVAN:

9 Q. Let's turn back to your declaration at
10 Paragraph 47.

11 A. Yes.

12 Q. It's a long paragraph, but I'm going
13 to refer you to the last sentence of
14 Paragraph 47.

15 A. Yes.

16 Q. You're referring to a pump of the size
17 disclosed in the Bourque 2001 reference;
18 correct?

19 A. Yes.

20 Q. And then you say that the only
21 practical options for placement would have been
22 either in the preperitoneal or the
23 intraabdominal pockets. Do you see that?

24 A. For this style of pump, yes.

25 Q. When you say "only practical options,"

1 are you talking about what would be practical
2 for a large population of patients?

3 MR. VARE: Objection; form.

4 THE WITNESS: I'm referring to,
5 because of its size, the only practical
6 locations would have been these two locations.

7 BY MS. RAGHAVAN:

8 Q. Are you saying that it would not --
9 withdrawn.

10 Are you saying that those are the only
11 practical options for any patient?

12 A. In general, when we talk about these
13 pumps, it really comes down to where would this
14 fit, whether it's a large patient, a small
15 patient. We would have to look at every
16 individual patient to understand whether one
17 device or another could fit. But a pump of this
18 size would not likely have been implantable in
19 most patients at the time.

20 Q. So you're not making this statement
21 for all patients; you're making this statement
22 for a large portion of patients?

23 A. Well, again, you're speaking
24 hypotheticals. If you're asking me would this
25 be able to go into an elephant? Probably. But

1 I don't believe that the elephant was the target
2 of this particular -- this would have been any
3 human, in terms of its size. So because of its
4 size, it would not have been practical to plan
5 to place this at the apex of the chest -- the
6 apex of the heart within the chest. It would
7 have been practical to place this in either
8 intraabdominal or in the preperitoneal pocket
9 position.

10 Q. Well, so let's limit our discussion to
11 humans for purposes of this conversation. And
12 my question still remains the same. Are you
13 saying it's the only practical option for a pump
14 of this size to be placed in either the
15 preperitoneal or intraabdominal pockets for all
16 patients, or just the large majority of
17 patients?

18 MR. VARE: Objection to form.

19 THE WITNESS: I believe I've
20 already answered this question, but I will tell
21 you that a person of skill in the art at the
22 time would have known that a pump of this size,
23 these were the practical places to implant the
24 device. Trying to place it within the chest
25 would have been impractical and likely would

1 have led to failure. So a person of skill in
2 the art would not have placed this in the chest
3 as described by Wampler because of the
4 limitations of this particular pump, the size
5 and the displacement.

6 BY MS. RAGHAVAN:

7 Q. So are you contending that it would
8 not have been possible for any patient?

9 A. I think my -- I think I've answered --

10 Q. Any human patient, to be --

11 A. I believe I've answered the question,
12 and it is stated in the document itself that the
13 person of skill in the art would not have
14 considered these practical places to implant.
15 The only two that would have been practical at
16 the time, because of the size and the pump
17 itself, would have been at those two locations.

18 COURT REPORTER: (Requests
19 clarification.)

20 THE WITNESS: Sure. Apologies.

21 (Discussion was had off the record.)

22 (11:15 a.m. - Recess taken.)
23
24
25

1 (At 11:30 a.m., with parties present
2 as before, the following proceedings were had,
3 to-wit:)

4 BY MS. RAGHAVAN:

5 Q. Dr. Gallegos, could you please look at
6 Paragraph 55 of your declaration.

7 A. Yes.

8 Q. You start out by saying, "It's my
9 opinion that the authors of Bourque 2001
10 understood that their pump was too large to be
11 positioned on the heart directly."

12 Do you see that?

13 A. Yes, I see that sentence.

14 Q. Is it your understanding that the
15 challenged claims require the pump to be placed
16 on the heart directly?

17 MR. VARE: Objection; form.
18 Outside the context -- or outside the scope.

19 THE WITNESS: Again, my
20 assignment with respect to what's written in
21 this document isn't going based on a
22 claim-by-claim analysis. My response is in
23 response to your expert, and I'm addressing his
24 statements with respect to combining the two
25 ideas. So I didn't go on a claim-by-claim

1 analysis, so I don't -- to that question --

2 COURT REPORTER: (Requests
3 clarification.)

4 MR. VARE: Looks like he froze.
5 Looks like your video froze.

6 (Requested record read.)

7 THE WITNESS: That's the total.

8 BY MS. RAGHAVAN:

9 Q. You've not offered any opinions about
10 whether the Bourque 2001 pump could sit in the
11 preperitoneal pocket with an axially aligned
12 inflow cannula that is inserted into the left
13 ventricle; correct?

14 MR. VARE: Objection; form.

15 THE WITNESS: I don't really
16 understand the question.

17 BY MS. RAGHAVAN:

18 Q. What part of it do you not understand?

19 A. What is the question?

20 Q. You haven't offered any opinions about
21 whether the Bourque 2001 pump could sit in the
22 preperitoneal pocket with an inflow cannula
23 that's inserted into the left ventricle;
24 correct?

25 MR. VARE: Objection; form.

1 THE WITNESS: I still don't
2 understand what the question is. That is what's
3 described by the paper. So I believe the
4 authors offered the opinion. But what is the
5 question you're asking me to answer?

6 BY MS. RAGHAVAN:

7 Q. Do you have an opinion about whether
8 the inflow cannula that's described in Bourque
9 2001 could have been made in an axially aligned
10 inflow cannula?

11 MR. VARE: Objection; form.

12 THE WITNESS: Again, with
13 relevance to what exactly are you referring to,
14 if you're talking about, again, placing the pump
15 in the preperitoneal pocket, I think that was
16 described by the authors.

17 BY MS. RAGHAVAN:

18 Q. Do you have any opinions at all about
19 modifying the inflow cannula that's described in
20 the Bourque 2001 pump?

21 A. I guess I would ask if you can point
22 to a point in my report where we discussed that,
23 I can give you that opinion. I didn't, to my
24 recollection, go into that detail because it
25 wasn't necessarily the assigned -- I wasn't

1 assigned to modify their pump.

2 Q. So your opinion is about whether the
3 Bourque 2001 pump, or a pump of its size, would
4 have been able to fit on the heart directly;
5 correct?

6 MR. VARE: Objection; form.

7 THE WITNESS: I believe my
8 opinions are can you combine these two ideas to
9 a pump that would be applicable in the fashion
10 discussed, and my opinions to that are reflected
11 in the report.

12 BY MS. RAGHAVAN:

13 Q. Have you considered any modifications
14 to the inflow cannula that's described in the
15 Bourque 2001 reference?

16 MR. VARE: Objection; form.

17 THE WITNESS: I believe that
18 would be a hypothetical because again, it wasn't
19 necessarily what I was assigned to do. I wasn't
20 assigned to come up with a pump that would work
21 for you.

22 BY MS. RAGHAVAN:

23 Q. And in response to Abbott's expert
24 opinions, you haven't considered the proposed
25 modifications to the inflow cannula that is

1 described in the Bourque 2001 reference;
2 correct?

3 MR. VARE: Objection; form.

4 THE WITNESS: Again, I don't
5 really quite understand what the difference is
6 in the two questions that you just asked me. I
7 was asked to look at these two concepts, could
8 they be mixed to form a pump that would work,
9 and the answer is that's what I looked at and
10 discussed in my report. I did not necessarily
11 come up with the notion that could a person of
12 skill in the art take one paper, decide to do a
13 lot of modifications, take another paper, and
14 then combine them together. Because that to me
15 would be asking for a lot -- the information
16 would not be disclosed in the two ideas that
17 would allow me to combine them to immediately
18 come to an answer. I would have to do a lot of
19 extra work in order to come to that idea.

20 So any modifications that you're
21 asking me to do would mean a person of skill in
22 the art would have to spend time thinking about
23 them, designing them, investigating them, and
24 then hopefully they would work. If not, I would
25 go back to the drawing board, reiterate, try to

1 come up with a pump design.

2 So the answer is no, I didn't
3 necessarily go through and contemplate every
4 modification that could have potentially allowed
5 me to take one idea in terms of position,
6 another idea in terms of the style of pump, and
7 combine them together to make a pump that would
8 work for you. No, I don't believe that was my
9 assignment.

10 BY MS. RAGHAVAN:

11 Q. What did you understand your
12 assignment to be?

13 A. As I just stated. You can reread it.
14 But again, the combination of the two ideas is
15 reflected in my opinions throughout the
16 document.

17 Q. Is your combinability analysis limited
18 to the size and weight of the pumps?

19 MR. VARE: Objection; form.

20 THE WITNESS: No, but it begins
21 there. Because again, if the size and weight
22 would not allow, then there is no possible
23 combination of these two concepts that would
24 allow me to achieve the response. It would not
25 be successful.

1 BY MS. RAGHAVAN:

2 Q. Does the configuration of the inflow
3 cannula factor into your analysis?

4 MR. VARE: Objection; form.

5 THE WITNESS: Again, all of them
6 could. If you want to point to a point in my
7 report where I specifically talk about this, we
8 can talk about it. I don't have an opinion
9 right now that I can easily tell you that -- I
10 don't recall specifically I even addressed that
11 in my report. But if you want to go to a
12 section in my report that does discuss that, we
13 can go through it. I don't remember that
14 section.

15 BY MS. RAGHAVAN:

16 Q. Do you think a small axial flow pump
17 would be suitable for implantation at the apex
18 of the heart?

19 MR. VARE: Objection; form.

20 Improper hypothetical.

21 THE WITNESS: Well, to the extent
22 that you're asking me to hypothesize, again, if
23 it was in the scope of my report, I would have
24 discussed it. I don't believe it's in my
25 report, so I don't have an opinion today that I

1 can offer you readily.

2 BY MS. RAGHAVAN:

3 Q. Okay. Let's turn to Paragraph 48 of
4 your report -- of your declaration.

5 A. Yes.

6 Q. I'm looking at the last sentence of
7 Paragraph 48, which is on Page 26.

8 A. Yes.

9 Q. You say here that there would be
10 significant complex changes required to reducing
11 the pump's size as disclosed in the Bourque 2001
12 reference; correct?

13 A. Yes, that's what it states.

14 Q. Would you agree that the electronics
15 that were to be incorporated in heart pumps
16 advanced between 2001 and 2007?

17 MR. VARE: Objection; form. It's
18 outside the scope.

19 THE WITNESS: I didn't
20 specifically go through and track the changes in
21 available parts at the time. So I don't believe
22 that's part of my report. So I would have to go
23 back and look at that specific question to
24 answer something for you today.

25 BY MS. RAGHAVAN:

1 Q. Would you agree that the development
2 of smaller electronics would have been relevant
3 to a POSA determining whether the Bourque 2001
4 pump could have been made smaller between 2001
5 and 2007?

6 MR. VARE: Objection; form.

7 THE WITNESS: I believe that's
8 just another way of asking the same question you
9 asked before, which is, again, I didn't
10 specifically track the development of equipment
11 in terms of electronics through other parts that
12 were available at the time. Just in the same
13 way I wouldn't have understood necessarily the
14 machining skills at the time. So no, I can't
15 really offer you an opinion today.

16 BY MS. RAGHAVAN:

17 Q. Let's turn to Paragraph 59 of your
18 report.

19 A. Yes.

20 Q. Okay. Here you have several
21 statements that Mr. Bourque made in 2006;
22 correct?

23 A. Yes, those are quotations that were
24 taken from those particular documents, yes,
25 exhibits.

1 Q. You see here that Mr. Bourque, in
2 2006, is stating that the HeartMate 3 could have
3 been miniaturized?

4 MR. VARE: Objection; form.

5 THE WITNESS: Where do I --
6 where?

7 BY MS. RAGHAVAN:

8 Q. On Page 34 you quote Mr. Bourque, and
9 it says, "In 2006 we said stop, let's stop,
10 let's do exactly this, the original larger
11 HeartMate 3 design, but let's make it the
12 clinical HeartMate 3 now, a mini one of those."

13 Do you see that?

14 A. That's the statement, yes.

15 Q. Do you understand that to --

16 A. I think he made the statement several
17 years later, and he also says that, let's stop,
18 do exactly this. So I think he's admitting that
19 at the time it didn't exist. So it would have
20 taken quite a long time for it to be realized.
21 So at the time in 2006 it would have been
22 aspirational to miniaturize it, but it took time
23 and development in order to get to that.

24 Q. Is it your understanding of the law of
25 obviousness that you have to realize the device

1 that you are designing?

2 A. I think the -- I believe I made a
3 statement before that it had to be considered
4 successful, that I could take these two concepts
5 and put them together and come up with a
6 product. He himself recognizes at the time of
7 the disclosure it would not have been possible
8 to be successfully able to miniaturize the
9 device --

10 COURT REPORTER: (Requests
11 clarification.)

12 THE WITNESS: That the technology
13 wasn't available and it would not have been
14 successfully implemented at that time. And that
15 it took quite a long time for them to, as he
16 said, go back to the drawing board, stop, pick
17 the original device, and make it into what is
18 the current HeartMate 3.

19 BY MS. RAGHAVAN:

20 Q. Do you understand that the law of
21 obviousness simply requires a reasonable
22 expectation of success?

23 MR. VARE: Objection; calls for a
24 legal conclusion.

25 THE WITNESS: I am not an

1 attorney. As I said before, I took it from the
2 perspective that I had to be able to take one
3 concept, meaning placing the pump at the apex,
4 the second concept, the particular pump that was
5 available to me at the time, to combine them
6 into something that would work. And the answer
7 is at the time it would not have worked. So it
8 would not have been a successful implant. And I
9 believe that Bourque himself recognizes that --
10 recognized it, stopped, went and developed an
11 entirely new pump for which he then got a patent
12 years later for.

13 So again, I think he is telling me
14 through his comments that yes, it wasn't
15 successful at the time to be able to take these
16 two concepts, put them together, and come up
17 with a working pump.

18 BY MS. RAGHAVAN:

19 Q. Would he have expected it to be
20 successful?

21 MR. VARE: Objection. That calls
22 for speculation.

23 THE WITNESS: I would not know
24 because I didn't know him personally. I didn't
25 interview him at the time and don't understand

1 whether he would have or would not have thought
2 it would have been successful. But clearly if
3 he had to say let's stop, rethink this whole
4 concept, with the available new technology,
5 clearly means to me it wasn't possible at the
6 time.

7 BY MS. RAGHAVAN:

8 Q. You would agree that he made these
9 comments in 2006, even though it's being
10 quoted --

11 A. Yeah, I would say --

12 MR. VARE: Objection. That
13 actually miss -- I'm sorry. Counsel, that
14 misstates the documents that are cited in
15 Paragraph 59 that you're referring to. Those
16 were not statements made in 2006. Those
17 documents were published years later. So that's
18 misleading and misstating the record.

19 MS. RAGHAVAN: Okay. Well, thank
20 you for your testimony, Todd. First of all, I
21 would appreciate it if you both let me finish my
22 question before objecting and answering. So
23 let's start there.

24 BY MS. RAGHAVAN:

25 Q. You would agree that the quotation

1 that you take from this article, that I
2 understand was published after 2007, refers to a
3 quote that Mr. Bourque made in 2006; correct?

4 MR. VARE: What article? What
5 article are you referring to, Counsel? Because
6 you cannot misstate -- it's not coaching the
7 witness, and it's a proper objection if you're
8 misleading the witness and misstating the
9 evidence. So what specific -- what --

10 BY MS. RAGHAVAN:

11 Q. Well, let's look at Paragraph 59.

12 MR. VARE: What specific document
13 are you referring to?

14 MS. RAGHAVAN: Do you want to ask
15 the questions?

16 MR. VARE: I'm asking you, what
17 specific documents are you referring to?

18 MS. RAGHAVAN: I'm asking the
19 questions but you keep interrupting. So if you
20 would let me ask the questions, maybe we can
21 move forward a little bit. Okay. Thank you.

22 BY MS. RAGHAVAN:

23 Q. Let's look at Paragraph 59. The end
24 of Paragraph 59 you are quoting from
25 Exhibit 2007; correct?

1 A. So I guess I'll stop you again. When
2 you say that, which portion -- if you just read
3 the components so that I can know what you're
4 talking about, because there are several
5 citations here. I don't want to confuse the
6 issue. So read the sentence to me, that way I
7 have an understanding of what you're asking.

8 Q. In the last sentence of Paragraph 59
9 it refers to a 2021 interview; is that accurate?

10 A. So beginning at "in 2021 interview,
11 Mr. Bourque noted that in 2006," that's the --

12 Q. Yes.

13 A. That's the -- yes.

14 Q. So we're referring to the same thing.
15 I'm not asking you to characterize the testimony
16 in any way. We're just referring to the last
17 sentence of Paragraph 59. Are we on the same
18 page?

19 A. So again, what is your question
20 related to this sentence?

21 Q. I'll get to that. I think there was
22 some confusion earlier and I wasn't able to ask
23 my question. So I just want to make sure that
24 we're all referring to the same thing now.

25 A. Well, yes, there was, but at one point

1 you asked me if he said this in 2006, and I
2 would have said no, the interview was in 2021.

3 Q. Okay. So there was an interview in
4 2021; correct?

5 A. Correct.

6 Q. At which he refers to his thoughts in
7 2006; correct?

8 A. That's what it appears to state, yes.

9 Q. Okay. And 2006 predates the invention
10 date of the challenge patents; correct?

11 MR. VARE: Objection; form.

12 THE WITNESS: Well, again, the
13 only thing I can say is that in 2021 he's
14 recognizing that even in 2006 they couldn't have
15 done this themselves with the current pump they
16 had. So they chose to stop, look at the product
17 again, and come up with a product eventually
18 that they wouldn't get a patent for until years
19 later.

20 So I would agree that taken from this
21 statement, he would say that in 2006 that he
22 would agree with any other person of skill in
23 the art that his pump, at the time, was not
24 technically feasible to implant at the apex of
25 the heart, and only after years of work did they

1 come up with something else that could be
2 patented that could be placed at the apex of the
3 heart.

4 BY MS. RAGHAVAN:

5 Q. So you would agree that the law of
6 obviousness does not require Mr. Bourque himself
7 to have miniaturized his earlier design;
8 correct?

9 MR. VARE: Objection; calls for a
10 legal conclusion.

11 THE WITNESS: Again, I'm not an
12 attorney. I was going at it, this project, from
13 the perspective of taking these two concepts and
14 asking, could a person of skill in the art at
15 the time of this disclosure come up with a
16 successful product that could have been
17 implanted at the position that was described
18 based on the really very limited technique that
19 was described in the paper, and the pumps that
20 were wholly inadequate to place at that position
21 in the body. And what I am telling you that as
22 a person of skill in the art, these two
23 combinations would not have worked. And I'm
24 also telling you that based on this article,
25 that the gentlemen himself, Mr. Bourque, in his

1 statement is saying that in 2006 they had to
2 stop because their pump would not work in this
3 position, and that they needed to do things to
4 make it work.

5 Now, I would say that as a person of
6 skill in the art, he agreed that these two
7 combinations wouldn't have worked at the time.

8 BY MS. RAGHAVAN:

9 Q. Is it possible that Mr. Bourque said,
10 let's stop for other reasons?

11 MR. VARE: Objection; calls for
12 speculation.

13 THE WITNESS: Again, I did not
14 personally know Mr. Bourque at the time of 2006,
15 or even in 2021. All I can read is what he
16 said. So from what I can see, he's saying in
17 2006, let's stop. Let's do exactly this. The
18 original larger -- and I use the word larger in
19 emphasis -- HeartMate 3 design, but let's make
20 it clinically the HeartMate 3 now, which are
21 very different pumps.

22 BY MS. RAGHAVAN:

23 Q. So prior to the priority date of the
24 patents, Mr. Bourque recognized, at least by
25 2006, that there was a need to make the pump

1 smaller?

2 MR. VARE: Objection; form.

3 THE WITNESS: I, again, did not
4 know him, cannot tell you whether or not he
5 recognized it or not. But what I am saying is
6 that he recognized that his pump could not be
7 placed at the apex of the heart.

8 BY MS. RAGHAVAN:

9 Q. Are you saying, then, that a POSA
10 would not have known how to make any third
11 generation LVAD pump small enough to be
12 implanted at the apex of the heart before 2007?

13 MR. VARE: Objection; form.
14 Improper hypothetical.

15 THE WITNESS: I would agree. Are
16 you asking me to come up with a pump which would
17 be outside the scope of what I was asked to do?
18 I was specifically asked can I combine these two
19 ideas, one, the pump, and one, the technique,
20 and perform what you asked successfully. The
21 answer is with those two particular designs, no.

22 BY MS. RAGHAVAN:

23 Q. Let's look at Paragraph 61 of your
24 declaration.

25 A. 61?

1 Q. Yes.

2 A. Okay.

3 Q. In this paragraph you mention
4 Mr. Bourque's patent, U.S. Patent
5 Number 10,500,321; correct?

6 A. That's in the report, yes.

7 Q. Did you look at the claims of this
8 patent?

9 A. Again, my assignment wasn't to look at
10 the claims of any individual patent to discuss
11 the specific claims. So I read through the
12 patent but again, do I have a comment about the
13 specific claims? No.

14 Q. Do you know whether the claims of
15 Mr. Bourque's '321 patent say anything about the
16 reduced size or weight relative to the earlier
17 design described in Bourque 2001?

18 A. I cannot recall. Again, this wasn't
19 my primary assignment to sit and analyze his
20 particular patent. So I don't recall.

21 Q. I'm going to refer you to the sentence
22 towards the middle of Paragraph 61 where you
23 say, "This patent also illustrates that the
24 smaller pump design can be positioned at the
25 apex of the heart."

1 Do you see that?

2 A. Yes, I see that.

3 Q. And you cite Exhibit 2009, figure 1;
4 is that right?

5 A. That's what it states.

6 Q. Exhibit 2009 is Mr. Bourque's patent?

7 A. I believe so. If you want to bring it
8 up, we can look at it.

9 Q. We can bring it up. One second.

10 MR. VARE: Dr. Gallegos, it's
11 also at tab 22 of your binder.

12 THE WITNESS: Yes, I'm there. I
13 just wanted to make sure that we were looking at
14 the same document.

15 BY MS. RAGHAVAN:

16 Q. Okay. So I believe you have a copy of
17 Exhibit 2009 in front of you but I've also
18 introduced it as an exhibit electronically.
19 Feel free to take a look that we are referring
20 to the same document.

21 A. Yes, we are.

22 Q. So let's turn to figure 1 of the
23 Bourque '321 patent.

24 A. I'm sorry, can you refresh my memory
25 of where we were in terms of my report, on what

1 page?

2 Q. Paragraph 61.

3 A. I just want to get to both so I can
4 understand what your question is. Okay.

5 Q. Okay. So in your declaration, again,
6 you say, "This patent also illustrates that the
7 smaller pump design can be positioned at the
8 apex of the heart."

9 Right?

10 A. Yes, that's a statement in the report.

11 Q. And for that statement you cite figure
12 1 of Mr. Bourque's '321 patent; correct?

13 A. That's correct.

14 Q. You'd agree that figure 1 isn't a
15 detailed anatomical drawing; correct?

16 A. It's a portion of the heart with a
17 portion of the device illustrated. But I'd
18 agree, it's cut off.

19 Q. It's an illustration?

20 A. It's an illustration.

21 Q. It's conceptual?

22 MR. VARE: Objection; form.

23 THE WITNESS: It's an
24 illustration; it's not a photograph.

25 BY MS. RAGHAVAN:

1 Q. But from this figure alone you were
2 able to determine that the smaller pump design
3 can be positioned at the apex of the heart; is
4 that correct?

5 MR. VARE: Objection; form.

6 THE WITNESS: No. I would say I
7 read the entire patent and -- read through the
8 entire patent. I expressed that the figure
9 demonstrates this fact, but that's about it. I
10 didn't say that that was the only reason.

11 BY MS. RAGHAVAN:

12 Q. But you would agree that the figure
13 demonstrates that fact?

14 MR. VARE: Objection; form.

15 THE WITNESS: Again, I would say
16 that this figure demonstrates what looks like a
17 pump being inserted into the -- what appears to
18 be the left ventricle.

19 BY MS. RAGHAVAN:

20 Q. And this is the only aspect of
21 Mr. Bourque's '321 patent that you cite in
22 support of the sentence that, "This patent also
23 illustrates that the smaller pump design can be
24 positioned at the apex of the heart."

25 Correct?

1 A. I believe I used the words "this
2 patent," so the patent in entirety, not just the
3 figure.

4 Q. But this is the only portion of the
5 patent that you cite after that sentence;
6 correct?

7 A. Again, I cite "this patent." I didn't
8 necessarily exclude any of the information that
9 was in the rest of the patent. That would be
10 artificially your assignment. I'm just simply
11 pointing to this particular figure that appears
12 to demonstrate his concept, which is that it's
13 being applied to the apex of the left ventricle.
14 So I wouldn't agree with you that I only
15 reference this figure as the only support. I
16 said "this patent."

17 Q. Let's take a look at Column 3 of the
18 '321 patent.

19 A. Again, I guess I would preface it by
20 saying I don't have this patent memorized. So
21 if you're asking me to evaluate this patent on
22 the fly, I don't know necessarily that I can
23 absolutely tell you that I can effectively give
24 you a solid opinion on this. I can tell you
25 what the words are written on the page but

1 again, I would have to read the whole patent
2 again today in order to understand the question
3 that you probably would be asking me.

4 So again, it wasn't my assignment to
5 evaluate this particular patent and report on
6 this particular patent, other than what I've
7 stated in my report. So -- but we can waste
8 your time if you'd like to specifically ask me a
9 question. But if it's in my report, it's
10 relevant. If you're asking me to opine on the
11 specifics of this particular patent, that wasn't
12 my assignment.

13 Q. I appreciate the disclaimer, but I'd
14 still like to proceed with asking my questions,
15 if that's okay with you.

16 A. Sure.

17 Q. So if we could turn to Column 3, lines
18 57 through 60. You can read the sentence that
19 says, "The first phase 111 of the housing 110
20 includes an inlet cannula 112 extending into
21 left ventricular LV of the heart H."

22 Do you see that?

23 A. Yes, I see that.

24 Q. You'd agree this is about the same
25 level of detail about the placement of the

1 inflow to being inserted into the left ventricle
2 as the Wampler reference; correct?

3 MR. VARE: Objection; form.
4 Outside the scope.

5 THE WITNESS: Again, I'll make
6 the statement, I would have to read the entirety
7 of the patent to understand it. I'd have to go
8 back and look at each of these reference figures
9 and spend a lot of time analyzing this
10 particular document to give you an answer in
11 comparison on a patent by patent. I wasn't
12 asked to specifically compare this patent to
13 that patent and give an opinion. I'm giving you
14 the references as I stated them.

15 So at this point I wouldn't
16 necessarily feel comfortable going in and giving
17 you an opinion about the statements of this
18 patent without spending time rereading the
19 entire patent, studying it again to answer those
20 questions. But again, as I said before, this
21 wasn't my assignment. So I don't believe that I
22 can answer your question.

23 BY MS. RAGHAVAN:

24 Q. I'm only asking you about the sentence
25 that you put into your declaration. I'm trying

1 to understand the basis for your statement.

2 MR. VARE: No, you're actually --
3 Counsel, you're actually asking about lines in a
4 patent, not about the declaration --

5 MS. RAGHAVAN: I'm going to cite
6 some case law for you that's going to explain to
7 you what is allowed in terms of objections from
8 opposing counsel. Objections are meant to be
9 brief. They are meant to be a couple of words
10 for us all to understand what your objection is.
11 And if I need clarification, I will ask for the
12 clarification. But if you could just, please,
13 going forward, keep your speaking objections to
14 a minimum, that will be appreciated. I can send
15 you case law on this point if you'd like.

16 MR. VARE: That's fine, I'm happy
17 to read the case law; I'm well aware of the case
18 law. When you say something that's not a
19 question that is misleading, then I am entitled
20 to correct the misleading statement. You're not
21 asking him a question, and I'm not objecting to
22 a question that you're asking him. You're
23 making a statement that is misleading.

24 MS. RAGHAVAN: To be fair, there
25 are several points in this deposition where

1 there wasn't even a question pending and the
2 witness was testifying on his own. So I don't
3 know what you have to say about that. But let's
4 just move on. I think I have the answers I
5 need.

6 THE WITNESS: I guess I don't
7 understand what your relevance is to this
8 question because you're making statements that
9 I'm testifying. I've asked you the same
10 statement, which is, what is the question.
11 Because if you're asking me to evaluate this
12 patent, that I did not do. And I told you I do
13 not feel comfortable giving you an answer about
14 this particular patent if I didn't specifically
15 have a task to go through line by line, claim by
16 claim, and address this patent relevant to other
17 patents. That is not what's stated in my
18 report.

19 BY MS. RAGHAVAN:

20 Q. Again, I was only asking you about the
21 sentence that was in your declaration and the
22 portion of the patent that you've cited, and --

23 A. So what is the question?

24 COURT REPORTER: (Requests
25 clarification.)

1 BY MS. RAGHAVAN:

2 Q. Can I finish?

3 A. Yes.

4 Q. As I said earlier, I'm done with this
5 portion of the patent. You can set it aside,
6 Dr. Gallegos.

7 I'm going to introduce another exhibit
8 here, which I believe should be marked Gallegos
9 Exhibit 1039. Let me know when you have a
10 chance to see it. You'll have to look at it
11 electronically.

12 (Exhibit 1039 marked for
13 identification.)

14 THE WITNESS: Yeah, I'm just
15 reading that now.

16 MR. VARE: Counsel, for my
17 benefit, is this an exhibit that has been used
18 in the proceeding?

19 MS. RAGHAVAN: It has not. I'm
20 introducing this document as a new exhibit.

21 MR. VARE: So it's not been used
22 in the proceedings at this point?

23 MS. RAGHAVAN: Correct.

24 MR. VARE: Thank you.

25 THE WITNESS: So 1039?

1 MS. RAGHAVAN: Yes.

2 BY MS. RAGHAVAN:

3 Q. It's an article titled Animal Models
4 For Cardiac Research. Let me know when you have
5 it up.

6 A. I can see it now, yes.

7 Q. This is an article that you
8 co-authored; correct?

9 A. Appears to be. My name is on it, yes.

10 Q. Do you recall writing it?

11 A. Yes. But I've written many articles,
12 and I haven't looked at this article in a number
13 of years.

14 Q. You didn't review this article in
15 preparing your declaration for this matter;
16 correct?

17 A. Not specifically that I can recall,
18 no.

19 Q. Let's turn to Page 573 of this
20 document. I'll give you a chance to read the
21 paragraph, and then I have some questions for
22 you.

23 MR. VARE: What paragraph?

24 THE WITNESS: Which paragraph?

25 BY MS. RAGHAVAN:

1 Q. Oh, sorry. The highlighted -- I
2 believe you can see the highlights. You can
3 read the highlighted paragraph.

4 MR. VARE: So again, just for the
5 record, the highlights are yours, Counsel, and
6 not in the original article?

7 MS. RAGHAVAN: Yes, that's right.

8 THE WITNESS: So you're asking me
9 to begin at 29.7.1?

10 BY MS. RAGHAVAN:

11 Q. That's right. So the subsection
12 29.7.1, Animal Model Selection For Device
13 Testing. If you could read the first paragraph
14 in that subsection.

15 A. Sure. Okay.

16 Q. Okay. You say here that, "Animal
17 models are necessary for research and
18 development of mechanical devices such as the
19 VAD, and for training of the medical personnel
20 involved in their use."

21 Do you still agree with that
22 statement?

23 A. I'm sorry, are you asking if
24 preclinical testing is important for medical
25 devices?

1 Q. I read back to you the first sentence
2 of this paragraph, and knowing that you're a
3 co-author of this article, I'm asking you if you
4 still agree with that statement.

5 A. Yes.

6 Q. Okay. Let's turn to paragraph -- or
7 sorry, Page 567.

8 A. Okay.

9 Q. Again, the highlights here are just to
10 make our lives a little bit easier in terms of
11 figuring out what we're referring to. They were
12 not part of the original article.

13 The paragraph that has highlighting
14 that starts with the ovine model, would you
15 please read that paragraph and then let me know
16 when you're ready for questions?

17 A. Okay.

18 Q. Ovine model is a sheep; correct?

19 A. Correct.

20 Q. And it says here that the ovine model
21 is accepted as the gold standard. Do you still
22 agree with that statement?

23 A. I would say that I'm not necessarily
24 in the field at the current state in the sense
25 that I haven't been doing animal testing. So at

1 the time of the article being written, I would
2 say that was the accepted gold standard. I
3 can't say that I -- again, it was not the
4 assignment of this task for me to go back and
5 verify that what I wrote a number of years ago
6 is still correct.

7 Q. Understood. You say here later in the
8 first sentence something about meeting FDA
9 requirements. Do you see that?

10 A. For that particular concept at the
11 time, yes.

12 Q. What do you understand to be the
13 relationship between testing on an ovine model
14 and meeting FDA requirements?

15 MR. VARE: Objection; outside the
16 scope.

17 THE WITNESS: Again, not
18 something that I spent time thinking about at
19 the current state to be able to go back and
20 answer you that question. But in general at the
21 time if you were involved in valve surgical
22 research in terms of replacement devices, that
23 would have been the appropriate animal model to
24 work in because it satisfied the requirements
25 that the FDA asked at that point in terms of any

1 preclinical documents that were being submitted
2 to them at that point.

3 Now, again, I'm not going to say that
4 I know that the -- I have not looked back at the
5 current standards to be able to answer your
6 question, is that still valid today or not. I
7 don't know.

8 BY MS. RAGHAVAN:

9 Q. It says -- in the second sentence it
10 says, "Normal cardiovascular physiological
11 parameters of sheep approximate those of humans
12 in blood pressure, heart rate, cardiac output,
13 and intracardiac pressure."

14 Do you see that?

15 A. Yes, I see that.

16 Q. Do you still believe that statement to
17 be true?

18 A. Again, it would depend on the specific
19 concept and device you're testing. In this
20 particular case for valve replacement concepts,
21 I would be -- would say that it's correct, yes.
22 If I'm looking at other types of devices, it may
23 or may not be correct. As I said, if you read
24 the entirety of this you'll find that there is
25 very specific information when it talks about

1 how to create an animal model, you have to know
2 what you're studying in terms of what the
3 condition is and how does it approximate the
4 human condition in order for us to obtain valve
5 information. Meaning that if you were studying
6 an animal model that didn't even remotely
7 correlate to the human conditions, the results
8 of which would then be somewhat confounding, we
9 wouldn't know whether or not it would be useful
10 to say is this safe to move on from animal to
11 human.

12 But it would very much depend on what
13 I am studying, what condition I expect to be
14 studying, what device I'm studying, and again,
15 related to the device, it would then depend on
16 is that device -- do we have a comparable size
17 in order to implant into the animal model that
18 would be the comparable size that I implant into
19 the human or not. So it's a complex -- this is
20 why this chapter is so long. It's not a simple
21 yes, no, I can use the same animal in every
22 condition to meet the requirements as I stated
23 here. But again, with respect to valve
24 replacement studies, that would have been true
25 at the time.

1 Q. Do you know whether it was true at the
2 time for testing implantable cardiac assist
3 devices?

4 MR. VARE: Objection; form.

5 THE WITNESS: As I said before,
6 it would have depended on the particular device
7 that we were looking at. If a device was too
8 large -- I think if you go back to the other
9 paragraph it said that you'd have to look at
10 other animal models. So if you go back to that
11 other paragraph -- let's see, where was that,
12 again?

13 BY MS. RAGHAVAN:

14 Q. Are you referring to Page 573?

15 A. I'm referring to Page 573, larger
16 pumps still require larger animals -- you
17 highlighted it as well, recognizing I think the
18 importance of understanding that there are
19 differences between devices. I should say
20 whomever highlighted this recognized the same
21 concept.

22 Q. Would you agree that it also depends
23 on the weight of the specific animal involved?

24 MR. VARE: Objection; form.

25 Outside the scope.

1 THE WITNESS: I guess are you
2 meaning -- are you trying to say that not only
3 the size or the placement of the pump, but the
4 weight of the pump --

5 BY MS. RAGHAVAN:

6 Q. Referring to the size or weight of the
7 animal itself. So there are anatomical
8 differences between sheep themselves; right?

9 A. Yes.

10 Q. So a smaller sheep would have a
11 smaller heart; a larger sheep would have a
12 larger heart.

13 MR. VARE: Objection. I mean,
14 Counsel -- hold on a second, Dr. Gallegos.
15 That's your testimony and it lacks foundation,
16 so I'll make that objection. I'm not sure
17 there's a question there.

18 THE WITNESS: If you could
19 rephrase your question, I might be able to
20 answer. I think what I'm saying here is that a
21 larger pump requires larger animals. So even
22 within the same species, if I was comparing,
23 let's say, a newborn sheep to an adult sheep,
24 trying to put in a device of this large size,
25 then you're absolutely correct, I couldn't put

1 it into a newborn sheep; I would require an
2 adult sheep.

3 But again, if that pump was even still
4 too large to put into an adult sheep, then I
5 would probably have to choose a different animal
6 model.

7 BY MS. RAGHAVAN:

8 Q. Understood. Okay. You can set that
9 aside.

10 Let's turn back to your declaration
11 and then turn to Paragraph 73.

12 A. I'm sorry, did you say 73?

13 Q. Yes, 73.

14 A. So now you're looking at the section
15 that begins, "At the Schima pump"?

16 Q. Yes, that's correct.

17 A. Okay.

18 Q. Okay. You say here that, "In my
19 opinion, the Schima pump is also similar to
20 other extracorporeal circulatory support pumps."

21 Correct?

22 A. That's what the statement says, yes.

23 Q. In making that statement, did you
24 consider whether the Schima pump is similar to
25 any implantable heart pumps as well?

1 A. I guess I don't really quite
2 understand the question. In general, this is
3 not a pump that would have been considered to be
4 implantable.

5 Q. Right. But you say here -- so in
6 Paragraph 73 you say that in your opinion the
7 Schima pump is similar to extracorporeal
8 circulatory support pumps; correct?

9 A. Yes, and those pumps are not typically
10 implantable pumps.

11 Q. And that's what you mean by
12 extracorporeal; correct?

13 A. That's the definition of
14 extracorporeal; means outside the body.

15 Q. Did you compare the structure of the
16 Schima pump to any implantable cardiac assist
17 devices?

18 MR. VARE: Objection; form.

19 THE WITNESS: I believe -- I
20 think I already answered that question which was
21 that this kind of pump was never implanted into
22 a patient; these are all extracorporeal pump
23 designs. So it's hard for me to compare it to a
24 pump that was never implanted.

25 BY MS. RAGHAVAN:

1 Q. I'm not sure if I understood your
2 testimony. Did you consider whether the Schima
3 pump is similar to a pump like VentrAssist?

4 A. I believe there's comments in the
5 report that we talk about that, yes.

6 Q. Do you recall where?

7 A. I don't. I'd have to go through the
8 paper. But I do recall it. I don't remember
9 which page it was. It refers to your expert,
10 Mr. Crosby, but I don't recall exactly what page
11 it's on. But I do believe it's in the report.

12 Q. Let's look at Paragraph 57.

13 A. I'm sorry, 57?

14 Q. 57.

15 A. Your connection every now and then
16 breaks on my end.

17 Q. Sorry.

18 A. That's okay. I can see you speak but
19 the voice cuts. So my apologies.

20 Q. Just let me know if you're not able to
21 hear the question.

22 A. Will do. So I'm at Paragraph 57. If
23 you don't mind, give me just a chance to figure
24 out where I'm at.

25 Q. No problem.

1 A. Okay. This was the paragraph that I
2 was referring to, yes.

3 Q. So in this paragraph you'd agree that
4 you were comparing the weight and purported
5 placement of various devices; correct?

6 A. That's a -- I guess that would be,
7 yes, the overall gist of that.

8 Q. And as part of that, you're noting the
9 VentrAssist device and its weight of around
10 298 grams, and noting that it was implanted in a
11 pocket below the diaphragm and that it was not
12 placed in the apex of the heart; correct?

13 A. That's what this statement says, yes,
14 paraphrased.

15 Q. You don't say anything here about the
16 shape of the Schima -- or shape of the
17 VentrAssist pump; correct?

18 A. I don't believe I do, no.

19 Q. Have you looked at the VentrAssist
20 pump?

21 A. In terms of have I ever had my hands
22 on it? I don't recall ever having my hands on
23 the device, no.

24 Q. Have you seen photographs of it?

25 A. I believe I've seen photographs but

1 it's been some time. I can't recall.

2 Q. Would you generally agree that there
3 could be commonalities between extracorporeal
4 pumps and implantable pumps?

5 A. Well, I think that's a big
6 generalization. I would agree that if they
7 function as an LVAD, that that could be the
8 similarity in the sense that they are replacing
9 or assisting the left ventricle and would be
10 defined as a left ventricular assist device.
11 But in terms of there is a big difference
12 between an implantable device and extracorporeal
13 device.

14 So the similarities very much stop at
15 the point when you're asking me can I take an
16 extracorporeal pump that wasn't designed to be
17 in the body and simply put it in the body? No.

18 Q. Could both extracorporeal pumps and
19 implantable pumps use MAG-NEAT-O coupling?

20 MR. VARE: Objection; form.

21 THE WITNESS: Again, what's
22 driving the pump can certainly -- they can
23 certainly work in a similar fashion. But again,
24 from my perspective it's really not relevant to
25 this concept because I'm asking, can I take this

1 pump and put it in the body at the apex of the
2 heart. Whether it's driven, how it's driven,
3 wasn't the scope of my thoughts and didn't have
4 to be the scope of my thoughts because I'm not
5 defending whether or not magnetically driven or
6 not has to be the case here. I'm simply asking
7 if I can take a pump of this type, using a
8 technique that is described by somebody else and
9 join them together and create a product that
10 could be successfully implanted. So you know,
11 again, I'm not the person you should be asking
12 that question to, I suppose, because that wasn't
13 my assignment.

14 BY MS. RAGHAVAN:

15 Q. When you say you're asking whether you
16 can take a pump of this type, are you referring
17 to a pump of a particular size or weight?

18 A. I'm referring to what your expert
19 asked or quoted as saying, that I can take one
20 product, use a technique that was described by
21 somebody else, and create a successful product.
22 So I'm responding to your expert. I'm not
23 setting the ground rules here. I'm simply -- in
24 my report as a response to your expert, in terms
25 of whether I thought his combinations would

1 work --

2 Q. But is the basis of your disagreement
3 the weight and size of the pump that's
4 disclosed?

5 MR. VARE: Objection; form.

6 THE WITNESS: That is one of
7 the -- one of what's stated in the report is the
8 size and weight of these devices and whether it
9 was practically applicable at the time of the
10 disclosure, could it be performed successfully,
11 and the answer at this point is in my report.
12 But there are other comments as well in the
13 report.

14 BY MS. RAGHAVAN:

15 Q. Would you agree that if a POSA had
16 some experience designing extracorporeal pumps,
17 that some of that experience would be relevant
18 to designing implantable pumps as well?

19 MR. VARE: Objection; form.
20 Improper hypothetical. Outside the scope.

21 THE WITNESS: I guess I'm not
22 really sure what your question is.

23 BY MS. RAGHAVAN:

24 Q. Earlier on today we talked about your
25 definition of a POSA; correct?

1 A. We did.

2 Q. And you said that a POSA is someone
3 who has experience designing, developing, using,
4 implanting, implantable cardiac devices;
5 correct?

6 A. I think we went over a much broader
7 definition, but it did have some of those
8 elements, yes.

9 Q. Okay. What I'm asking you now is if a
10 POSA had some experience designing
11 extracorporeal pumps, would some of that
12 experience be relevant to designing implantable
13 pumps as well?

14 MR. VARE: Objection; form.
15 Improper hypothetical. Outside the scope.

16 THE WITNESS: Well, by definition
17 you're drawing a difference between
18 extracorporeal and intracorporeal designs. So
19 if the expert only had experience designing
20 pumps that were used outside the body and didn't
21 have any understanding of the anatomic
22 considerations, then that would not necessarily
23 fulfill the requirements of the person of skill
24 in the art in this particular topic.

25 So again, very much like a C-suite

1 person in charge of signing documents related to
2 approving an experiment or not approving an
3 experiment, if that individual didn't actually
4 have working knowledge of the anatomy, as well
5 as the pump design, never actually stepped foot
6 in the laboratory to see a product and only
7 pushed paper, signing documents, I would say
8 that person did not necessarily have enough to
9 qualify as a person of skill in the art.

10 BY MS. RAGHAVAN:

11 Q. If you were a POSA trying to
12 understand what the general knowledge was about
13 implantable cardiac assist devices at a
14 particular time, are you saying that you would
15 not look to any literature about extracorporeal
16 pumps at all?

17 MR. VARE: Objection; outside the
18 scope.

19 THE WITNESS: I didn't say that.
20 That would be your statement.

21 BY MS. RAGHAVAN:

22 Q. So you'd agree that a reference
23 describing extracorporeal pumps could have some
24 relevance to designing implantable pumps;
25 correct?

1 MR. VARE: Objection; outside the
2 scope.

3 THE WITNESS: Again, I wasn't
4 asked by your -- again, your expert is trying to
5 combine pumps that are fully inadequate that
6 could not be applied in this particular
7 location. I didn't say that understanding the
8 concept of extracorporeal pumps was not
9 relevant. But again, at the end of the day, the
10 same statement -- my report speaks to what I
11 describe, can I combine these two kind of
12 concept pumps with this particular location. My
13 report is pretty explicit in that. I did not
14 comment to what you're asking.

15 BY MS. RAGHAVAN:

16 Q. Is it possible that a particular pump
17 can be used both as an implantable device and an
18 extracorporeal device?

19 MR. VARE: Objection;
20 hypothetical and outside the scope.

21 THE WITNESS: Again, I'm not sure
22 how it could be relevant to this particular case
23 because I'm not being asked to design a pump
24 that could be placed outside the body, and I
25 don't believe that your expert was referring to

1 designing a pump that was outside the body. He
2 was trying to place a pump at the apex that
3 would work using the combined disclosed
4 inventions. So I don't believe that I can
5 answer that question because it's not part of
6 what I looked at. And I don't believe it's
7 relevant, necessarily, or else I would have
8 discussed it.

9 BY MS. RAGHAVAN:

10 Q. So I understand that you don't believe
11 it's relevant, but I'm asking a question sitting
12 here today, as a cardiac surgeon or someone who
13 is purportedly a POSA in the field. So sitting
14 here today as a cardiac surgeon with experience
15 in the field, is it possible that a particular
16 pump can be used as both an implantable device
17 and an extracorporeal device?

18 MR. VARE: Objection; improper
19 hypothetical. Outside the scope.

20 THE WITNESS: So after nearly
21 20 years of practice I don't think I've ever
22 been referred to as "purportedly an expert" in
23 my field before. So what I will answer to you
24 is I think that's, Number 1, an offensive
25 question. And Number 2, not within the scope of

1 what I looked at.

2 So again, if you want me to answer
3 that question, I would, as an expert, go through
4 and look for any particular pump that might have
5 been used in both scenarios and maybe could
6 answer that question. But again, otherwise,
7 you're asking me to create a hypothetical. So
8 the answer would be I don't feel comfortable
9 today answering you a hypothetical question.
10 I'm not here to give you ideas on new pumps.
11 I'm here to give you what I testified, and
12 you're asking me to answer something that's not
13 in my testimony, which is my report.

14 BY MS. RAGHAVAN:

15 Q. Let's turn to Paragraph 65 of your
16 declaration.

17 A. I'm there.

18 Q. It says here that, "In many cases the
19 primary goal of an LVAD is to allow for heart
20 recovery, meaning the goal is to allow the heart
21 to beat and regain its strength over time, for
22 example, potentially to include reducing the
23 function of the LVAD over time as the heart
24 regains strength."

25 Do you see that?

1 A. Yes.

2 Q. You say in many cases it's a primary
3 goal. Do you have an understanding of in what
4 percentage of cases it's a primary goal that the
5 heart regain strength over time?

6 A. I believe if I had a statement as to
7 the exact percentage, I probably would have
8 placed it. But again, this is in context of a
9 period of time in terms of what the thoughts
10 were at the time, meaning that we had different
11 classifications. It was bridge-to-transplant,
12 meaning that we did not think the heart was
13 going to recover, at least -- let me rephrase
14 that -- that the left ventricle was going to
15 recover specifically, because there are other
16 components of the heart that can recover if the
17 left ventricle is recovered, meaning the right
18 ventricle, as well as the rest of the body,
19 lungs, everything else.

20 There was bridge-to-decision, meaning
21 that we would decide whether or not the patient
22 could go on to transplant or if they recovered
23 and we could have successfully removed the
24 device.

25 And then there are those later went on

1 to bridge-to-destination, or what we call
2 destination therapy. So over the years that
3 proportion of patients can vary. Depends on the
4 patients in front of you. So no, I don't
5 necessarily. But in general, an LVAD does
6 exactly what it states it does, it takes over
7 the function of the left ventricle. There are
8 other components of the heart that still have to
9 function. And there are other portions of the
10 heart that can recover even though you're
11 replacing the function of the left ventricle.

12 So yes, that statement still would be
13 true in that an LVAD doesn't replace the total
14 heart. That would be referred to as a total
15 artificial heart. In the case of an LVAD, if I
16 overrun the heart, meaning that I overpower the
17 right heart, I would then have to place a
18 biventricular assist device, or a BiVAD--

19 COURT REPORTER: (Requests
20 clarification.)

21 THE WITNESS: If I'm asked to
22 replace the entire function of the heart, I
23 would have to implant what we call a BiVAD, or
24 biventricular assist device, meaning both left
25 heart and right heart assist devices in order to

1 replace the function of the whole heart. So
2 that's what this is referring to.

3 BY MS. RAGHAVAN:

4 Q. How often would you say this goal is
5 achieved such that the LVAD is removed after a
6 period of time?

7 A. At this point, again, I can't
8 necessarily quote you an exact number. I don't
9 recall. It varied based on the center, it
10 varied based on the condition. It also probably
11 varied on the cause of the heart failure to
12 begin with. Somebody with a viral -- I'll slow
13 down here -- somebody with a viral indication
14 for heart failure would certainly have a greater
15 potential of recovering versus somebody who had
16 a massive infarct where the entire heart was --
17 let me rephrase that -- the entire left
18 ventricle was damaged.

19 So it, again, would depend on the
20 etiology of the heart failure in terms of how
21 likely you were to be able to explant a left
22 ventricular assist device.

23 Q. How many LVADs would you say you've
24 implanted over the course of your career?

25 A. I couldn't even begin to count you the

1 numbers. I've been involved with it for an
2 extended period of time. I can give you rough
3 numbers that I can recall on average. I
4 probably put in close to somewhere between 30 to
5 50 pumps a year at the peak of when I was
6 implanting. Now, again, how many was I involved
7 in totally? We often did this as teams. So
8 although I might not have been the primary
9 surgeon, I was certainly involved in even more
10 cases than what I would claim as the primary
11 surgeon. So a large number is about the best
12 answer I can give.

13 Q. Can you ballpark it --

14 A. No, I would --

15 COURT REPORTER: (Requests
16 clarification.)

17 THE WITNESS: Sorry. She asked
18 if I could ballpark it and the answer is no, I
19 don't necessarily know that I can ballpark it
20 today. I'd have to go back and look at every
21 institution I worked at and get every number. I
22 don't have that with me today. So anything I
23 would answer today would only be a guess and I
24 don't think you want a guess.

25 BY MS. RAGHAVAN:

1 Q. How many LVADs have you removed
2 because the patient's heart has recovered?

3 A. I would give you the same answer, that
4 I would have to go back and look. But, you
5 know, again, today we use many different types
6 of ventricular assist device, including the
7 Impella device, which is often used specifically
8 for that purpose if we think a patient has a
9 higher likelihood of recovering. It's a
10 temporary left ventricular assist device that can
11 inserted and removed. So we recover several
12 patients today. Now, that technology wasn't
13 necessarily available back in this time period.
14 So again, would I have used it back then if it
15 was available? Possibly. But again, I think it
16 makes it difficult to give you an overall
17 estimation of how many people can recover. So I
18 don't really have a good answer for you.

19 Q. So you can't ballpark how many LVADs
20 you've removed from patients?

21 A. Well, by definition, if you're asking
22 me to ballpark it, you're asking me to guess. I
23 don't know very many experts that will guess.

24 Q. But you can give me a range, can't
25 you?

1 A. It's a large number, but I don't know.
2 Again, it depends on the etiology of the heart
3 failure; it depends on what's going on with the
4 patient. So again, you're asking me to profess
5 that I can tell you that every patient, what
6 will they be able to recover. I can't
7 necessarily tell you that. So again, if you're
8 asking me by definition to ballpark, you're
9 asking me to guess, and at this point I don't
10 feel comfortable guessing.

11 Q. So would you say it's like a handful
12 or would you say it's more in like the hundreds
13 or thousands range?

14 MR. VARE: Objection; form.

15 THE WITNESS: I would say that,
16 again, I did not include this in my report. It
17 was outside the scope of what I was asked to do.
18 I am simply stating what was thought at the time
19 in terms of the different types of categories of
20 patients; those who could recover, those who
21 could not recover. But in either case, taken
22 out of context, what this paragraph is saying is
23 that you are replacing the function of the left
24 ventricle with a left ventricular assist device.
25 You still need to allow the other portions of

1 the heart to function and recover.

2 If a person is in heart failure
3 because the left ventricle has failed, they're
4 volume overloaded, their right heart would be
5 overloaded, so it may begin to fail. In between
6 are the lungs, which if they're overloaded will
7 begin to fail. They will collect edema fluid,
8 which might affect their kidneys.

9 So again, a left ventricular assist
10 device is more than just simply replacing the
11 function of one component of the heart; it's
12 replacing the cardiac function, which allows
13 many different portions of the heart and the
14 body to recover.

15 I think that's what the next sentence
16 basically would continue to describe to you. It
17 says, "In addition, an LVAD is by definition a
18 device to assist the left side of the heart
19 operation. It does not support the operation of
20 the right side of the heart. It is therefore
21 important to permit the right side of the heart
22 to continue beating, even if the LVAD is being
23 used to completely alleviate the workload of the
24 left side of the heart such that the left side
25 of the heart does not meet" -- does not or

1 meet -- "not beat."

2 I think those two paragraphs taken
3 together pretty much will describe to you
4 exactly what I've just been describing to you.

5 MS. RAGHAVAN: Let's take a break
6 and then we will reassess where we are.

7 THE WITNESS: Okay. Five
8 minutes?

9 MS. RAGHAVAN: Yeah, let's do
10 five.

11 THE WITNESS: Okay. Thank you.

12 (12:41 p.m. - Recess taken.)
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1 (At 12:50 p.m., with parties present
2 as before, the following proceedings were had,
3 to-wit:)

4 MS. RAGHAVAN: Dr. Gallegos, I
5 have no further questions for you today.

6 MR. VARE: Thank you. I just
7 have a few questions.

8 CROSS-EXAMINATION

9 BY MR. VARE:

10 Q. In your Exhibit Share can you scroll
11 back to Exhibit 1038?

12 A. Yes.

13 Q. And you recall counsel asked you
14 questions about Exhibit 1038?

15 A. I do.

16 Q. And do you see at the bottom right
17 that it's also labeled Abbott Exhibit 1015?

18 A. Yes, I see that.

19 Q. And if you can go to your expert
20 declaration in this case, Paragraph 54, and in
21 particular Page 31.

22 A. Page 31?

23 Q. Yes. It's the last sentence.

24 A. Yes.

25 Q. You see that last sentence in your

1 declaration of Paragraph 54 where you are
2 stating the weight of an HVAD and you cite --
3 you have two cites, and one of the cites is
4 Exhibit 1015?

5 A. Yes, I see that.

6 Q. Look at tab 16 of your binder.

7 A. Yes, I see it.

8 Q. Is Exhibit 1015 that you cited in your
9 report and that you're looking at in your binder
10 the same document as Exhibit 1038?

11 A. It appears to be, yes.

12 Q. So you in fact cited what counsel
13 identified as 1038, you just simply cited it as
14 the original Abbott Exhibit 1015; correct?

15 A. Yes, yes. So when it was presented to
16 me as a new paper that it was stated I hadn't
17 seen before, to be flat honest, with the number
18 of papers and other things that I've looked at,
19 I didn't immediately recognize it. But going
20 back and seeing the reference, yes, I do.

21 Again, as I said here, what I was
22 focusing on in terms of the context of the
23 paragraph should be thought of. So it was
24 something I considered, obviously, since I cited
25 it. Did I recall it immediately? Well, you're

1 asking me to recognize one of God knows how many
2 papers I have reviewed, not only for this, but
3 other things. No, I wouldn't have immediately.

4 But again, I'll stick with the
5 statement that although it does start to
6 describe the importance of the size, even here
7 it doesn't disclose how exactly it would be
8 done. Simply that size is an important factor.
9 Which again, when somebody else asked me why did
10 I think of size, well, I wasn't the only person
11 of skill in the art thinking of sizes and
12 displacement as being an important feature.

13 MR. VARE: I have no further
14 questions. Thank you, Dr. Gallegos. I
15 appreciate your time today.

16 THE WITNESS: Thank you.

17 MS. RAGHAVAN: Nothing else here.

18 MR. VARE: We are concluded. I
19 will have the witness sign and read the
20 transcript because I think it's going to be
21 important to just correct spellings and verbiage
22 that was used.

23 THE WITNESS: Yes, I'll pay
24 particular attention. Again, I have to
25 apologize, when I was referencing Wampler versus

1 Bourque, Wampler's name was in front of me and
2 it's what jumped out at me in terms of what I
3 misstated. So I'll make sure that the correct
4 pump design is being referred to in each of
5 those sections, because that was my error and I
6 apologize for the confusion.

7 COURT REPORTER: (Requests orders
8 for the record.)

9 MS. RAGHAVAN: We would like it
10 expedited. If you could get us the rough
11 tonight, that would be great. If you can get
12 final to us by Wednesday of this week, that
13 would be really appreciated.

14 COURT REPORTER: Final by
15 Wednesday. All right. Mr. Vare, normal
16 turnaround?

17 MR. VARE: That's fine.

18 THE WITNESS: Thank you.
19 Appreciate it.

20 (12:55 p.m. - Adjournment.)

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A C K N O W L E D G E M E N T

I, ROBERT GALLEGOS, certify
that I have read the transcript of my
testimony taken under oath on December 15,
2025, and that the transcript is a
true, complete and correct record of
what was asked, answered and said
during this deposition, and that the
answers on the record as given by me
are true and correct.

ROBERT GALLEGOS

Signed and subscribed to
before me, this day
of , 20 .

Notary Public

C E R T I F I C A T E

STATE OF NEBRASKA)
) ss.

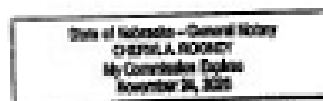
COUNTY OF DOUGLAS)

I, Cheryl A. Rooney, Registered
Professional Reporter, General Notary Public
within and for the State of Nebraska, do hereby
certify that the foregoing testimony of ROBERT
GALLEGOS, M.D. was taken by me in shorthand and
thereafter reduced to typewriting by use of
Computer-Aided Transcription, and the one
hundred sixty-nine (169) pages contain a full,
true and correct transcription of all the
testimony of said witness, to the best of my
ability;

That I am not a kin or in any way
associated with any of the parties to said cause
of action, or their counsel, and that I am not
interested in the event thereof.

IN WITNESS WHEREOF, I hereunto affix
my signature and seal this 17th of December,
2025.

Cheryl A. Rooney



CHERYL A. ROONEY, RPR

GENERAL NOTARY PUBLIC

Registered Professional Reporter

My Commission Expires: November 24, 2026

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ERRATA SHEET
VERITEXT/NEW YORK REPORTING, LLC

CASE NAME: Abbott Laboratories v. Miracor Medical SA
DATE OF DEPOSITION: 12/15/2025
WITNESSES' NAME: Robert Gallegos , M.D.

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