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BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,

Plaintiff,

v.

Case No.

MIRACOR MEDICAL SA,

IPR202500096(PTAB)

Defendant.

DEPOSITION OF

PETER CROSBY

DATE: Thursday, September 4, 2025

TIME: 9:05 a.m.

LOCATION: Winston & Strawn, LLP

333 South Grand Avenue, 38th Floor

Los Angeles, CA 90071

OFFICIATED BY: Ruby Moreno

JOB NO.: 7565630

<p>1 Could you take a look inside that binder and just 2 confirm that's your declaration for the 096 IPR?</p> <p>3 A Yes, I see this.</p> <p>4 Q And then the second binder has some of the 5 references that we're going to talk about. It includes 6 the 356 patent, which is the patent at issue in the 096 7 IPR, the Akamatsu reference, the Bourque reference, the 8 Schima reference, the Wampler reference, and then also 9 Exhibit 1019, which is some infringement allegations 10 made by Miracor Medical that you cite to in your 11 declaration. So you have those two binders there?</p> <p>12 A I have the two binders, yes.</p> <p>13 Q Okay. Have you had your deposition taken 14 before, Mr. Crosby?</p> <p>15 A Yes.</p> <p>16 Q How many times?</p> <p>17 A Twenty.</p> <p>18 Q And how many of those were patent related 19 matters?</p> <p>20 A In what period of time?</p> <p>21 Q I guess in the period of time that you've been 22 giving depositions. How about in the last ten years?</p> <p>23 A About six, I think. Plus or minus.</p> <p>24 Q Okay. And you understand that today I 25 represent Miracor Medical, and I will be asking you</p> <p style="text-align: right;">Page 6</p>	<p>1 A Meeting with the attorneys? Twelve to fifteen 2 hours, thereabouts.</p> <p>3 Q Now, you reviewed one or more of your 4 declarations given in these matters as part of your 5 preparation. Did I hear that right?</p> <p>6 A Yes.</p> <p>7 Q During your review, did you see any errors 8 that you need to correct?</p> <p>9 A I think there are a few typographical errors 10 that you'd expect in any long document. I can't recall 11 what they are specifically at the moment. Nothing that 12 changes the substance of my arguments or my opinions.</p> <p>13 Q And in your preparation, did you review the 14 Bourque 2001 reference?</p> <p>15 A Yes.</p> <p>16 Q Did you review the Wampler reference?</p> <p>17 A Which one?</p> <p>18 Q The one that's cited in the grounds. So the 19 published patent application, Exhibit No. 1008. It's 20 number 2002 0102169.</p> <p>21 A Yes. I did review that.</p> <p>22 Q Did you review other Wampler publications?</p> <p>23 A I think there are multiple Wampler 24 publications listed in my materials considered.</p> <p>25 Q Did you review the Akamatsu reference?</p> <p style="text-align: right;">Page 8</p>
<p>1 questions related to IPRs in which Abbott is challenging 2 Miracor Medical patents. Do you understand that?</p> <p>3 A I do understand that.</p> <p>4 Q Okay. Is there any reason why you cannot give 5 truthful answers to questions I pose today?</p> <p>6 A No.</p> <p>7 Q Did you prepare for your deposition today?</p> <p>8 A Yes.</p> <p>9 Q What did you do to prepare for your 10 deposition?</p> <p>11 A I read many, many documents or reread many 12 documents, including my declaration. I met with 13 attorneys for Abbott on a couple of occasions. That's 14 the major work I did to prepare.</p> <p>15 Q Okay. And how many times did you meet with 16 counsel for Abbott?</p> <p>17 A I met in person the last two days and by Zoom 18 once or twice I think last week.</p> <p>19 Q Okay. And what do you think the total amount 20 of time was?</p> <p>21 A I'm having difficulty hearing. I have hearing 22 aids, so I have real hearing problems, and you speak 23 quietly. So try it again, please.</p> <p>24 Q Sure. What was the total amount of time that 25 you spent meeting with Abbott's attorneys?</p> <p style="text-align: right;">Page 7</p>	<p>1 A Akamatsu is a body of work referred to as 2 Akamatsu. I reviewed the paper, I think that you're 3 referring to, plus one or two other articles, yes.</p> <p>4 Q And did you review the Schima reference?</p> <p>5 A Which one are you referring to?</p> <p>6 Q It's in there in your binder. It's Exhibit 7 No. 1005, published patent application number 2003 8 0124007.</p> <p>9 A Yes. I did review that.</p> <p>10 Q And do you understand those four references to 11 be cited in the grounds on which Abbott alleges 12 Miracor's patent claims are invalid?</p> <p>13 A Could you repeat that question, please? What 14 do I understand?</p> <p>15 Q Sure. We just mentioned four references.</p> <p>16 A Yes.</p> <p>17 Q And do you understand those four references to 18 be references cited in the grounds of invalidity 19 provided by Abbott in these IPRs?</p> <p>20 A Yes, I do.</p> <p>21 Q Now, you worked for a company called 22 Ventracor; didn't you?</p> <p>23 A Yes.</p> <p>24 Q And did you leave Ventracor in 2009?</p> <p>25 A Yes.</p> <p style="text-align: right;">Page 9</p>

<p>1 Q Have you worked with continuous flow blood 2 pumps since you left Ventracor?</p> <p>3 A What do you mean "worked with"? You mean, 4 have I designed? Have I run a company? Have I 5 implanted that? It's a very vague term. What do you 6 mean "worked with"?</p> <p>7 Q Well, let's start with that. Have you, sort 8 of, worked with in the hands-on sense that you have been 9 employed directly by a company that was designing or 10 building or implanting continuous flow blood pumps?</p> <p>11 A No. I have not been employed by a company 12 working with designing or selling continuous flow blood 13 pumps.</p> <p>14 Q Have you consulted for any companies that 15 develop or sell continuous flow blood pumps?</p> <p>16 A In a sense, yes.</p> <p>17 Q Okay. Could you describe that circumstance?</p> <p>18 A Sure. Ventracor Limited, the Australian 19 company, was put into receivership in early 2009. I 20 retained my position as CEO for a while. I also 21 retained my position as president of the U.S. subsidiary 22 of Ventracor, Ventracor Inc., and I retained that 23 position until the company was wound up in, gosh, early 24 2010.</p> <p>25 Q Okay. Are there any other circumstances where Page 10</p>	<p>1 Q Okay. And what were the blood pumps that 2 Ventracor was developing at that time?</p> <p>3 A Ventracor developed a blood pump called the 4 VentrAssist, V-E-N-T-R-A-S-S-I-S-T, which was a 5 centrifugal blood pump with hydrodynamic bearings. It 6 was implanted in several hundred people, eventually got 7 approval for bridge to transplant, eventually got CE 8 mark approval for sale in Europe and was conducting -- 9 in the process of being -- conducting multiple clinical 10 trials.</p> <p>11 Q Okay. And now, the VentrAssist blood pump had 12 been implanted in humans before you joined Ventracor; is 13 that right?</p> <p>14 A I think so. A small number, yes.</p> <p>15 Q So then were your contributions to the 16 research and design -- were those design changes to the 17 Ventracor pump?</p> <p>18 A Well, the first of the Ventracor pumps, the 19 VentrAssist, which was implanted in humans as you talked 20 about, was the first of a series of products. We had a 21 pipeline of products. I was involved not only in 22 working to improve the existing device, but also in the 23 pipeline of new products that was under development.</p> <p>24 Q And did that pipeline include continuous flow 25 blood pumps? Page 12</p>
<p>1 you consulted with a company that was -- in the time 2 since you left Ventracor, have you consulted with a 3 company that was designing or selling continuous flow 4 blood pumps?</p> <p>5 A No.</p> <p>6 Q Have you, yourself, ever designed a continuous 7 flow blood pump?</p> <p>8 A I don't think there's anyone on earth who -- 9 who has alone designed a continuous flow blood pump. 10 I've certainly been parts of research and development 11 teams that have worked on continuous flow blood pumps. 12 It's rarely a solo effort.</p> <p>13 Q Okay. Could you describe those circumstances 14 where you worked with R&D teams to design a continuous 15 flow blood pump?</p> <p>16 A When I joined Ventracor in 2005 initially as 17 chief operating officer, all of the research and 18 development and manufacturing parts of the organization 19 were responsible to me. I subsequently became chief 20 executive officer of Ventracor in, gosh, early 2006, I 21 think, and was actively involved in all aspects of the 22 business, including having the last signoff of all 23 design documentation for the blood pumps that the 24 company was designing and manufacturing. I was involved 25 in many of the research and development meetings. Page 11</p>	<p>1 A Yes.</p> <p>2 Q Did it include centrifugal flow blood pumps?</p> <p>3 A Yes.</p> <p>4 Q In human anatomy, what is the diaphragm?</p> <p>5 A Are you asking me as an anatomy specialist? I 6 didn't know that was the brief.</p> <p>7 Q Diaphragms appear in some of the references 8 that we're talking about, and I'd just like to get your 9 understanding of what it is.</p> <p>10 A The diaphragm is a large flat muscle that 11 spans the width of the abdomen underneath the lungs and 12 between the lungs and the peritoneal cavity, and it is 13 the muscle that is used primarily to cause breathing. 14 When the diaphragm contracts, the lungs inflate. When 15 it relaxes, they expel air.</p> <p>16 Q Okay. So the diaphragm moves during 17 breathing?</p> <p>18 A I beg your pardon?</p> <p>19 Q So the diaphragm moves during breathing?</p> <p>20 A Yes. Most of your body does.</p> <p>21 Q How close is the diaphragm to the apex of the 22 heart?</p> <p>23 A You mean in humans?</p> <p>24 Q Yes. In humans.</p> <p>25 A 'Cause it's different in different animals. Page 13</p>

<p>1 It's generally very close to it. It depends. The 2 diaphragm moves, as we say, so it can be -- it can be 3 close sometimes, and it can be far away sometimes. So 4 there's no one answer to your question. It's closer 5 than the foot.</p> <p>6 Q Okay. So then if I understand you correctly, 7 when one exhales, the diaphragm will be closer to the 8 apex than when one inhales?</p> <p>9 A It may be. You can exhale just by moving your 10 rib cage. It doesn't necessarily require the diaphragm.</p> <p>11 Q But typically, the diaphragm does move during 12 breathing?</p> <p>13 A Typically.</p> <p>14 Q How does the apex of the human heart move 15 during a heartbeat?</p> <p>16 A How does the apex of a human heart during -- 17 move during heartbeat? Well, it depends on the 18 individual's anatomy. And if you're talking about a 19 normal heart, generally the apex moves in a slightly 20 circular motion. The heart will contract, so the apex 21 will contract longitudinally towards the coronal area 22 plane. And it may also move in a slightly twisting 23 movement when the -- the ventricle contracts. In 24 different types of cardiac disease, the movement can be 25 quite different.</p> <p style="text-align: right;">Page 14</p>	<p>1 opposite direction. So it just depends whether you are 2 sitting or standing or lying or running or walking or 3 swimming. There is no single answer to your question.</p> <p>4 Human anatomy is very variable, and the motion 5 of the heart depends on what it's trying to do. The 6 motion of your heart when you're running a marathon and 7 your heart is beating 200 beats a minute is quite 8 different from the motion of your heart when you're 9 asleep and it's beating 55 beats a minute. There's no 10 single answer to your question.</p> <p>11 Q You're aware, aren't you, Mr. Crosby, that the 12 Miracor patents use the term "at a position axially 13 adjacent"?</p> <p>14 A Can you refer to which patent, so I know -- 15 there are lots of terms in the patents. So can you tell 16 me which one you're referring to, please?</p> <p>17 Q Well, tell you what. Why don't we go to 18 paragraph 355 of your declaration that's in front of 19 you.</p> <p>20 A Three-fifty-five. I have that.</p> <p>21 Q Now you see claim element 1H that you discuss 22 here uses the phrase "at a position axially adjacent." 23 Do you see that?</p> <p>24 A Yes.</p> <p>25 Q What does "axially adjacent" mean in this</p> <p style="text-align: right;">Page 16</p>
<p>1 Q But in general, it does move during your 2 heartbeat; is that right?</p> <p>3 A It? You mean the apex or the heart?</p> <p>4 Q Yes. The apex.</p> <p>5 A The apex of the heart generally can move 6 during a heartbeat, yes.</p> <p>7 Q And it moves in a way that's not linear; is 8 that right?</p> <p>9 A Not regular, did you say?</p> <p>10 Q Linear.</p> <p>11 A Not linear. It can.</p> <p>12 Q I thought you --</p> <p>13 A The -- the heart is a very flexible organ. 14 They can move in any way you like. I've held a heart in 15 my hands, and it moved in multiple directions.</p> <p>16 Q I thought you described the motion as being 17 circular.</p> <p>18 A It -- it can be.</p> <p>19 Q Well, I guess, when it is circular, I'm trying 20 to envision what that means, in which direction it 21 curves. Can you describe that?</p> <p>22 A Think of you contracting your fist; right? If 23 -- sometimes when you contract your fist, you might 24 rotate your arm. So which direction does your -- does 25 your fist move? Sometimes you might rotate it in the</p> <p style="text-align: right;">Page 15</p>	<p>1 context?</p> <p>2 A Well, I think there are multiple answers to 3 that question depending on which context you're asking. 4 The context of the claims in the 356 patent that this 5 declaration is concerning? The claims in other patents 6 may use that term differently the way a person of 7 ordinary skill in the art might understand that term to 8 mean and then the way that the patent owners would 9 understand that term to mean, and -- and you referenced 10 before, I think, their claim chart. So which way would 11 you like me to approach that question? There are 12 multiple answers.</p> <p>13 Q How would a person of ordinary skill in the 14 yard reading this claim element in the context that you 15 use it here -- what would they understand the term 16 position "axially adjacent" to me?</p> <p>17 A That's -- can you show me where in the 356 18 patent? Can I read the 356 patent claim? 'Cause this 19 is one fragment of a claim. So it had to be seen in 20 context of the whole claim, I think.</p> <p>21 Q Well, I think you've already done this.</p> <p>22 A I've already done what?</p> <p>23 Q I think you've already done this work, Mr. 24 Crosby. So in paragraph 355 at the bottom of page 184, 25 you say, "Passively magnetic element are axially</p> <p style="text-align: right;">Page 17</p>

<p>1 adjacent along the central axis." So as you apply that</p> <p>2 term, does that mean axially adjacent means they're</p> <p>3 adjacent along the central axis?</p> <p>4 A Well, that -- that's what I say in my -- thank</p> <p>5 you for reading out my declaration. That's exactly what</p> <p>6 I say.</p> <p>7 Q And then in the next sentence, you say,</p> <p>8 "Further, in order to provide the torque necessary to</p> <p>9 rotate the impeller, the passively magnetic elements are</p> <p>10 axially adjacent," and then you say, "situated next to</p> <p>11 each other on the same axis."</p> <p>12 A Where -- where are you reading? And --</p> <p>13 Q It's the next sentence. It's right underneath</p> <p>14 the figure on the top of page 185.</p> <p>15 A Oh, I see. Yes. "The passively magnetic</p> <p>16 elements are axially adjacent, situated next to each</p> <p>17 other on the same axis to the impeller, such that when</p> <p>18 the magnetic forces applied to rotate the passively</p> <p>19 magnetic elements, the impeller may then rotate about</p> <p>20 its axis."</p> <p>21 Q So as you've applied it, is "situated next to</p> <p>22 each other on the same axis" -- is that a fair</p> <p>23 definition of "axially adjacent"?</p> <p>24 A That -- that is fair in the context of this</p> <p>25 discussion of the Bourque device, yes.</p> <p style="text-align: right;">Page 18</p>	<p>1 art would have to read the claims in conjunction with</p> <p>2 the description and try and figure out what the inventor</p> <p>3 means in that claim.</p> <p>4 Q So as you sit here today, would you object to</p> <p>5 the definition of "axially adjacent" as meaning adjacent</p> <p>6 to one another measured along a central axis?</p> <p>7 MR. BORDER: Object to form.</p> <p>8 THE WITNESS: I think that's acceptable</p> <p>9 as one definition. I don't think it's the only</p> <p>10 definition, and it depends on the context in which it's</p> <p>11 being used.</p> <p>12 BY MR. CAHILL:</p> <p>13 Q So, Mr. Crosby, I'd like to talk about the</p> <p>14 person of ordinary skill in the art for a moment. So</p> <p>15 you discuss the qualifications of a person --</p> <p>16 A Where -- where are you looking in my report,</p> <p>17 please?</p> <p>18 Q I am about to tell you.</p> <p>19 A Sorry. I shouldn't interrupt. I apologize.</p> <p>20 Q You discuss the qualifications of a person of</p> <p>21 ordinary skill in the art in your declaration at</p> <p>22 paragraph 18. You're welcome to look at it.</p> <p>23 A Eighteen?</p> <p>24 Q Yes.</p> <p>25 A Here we go. Yes. I have it here.</p> <p style="text-align: right;">Page 20</p>
<p>1 Q Would it be fair to say "at a position axially</p> <p>2 adjacent" means at a position adjacent to one another as</p> <p>3 measured along a central axis?</p> <p>4 A Where are you reading from in my report?</p> <p>5 Q That isn't in your report. I'm asking you a</p> <p>6 question.</p> <p>7 A Well, ask me the question again, and -- and in</p> <p>8 what context? I'm -- I'm trying to understand the</p> <p>9 question. All my answers are in the report. So if it's</p> <p>10 something that's not in the report, I have to think</p> <p>11 about it afresh. If you refer to something in my</p> <p>12 report, that's great.</p> <p>13 Q So I'm asking you if this definition is</p> <p>14 consistent with what we just talked about in your report</p> <p>15 as to what "axially adjacent" means. Is it fair to say</p> <p>16 that "axially adjacent" means adjacent to one another as</p> <p>17 measured along a central axis?</p> <p>18 A That could be one -- one meaning, yes. I'm</p> <p>19 sure there are many other meanings.</p> <p>20 Q Based on what you know today, that definition</p> <p>21 isn't wrong; is it?</p> <p>22 A Well, we're discussing this in the context of</p> <p>23 the 356 patent. The term "axially adjacent" appears</p> <p>24 only in the claims. The patent itself does not define</p> <p>25 what "axially adjacent" is. So a person of skill in the</p> <p style="text-align: right;">Page 19</p>	<p>1 Q Okay. And this definition in paragraph 18, is</p> <p>2 that the person of ordinary skill in the art that you</p> <p>3 had in mind when you did your analysis described in your</p> <p>4 declaration?</p> <p>5 A Yes.</p> <p>6 Q Now, you say here, "The person of ordinary</p> <p>7 skill in the art would have knowledge and experience in</p> <p>8 the anatomy and physiology of the human circulatory</p> <p>9 system," and I'd like to ask you what you mean by that.</p> <p>10 So, I mean, we talked a little bit about the nature of</p> <p>11 the human diaphragm and how it moves. Is that something</p> <p>12 that the person of ordinary skill in the art should know</p> <p>13 in your definition?</p> <p>14 A Well, the diaphragm is not part of the human</p> <p>15 circulatory system, but someone who has knowledge and</p> <p>16 experience of anatomy and physiology of the human</p> <p>17 circulatory system would clearly have knowledge and</p> <p>18 experience of the things that surround the human</p> <p>19 circulatory system.</p> <p>20 Q Would that person have knowledge of where and</p> <p>21 how left ventricular assist devices had typically been</p> <p>22 implanted?</p> <p>23 A Perhaps. Not necessarily by this definition.</p> <p>24 Someone who had knowledge and experience of human left</p> <p>25 ventricular assist devices would satisfy most of this,</p> <p style="text-align: right;">Page 21</p>

<p>1 provided that experience and design and development is 2 at least five years, and that was the only medical 3 device that person had been working on. 4 Q So should the person of ordinary skill in the 5 art for these purposes -- should that person know how 6 left ventricular assist devices have typically been 7 implanted in humans? 8 A The definition as written here doesn't require 9 that. It would certainly be helpful if that person does 10 have that knowledge. 11 Q You talked about this a little bit already, 12 but I'd like to follow up in just a little bit more of a 13 structured way. Your role with Ventracor. Now, you 14 started there in 2005; is that right? 15 A Yes. 16 Q And you were COO when you started? 17 A Yes. 18 Q And what were your responsibilities as COO? 19 A The chief operating officer is responsible for 20 all the operations of the company. That generally means 21 research and development, manufacturing, quality 22 systems, procurement, but does usually not involve sales 23 and marketing, finance, government relations. It may 24 involve regulatory and clinical trials depending on the 25 company.</p> <p style="text-align: right;">Page 22</p>	<p>1 officer is the person responsible for literally 2 everything. And so my responsibility wingspan got 3 bigger, and so I took on additional responsibilities of 4 the other things we talked about, like finance, sales 5 and marketing. 6 Q Now, you were familiar with the design of the 7 VentrAssist pump; weren't you? 8 A Yes. 9 Q Could you describe -- could you give an 10 overview of the important features of the VentrAssist 11 pump? 12 A The VentrAssist pump would be described as a 13 third generation centrifugal pump with a fully 14 hydrodynamically supported impeller, machined from 15 titanium. It had a flow rate of about ten liters per 16 minute against a head of about a hundred millimeters of 17 pressure. It had an external controller attached to the 18 pump or connected to the pump via an electrical cable 19 that came through the skin, a so-called percutaneous 20 lead. Which other aspects would you like to know? 21 Q How was the VentrAssist pump implanted in the 22 human body? Where did it go? 23 A It had a -- an inflow tube made of hard 24 silicone rubber attached to the central axis of the 25 pump, and that was implanted in the apex of the heart.</p> <p style="text-align: right;">Page 24</p>
<p>1 Q Were there clinical trials going on for the 2 VentrAssist product in 2005? 3 A Multiple. 4 Q And were you involved in those? 5 A Yes. 6 Q And what was your role in those clinical 7 trials? 8 A I contributed to the clinical trial protocol 9 design and development. I was one of the authors of 10 that. I was part of the clinical trial steering 11 committee. I think I signed off on most, if not all of 12 the contracts between the company and the clinical trial 13 investigators and the institutional review boards. I 14 reviewed and contributed to most of the submissions to 15 the regulatory authorities, such as the United States 16 Food and Drug Administration and the notified body in 17 Europe leading to CE mark. So my fingers were all over 18 those clinical trials. 19 Q And then in July 2006, you became CEO of 20 Ventracor; is that right? 21 A That's -- about that time, yes. 22 Q And with respect to the VentrAssist product, 23 how did your responsibilities changed when you moved 24 from COO to CEO? 25 A Well, as in any company, a chief executive</p> <p style="text-align: right;">Page 23</p>	<p>1 So the pump was positioned either inside or outside the 2 peritoneal space, depending on the patient's 3 circumstances, at the apex of the heart. The cable then 4 transitioned laterally across the abdomen and exited the 5 abdomen, usually about the -- six inches or so laterally 6 to the right of the umbilicus. 7 MR. CAHILL: Could we mark this 2012? 8 (Exhibit 2012 was marked for 9 identification.) 10 MR. BORDER: Thank you. 11 BY MR. CAHILL: 12 Q Mr. Crosby, I've handed you Exhibit No. 2012, 13 and this is an article from the European Journal of 14 Cardio-thoracic Surgery entitled, "VentrAssist left 15 ventricular assist device: clinical results and clinical 16 development plan update." Do you see that? 17 A I see that, yes. 18 Q Have you seen this paper before? 19 A Yes. Not for a while, but I have seen it 20 before. I think I contributed to it. 21 Q So it looks like this paper was published in 22 2007. Does that seem right? 23 A It's copyrighted 2007. It was received 13th 24 of March 2007 and available online September 2007. 25 Q And that was during the time that you were CEO</p> <p style="text-align: right;">Page 25</p>

<p>1 at Ventracor; is that right?</p> <p>2 A That is correct.</p> <p>3 Q Who is John Woodard?</p> <p>4 A John Woodard was one of the founders of</p> <p>5 Ventracor, a Ph.D. in biophysics if I remember</p> <p>6 correctly, and one of the inventors of the VentrAssist</p> <p>7 pump. At the time, I think he was the chief technology</p> <p>8 officer of Ventracor.</p> <p>9 Q So this article -- and I'm looking</p> <p>10 specifically at page 736, the second page of the article</p> <p>11 in the first column.</p> <p>12 A I haven't read this article for a while. Can</p> <p>13 I read it now, or do you want to point out just some</p> <p>14 parts of it?</p> <p>15 Q I have a couple of specific questions and let</p> <p>16 me know -- if you need to read more of it to answer the</p> <p>17 question, let me know. So the article states that</p> <p>18 VentrAssist was conceived in 1998 with first human use</p> <p>19 in June 2003?</p> <p>20 A Where are you looking at that?</p> <p>21 Q Page 736, first column, second full paragraph.</p> <p>22 A The first column?</p> <p>23 Q First column, second full paragraph.</p> <p>24 A Oh, yes. Yes.</p> <p>25 Q So that timeline conceived in 1998 and first</p> <p style="text-align: right;">Page 26</p>	<p>1 Q Was the system used that way?</p> <p>2 A Which way are you referring to?</p> <p>3 Q The way that it appears in the figure two.</p> <p>4 A Well, are you referring to the shoulder strap</p> <p>5 and the external controller? Because that was certainly</p> <p>6 different by the time I was there. Are you referring to</p> <p>7 the exit location of the percutaneous lead or how the --</p> <p>8 there are multiple elements of that system. So I'm not</p> <p>9 sure which element you're asking about.</p> <p>10 Q How about the inflow cannula and pump?</p> <p>11 A It's hard to see with my old eyes exactly what</p> <p>12 that's talking about. But that appears to be an inflow</p> <p>13 cannula, which is sewn to the apex of the left -- left</p> <p>14 ventricle and then connected to the pump. I think that</p> <p>15 whole inflow cannula system had developed a bit</p> <p>16 differently by the time I was there and by the time the</p> <p>17 device was available for market.</p> <p>18 Q How was it different?</p> <p>19 A Difficult for me to answer that, because as I</p> <p>20 say, this is a -- an artist's rendition that's just</p> <p>21 difficult to see. I know what it looked like by the</p> <p>22 time I was there, but I don't know what this is -- it's</p> <p>23 hard to tell. I'd refer you to some of the actual</p> <p>24 photographs of the device that appear at other</p> <p>25 publications or some of the FDA submissions that will</p> <p style="text-align: right;">Page 28</p>
<p>1 human use in 2003, I mean, does that seem right to you?</p> <p>2 Does that accord with your recollection of the history?</p> <p>3 A Yeah. I think the first human use in 2003 was</p> <p>4 an acute use, not a chronic use, you know. We'd put it</p> <p>5 in and see if it worked and take it out again. But the</p> <p>6 timeline is about right.</p> <p>7 Q In your experience, is that a typical timeline</p> <p>8 for the development of a left ventricular assist device?</p> <p>9 A Is what a typical timeline? What are you</p> <p>10 referring to?</p> <p>11 Q Conceived in 1998, first human use in 2003.</p> <p>12 A It depends. In 1998, the field of left</p> <p>13 ventricular assist devices was in its infancy. So the</p> <p>14 development time or the time from conception to first</p> <p>15 human use was pretty long in the early years. Nowadays,</p> <p>16 if you were doing one in 2025, it would be shorter,</p> <p>17 because there's 30 years of experience behind us that --</p> <p>18 that answers some of the questions. So I imagine, if</p> <p>19 necessary, one could do it a bit faster today.</p> <p>20 Q Do you see figure two on page 736?</p> <p>21 A Yes. I see figure two. Yep.</p> <p>22 Q So that appears to illustrate an implantation</p> <p>23 of the VentrAssist system; is that right?</p> <p>24 A That's an artist's rendition of how the system</p> <p>25 might be used, yes.</p> <p style="text-align: right;">Page 27</p>	<p>1 tell you the design details. This is an artist's</p> <p>2 rendition. Doesn't tell me much.</p> <p>3 Q Okay. There's a description of the location</p> <p>4 of the pump on page 737 at the top of the second column.</p> <p>5 A This -- 737 top of the second. Okay.</p> <p>6 Q Right. It says, "The pump is placed in a</p> <p>7 pocket on the left side below the diaphragm, either in a</p> <p>8 pocket formed in the" --</p> <p>9 A I'm sorry. You're talking, and I'm reading.</p> <p>10 Which --</p> <p>11 Q Sure. The sentence at the top of the second</p> <p>12 column, if you could read that.</p> <p>13 A "The VentrAssist was primarily designed as a</p> <p>14 permanent alternative to heart transplant for patients</p> <p>15 with heart failure." That sentence?</p> <p>16 Q No. At the -- on page 737, the top of the</p> <p>17 second column.</p> <p>18 A Oh, second column. Beg your pardon. "The</p> <p>19 pump is placed in a pocket on the left side below the</p> <p>20 diaphragm, either in a pocket formed in the posterior</p> <p>21 rectus sheath or in a preperitoneal position behind the</p> <p>22 rectus. The diaphragm is reflected off the anterior</p> <p>23 chest wall to allow passage of the inflow and outflow</p> <p>24 cannula."</p> <p>25 Q So is that description generally accurate from</p> <p style="text-align: right;">Page 29</p>

<p>1 your recollection of the time, 2007, when this 2 published?</p> <p>3 A It's one way the pump was implanted at that 4 time. Surgical procedures developed along with 5 development of the engineering. So surgeons did a lot 6 of work to try and find -- make the surgical procedure 7 better, easier, more reliable. That's one way.</p> <p>8 Q So you've described this as one way you might 9 implant VentrAssist. Do you know why someone would 10 choose to implant it this way, to place the pump in a 11 pocket on the left side below the diaphragm?</p> <p>12 A You're referring to the VentrAssist pump or 13 all left ventricular assist devices?</p> <p>14 Q The VentrAssist pump.</p> <p>15 A Just the VentrAssist pump?</p> <p>16 Q Yep.</p> <p>17 A Gosh, I haven't thought about this for a 18 while. I think in the early days, the surgical approach 19 was fairly conservative, and there was some attempt to 20 try and retain a natural motion of the heart. As time 21 went on, people realized natural motion of the heart 22 with an LVAD implanted is irrelevant, 'cause the heart's 23 not doing the pumping.</p> <p>24 So if the heart's immobile, it kind of doesn't 25 matter. And over time there were experiments done on</p> <p style="text-align: right;">Page 30</p>	<p>1 there?</p> <p>2 A Which drawings are you referring to in 3 Wampler?</p> <p>4 Q So let me just ask you a general question 5 first, and then we'll -- we can turn and look at it. If 6 you can't answer without looking at it, that's fine too.</p> <p>7 Wampler has at least one version of a pump that has a 8 thrust bearing; is that right?</p> <p>9 A I -- which drawing are you referring to?</p> <p>10 Q Why don't we turn to -- so figures 1 to 8 of 11 Wampler.</p> <p>12 A Okay.</p> <p>13 Q Do those describe a pump that has a thrust 14 bearing?</p> <p>15 A The thrust bearing is at the -- yes. I can 16 see the thrust bearing in figures 1 to 8.</p> <p>17 Q And then in figures 11 to 16, Wampler 18 describes a pump or pumps that have hydrodynamic 19 bearings but not thrust bearings; is that right?</p> <p>20 A I think figures 11 to 16 have a combination of 21 hydrodynamic bearings and electromagnetic bearings, but 22 you're correct. There is no thrust bearing.</p> <p>23 Q Now, the motor illustrated, for example, in 24 figure 11, that has dual stators; doesn't it?</p> <p>25 A I'm sorry. What was the question?</p> <p style="text-align: right;">Page 32</p>
<p>1 implanting it between the apex of the heart and the 2 diaphragm. In other words, not having a penetration 3 through the diaphragm. In some pumps, that worked; in 4 some patients, that worked. Patients are of different 5 sizes. And so what might work in a 300 pound man might 6 be quite inappropriate for a 120 pound child.</p> <p>7 So the surgeons had to develop ways of 8 implanting a device that would be appropriate for the 9 patient's anatomy and also for the device to be 10 implanted. So as I said, early human trials were done 11 with a fairly limited range of human sizes, and as time 12 went on and surgeons became better, the surgical 13 approach became better and was more tuned to the 14 patient's anatomy.</p> <p>15 Q I'd like to change gears and discuss the 16 Wampler reference. You refer to it in your declaration 17 as Wampler 169.</p> <p>18 A At 16, I think.</p> <p>19 Q Yeah. So the -- yes.</p> <p>20 A It's Exhibit 1008? Is that the one you're 21 referring to?</p> <p>22 Q Yes. That's right.</p> <p>23 A Okay.</p> <p>24 Q Now, there's more than one embodiment of a 25 centrifugal blood pump described in Wampler; isn't</p> <p style="text-align: right;">Page 31</p>	<p>1 Q The pump illustrated in, for example, figure 2 11 of Wampler.</p> <p>3 A Yes.</p> <p>4 Q That has dual stators; doesn't it?</p> <p>5 A Dual stators. I'd have to look at the -- the 6 reference again. Which -- which elements are you 7 referring to for that dual stators?</p> <p>8 Q So paragraphs 83 and 84 of Wampler.</p> <p>9 A I've read them.</p> <p>10 Q Okay. And those describe two stators; don't 11 they? One on either side of the rotor.</p> <p>12 A Yes. Paragraph 83 describes a first motor 13 stator at number 90, and paragraph 84 describes a second 14 motor stator at 94.</p> <p>15 Q And actually, if you turn in your declaration 16 to paragraph 205.</p> <p>17 A Two hundred and five. Yes. I've read it.</p> <p>18 Q So you've colored there the two stators blue; 19 haven't you?</p> <p>20 A Well, technically, what's colored is the sub- 21 components, the motor windings, the back iron, the 22 windings, the back iron, and the teeth, which together 23 form the stators.</p> <p>24 Q Okay. But there are two stators; right?</p> <p>25 Motor stators 90 and 94. And you've colored them blue;</p> <p style="text-align: right;">Page 33</p>

<p>1 correct?</p> <p>2 A Paragraph 205 says, "Elements of the pump</p> <p>3 motor, including motor stators 90 and 94, which are</p> <p>4 colored in light blue."</p> <p>5 Q And the pump that Wampler describes in figures</p> <p>6 one to four -- I'm sorry -- one to eight, that pump does</p> <p>7 not have dual stators; does it?</p> <p>8 A I wonder if you could have printed this with</p> <p>9 any smaller font. Where are you referring to -- maybe</p> <p>10 you can save us both some time. Where are you referring</p> <p>11 to in the Wampler patent?</p> <p>12 Q Well, I'm not. We just looked at the versions</p> <p>13 that have dual stators; right? And in your declaration</p> <p>14 --</p> <p>15 A Yes.</p> <p>16 Q -- we looked at the example where you color</p> <p>17 the dual stators light blue. And my question is, the</p> <p>18 pump that Wampler illustrates in figures one to eight,</p> <p>19 that pump does not have dual stators; does it?</p> <p>20 A Well, Wampler has multiple embodiments of his</p> <p>21 pump and his patent. I think my report only refers to</p> <p>22 the second embodiment, which is figures -- whatever we</p> <p>23 talked about before. I don't think I talk about the</p> <p>24 first embodiment in my report. I only talk about the</p> <p>25 embodiment that's in figures 11 through -- whatever it</p> <p style="text-align: right;">Page 34</p>	<p>1 report anywhere?</p> <p>2 MR. CAHILL: I don't know.</p> <p>3 THE WITNESS: I don't think I refer to it</p> <p>4 in my report. So to the extent that I've looked at it,</p> <p>5 yes, I've looked at it. I don't think I've provided any</p> <p>6 opinions on it or any analysis of it in my report.</p> <p>7 BY MR. CAHILL:</p> <p>8 Q Do you see in figure eight that there are a</p> <p>9 number of magnets numbered 23, 24, 28, 29?</p> <p>10 A I -- I can see a number of magnets in figure</p> <p>11 eight, but again, I haven't analyzed this in any</p> <p>12 particular way. And I don't think I refer to it in my</p> <p>13 report.</p> <p>14 Q Do you know what function those magnets</p> <p>15 perform?</p> <p>16 A I can read the patent and see what the -- what</p> <p>17 the description is of those -- of the function of those</p> <p>18 magnets if you'd like me to today.</p> <p>19 Q So you do see those magnets in figure eight;</p> <p>20 don't you? See where they are?</p> <p>21 A I see several magnets depicted in figure</p> <p>22 eight, yes.</p> <p>23 Q Well, in particular, I'm talking about the</p> <p>24 ones number 23, 24, 28, and 29.</p> <p>25 A Okay. There's also a 34 and 32 maybe, maybe</p> <p style="text-align: right;">Page 36</p>
<p>1 is. So I haven't referred to that first embodiment in</p> <p>2 my report that I remember.</p> <p>3 Q Certainly, you refer to figure five. Also in</p> <p>4 your report, you refer to several paragraphs that</p> <p>5 describe the pump at figures one to eight. So as you</p> <p>6 sit here today, you can't look at figures one to eight</p> <p>7 of Wampler and tell me whether or not they have dual</p> <p>8 stators?</p> <p>9 MR. BORDER: Objection to form.</p> <p>10 THE WITNESS: I don't think that's what I</p> <p>11 said. I -- I'll read the Wampler patent and see what it</p> <p>12 says about figures one to eight. But the analysis in my</p> <p>13 report which talks about stators is at least with the</p> <p>14 second embodiment. So I don't recall sitting here today</p> <p>15 whether the first embodiment has zero, one, or 57</p> <p>16 stators. And I could read the patent and answer your</p> <p>17 question if that's what you'd like me to do.</p> <p>18 BY MR. CAHILL:</p> <p>19 Q Okay. Could you look at figure eight of the</p> <p>20 Wampler patent?</p> <p>21 A Figure eight. Yes.</p> <p>22 Q Have you looked at, analyzed, thought about</p> <p>23 this figure before?</p> <p>24 MR. BORDER: Objection. Form.</p> <p>25 THE WITNESS: Do I refer to it in my</p> <p style="text-align: right;">Page 35</p>	<p>1 31. So there's multiple magnets in this configuration.</p> <p>2 Q But I'm asking you about the magnets number</p> <p>3 23, 24, 28, and 29. Do you see those?</p> <p>4 A I -- I see them in the illustration, yes.</p> <p>5 Q Do those magnets appear in, for example, the</p> <p>6 Wampler pump illustrated in figure 13?</p> <p>7 A Well, figure 13 is a different embodiment of a</p> <p>8 pump described in this patent. So they -- and it's a</p> <p>9 completely different view of the patent of -- of a -- of</p> <p>10 a pump. One is a 3D isometric view; one appears to be a</p> <p>11 -- almost a cross-sectional depiction. So the</p> <p>12 illustrations at least are not identical.</p> <p>13 Q Could you turn to paragraph 160 of your</p> <p>14 report?</p> <p>15 A One six zero, yes?</p> <p>16 Q Yes. I'd like to ask you some questions about</p> <p>17 your use of the term "rotor." Now, you refer to Wampler</p> <p>18 169 in this paragraph 160, and in particular, in that</p> <p>19 first paragraph, there's a parenthetical at the end.</p> <p>20 You quote Wampler, and you say, "A centrifugal pump</p> <p>21 impeller is attached to an impeller support shaft or</p> <p>22 spindle to form the pump rotor."</p> <p>23 A I say that, yes.</p> <p>24 Q Now, later in the paragraph -- and I encourage</p> <p>25 you to read the paragraph if you would like to -- you</p> <p style="text-align: right;">Page 37</p>

<p>1 limit your application of the term rotor, it appears to 2 me, to only the impeller portion; is that correct? 3 A Yes. I say, "For the purpose of my analysis, 4 I mapped the limitation of a magnetically driven rotor 5 to the impeller 74 of the embodiment of the rotor 17 6 described in figure 11 of Wampler 169 in the same way." 7 Q Okay. So Wampler calls the rotor number 17? 8 A I understand your question. Yes. 9 Q And you limit rotor to the impeller portion 10 74; is that right? 11 A For this analysis, yes. 12 Q So why isn't the support shaft or spindle part 13 of the rotor? 14 A Well, it seems from your question that you're 15 suggesting that everything that rotates is called the 16 rotor, but that's not how it's used in common use. You 17 drove here in a car presumably, which has disc brakes. 18 The disc brakes themselves are what's called the rotor, 19 but that's not the only thing that moves in the wheel. 20 The rotor is just that part of the brake -- of 21 the wheel system that is compressed between the brake 22 pads. So the idea that a rotor is everything that 23 moves, it's just not borne out in common usage. Because 24 the term is not -- the term is a little ambiguous in the 25 365 patent, I'm trying to map the use of the term</p> <p style="text-align: right;">Page 38</p>	<p>1 both agree that it rotates, but why is it there? What 2 does it -- 3 A What -- what do we both agree? I didn't hear 4 that. 5 Q Well, I think we both agree that the support 6 shaft or spindle rotates; is that true? 7 A It rotates, yes. 8 Q Okay. What is the function of that support 9 shaft or spindle in the Wampler patent? 10 A As I understand Wampler, one of the functions 11 of that support shaft is to provide stability of the 12 rotating elements within the pump. If you were to look 13 at the 357 patent -- or excuse me -- the 356 patent, 14 which is Exhibit 1001, the similar situation occurs 15 here. And that is, if you look to figure two, element 16 18 is described as or listed as the rotor, but it's not 17 the only thing that rotates. There's also a shaft and a 18 magnet that rotates. 19 So the idea that a rotor is everything that 20 rotates is not supported by the 356 patent itself. So 21 I've tried to map the way the 356 patent uses the term 22 to the way Wampler uses the term. And it appears that 23 the 356 patent, the term rotor is really used to 24 describe the element that rotates that pumps the blood, 25 and I've tried to use the same approach in the Wampler</p> <p style="text-align: right;">Page 40</p>
<p>1 "rotor" to what it appears to be it is in the 365 2 patent. 3 And in the 365 patent, there are multiple 4 elements that move, only one of which is labeled the 5 rotor. In Wampler, there are multiple elements that 6 move. He uses the term "rotor," but I'm trying to map 7 it to what's in the 365 patent. And this seems to make 8 sense to me. 9 Q What is the function of the support shaft or 10 spindle? 11 A In what? 12 Q In Wampler. 13 A In which embodiment? 14 Q The one you're discussing in this paragraph 15 160. 16 A What is the function of the support shaft? So 17 is your question referring to the illustration figure 11 18 that you mentioned before? 19 Q I'm trying to understand your paragraph 160, 20 and you quote Wampler from paragraph 51 saying, "A 21 centrifugal pump impeller is attached to an impeller 22 support shaft or spindle to form the pump rotor." And 23 you've described why you believe the impeller portion is 24 actually the rotor, and I'm just wondering what the 25 function then is of the shaft or spindle. I think we</p> <p style="text-align: right;">Page 39</p>	<p>1 description. So to make them consistent here. 2 Q Now, I think I heard you say that the support 3 shaft or spindle provides stability in Wampler. Does it 4 perform any other functions? 5 A I'd have to read Wampler again to see how he 6 describes it as the function. I didn't focus much 7 attention on it at that -- at this time. But let's have 8 a look, see what he says. Page seven. Very difficult 9 for my old eyes. I'm sorry. I couldn't find anything 10 in Wampler where he specifically describes the function 11 of the support shaft 18. 12 I may have missed it, 'cause I have just read 13 it again today. He mentions the shaft or spindle 18 in 14 paragraph 81, but I am -- so far haven't found anywhere 15 else that he mentioned it in terms of its function. If 16 you can point me to somewhere that would help me 17 understand that, it'd be great. When you have a moment, 18 it's a good time to have a break when you're ready, 19 please. 20 MR. CAHILL: Yes. There is no question 21 pending. We can go ahead and take a break now if you'd 22 like. 23 THE WITNESS: Thank you. 24 THE OFFICER: It is 10:19 a.m. We are 25 now off the record.</p> <p style="text-align: right;">Page 41</p>

<p>1 (Off the record.) 2 THE OFFICER: We are now back on the 3 record. It is 10:28 a.m. 4 BY MR. CAHILL: 5 Q Mr. Crosby, I would like to ask you some 6 questions about figure five in Wampler. 7 A Figure five in Wampler? 8 Q Yes. Is figure five an anatomically correct 9 illustration of the implantation of a Wampler pump? 10 A Figure five is an artist's illustration of how 11 the pump would be implanted in a heart. I don't think 12 its intent is to be anatomically correct, but in which 13 aspect are you asking? 14 Q I'm not asking in an aspect. I'm just asking 15 generally whether it's anatomically correct. 16 A Well, the heart doesn't lie on its side. So 17 that's anatomically not correct. The orientation is not 18 horizontal in the chest. 19 Q Anything else about it? 20 A Well, I can't see any of the details about the 21 coronary arteries or the four cardiac valves or the 22 papillary muscles that connect to the valve inside the 23 ventricle. So to me it looks like it's an artist 24 depiction of the essential elements to illustrate the 25 concepts and not intended to be anatomically correct.</p> <p style="text-align: right;">Page 42</p>	<p>1 mounting of left ventricular assist devices to the 2 heart. 3 Q Do you know if the HeartWare left ventricular 4 assist device was the first centrifugal flow pump to be 5 implanted in humans mounted directly to the apex of the 6 heart? 7 MR. BORDER: Object to form. 8 THE WITNESS: Well, the HeartWare device 9 was the resurrection of a Florida company that went 10 bankrupt that was developing a centrifugal pump. So the 11 origin of that pump, which is Rick Wampler's pump by the 12 way, goes back many years prior to HeartWare. I don't 13 know if it was implanted in a human even on a temporary 14 basis at around this timeframe. I just don't know. 15 I know that the Akamatsu pump that we 16 refer to, which was developed by Terumo, certainly was 17 implanted in animals by around this time in -- in the 18 early 2000s. I think there were a couple of 19 experimental devices in Europe that -- which didn't go 20 anywhere that were tested in -- in animals at around 21 this time. 22 BY MR. CAHILL: 23 Q So the pump that's illustrated in figure five, 24 do you know how big it is? 25 A Well, there are no dimensions on the figure,</p> <p style="text-align: right;">Page 44</p>
<p>1 So it's missing some anatomical elements, which in my 2 view are probably not necessary to explain the concepts 3 that I've been trying to explain with this illustration. 4 Q And it doesn't show you how the pump is 5 connected to the heart; does it? 6 A Doesn't show how the what? 7 Q How the pump is connected to the heart. 8 A No. There are multiple ways it could be 9 connected to the heart. 10 Q So at the time -- Wampler is dated on the top 11 of it, 2002 -- 12 A Oh, I'm sorry. I'm having real trouble 13 hearing. 14 Q Yeah. Wampler is dated on the top of it, 15 2002. In 2002 timeframe, were there centrifugal flow 16 pumps that were mounted to a heart in the manner that 17 figure five shows? 18 A I think there were several experimental 19 devices that were mounted to hearts, at least in 20 animals, in a similar way. Many of them would have had 21 a Dacron suture ring surrounding the inflow cannula, 22 which was sutured to the left ventricle. There are lots 23 of ways of mounting it. I don't think the mounting of 24 the pump in the heart is the focus of this particular 25 patent. That's another complete body of work to do with</p> <p style="text-align: right;">Page 43</p>	<p>1 and I don't know which heart that is, if it's a human or 2 a -- or an elephant or a sheep or a calf. I don't know. 3 So it's hard to really know what the dimensions are of 4 this artist's rendition of how it's configured in a 5 heart. 6 Q Do you know its weight? 7 A I beg your pardon? 8 Q Do you know the weight of this pump in figure 9 five? 10 A I don't recall that Wampler disclosed the 11 weight of the pump. He may have, but I don't recall. 12 Q Do you know whether anyone actually built the 13 pump that's illustrated in figure five? 14 A I don't know. 15 Q Do you know whether anyone ever tried to 16 implant one in a human? 17 A Well, if I don't know if it was ever built, 18 then I could not also know if it was implanted in a 19 human. 20 Q Now, you mentioned that the HeartWare pump was 21 one of Wampler's pumps. Did I hear that correctly? 22 A Wampler was one of the key inventors of and 23 contributors to the HeartWare pump, yes. 24 Q But that pump was different than the one we 25 see in figure five; wasn't it?</p> <p style="text-align: right;">Page 45</p>

<p>1 A In what way are you -- are you thinking?</p> <p>2 Q Well, it was shaped differently; wasn't it?</p> <p>3 A Well, the HeartWare pump, to my recollection</p> <p>4 -- and I don't think I've talked about it much in my</p> <p>5 report, but my recollection it is a centrifugal pump of</p> <p>6 a similar configuration to the Wampler device that's</p> <p>7 described here. There's some changes, but, you know,</p> <p>8 it's while since I've looked at one.</p> <p>9 Q In the LVAD business, does the term "second</p> <p>10 generation" have a generally understood meaning?</p> <p>11 A In the LVAD industry, the first generation</p> <p>12 pump term is used to describe pulsatile devices, like</p> <p>13 the HeartMate XVE or the World Heart device. The term</p> <p>14 "second generation pump" is generally used to describe</p> <p>15 rotary pumps, and there are multiple versions of that.</p> <p>16 And the term "third generation" is generally used to</p> <p>17 apply to left ventricular assist devices without</p> <p>18 bearings.</p> <p>19 Q Now, I'm looking at paragraph 47 of your</p> <p>20 declaration. Now, you say there that HeartMate II was a</p> <p>21 second generation device; don't you?</p> <p>22 A Yes.</p> <p>23 Q And it's typically implanted in a</p> <p>24 preperitoneal pocket in the patient?</p> <p>25 A Yes.</p> <p style="text-align: right;">Page 46</p>	<p>1 generally downward; is that right? From the heart?</p> <p>2 A Well, you're assuming this patient is standing</p> <p>3 up?</p> <p>4 Q Yes.</p> <p>5 A If the patient is lying down, it's not</p> <p>6 extending downward. So it extends distally from the</p> <p>7 heart in the general direction along the line of the</p> <p>8 left ventricle.</p> <p>9 Q That sounded like a long-winded way of saying</p> <p>10 generally down. But the pump extends horizontally;</p> <p>11 doesn't it?</p> <p>12 A It's in a generally transverse location, yes.</p> <p>13 Q And so there will be an elbow somewhere in the</p> <p>14 portion of the apparatus that we can't see; is that</p> <p>15 right?</p> <p>16 A The flow changes direction, whether it's</p> <p>17 through an elbow or a -- a compressible tube or a -- a</p> <p>18 bellows mechanism, it's not shown in this. And the</p> <p>19 reason I say that is because all of those ideas have</p> <p>20 been tried at one time or another.</p> <p>21 Q But this illustration is taken from the</p> <p>22 HeartMate II patient management guidelines; right?</p> <p>23 A Yes.</p> <p>24 Q And HeartMate II was implanted in many</p> <p>25 patients; wasn't it?</p> <p style="text-align: right;">Page 48</p>
<p>1 Q Okay. And then you provide an artist's</p> <p>2 rendition that illustrates preperitoneal placement of</p> <p>3 the HeartMate II pump; is that right?</p> <p>4 A Yeah.</p> <p>5 Q And that pump is located below the diaphragm;</p> <p>6 isn't it?</p> <p>7 A Well, yes.</p> <p>8 Q And there's an inflow tube or cannula that's</p> <p>9 connected to the left ventricle; right?</p> <p>10 A Well, it's not marked in that illustration,</p> <p>11 but I know there is, yes.</p> <p>12 Q And you can see it there; can't you?</p> <p>13 A Well, I can see part of it.</p> <p>14 Q Fair enough. Part of it is hidden behind the</p> <p>15 skin of the patient; right?</p> <p>16 A Yes.</p> <p>17 Q As is part of the pump itself?</p> <p>18 A Yes.</p> <p>19 Q But there is a change of direction there;</p> <p>20 isn't it?</p> <p>21 A Change of direction of what?</p> <p>22 Q Of the inflow of the blood into the pump.</p> <p>23 A There's a change of direction of the inflow</p> <p>24 and of the outflow, yes.</p> <p>25 Q So the inflow tube or cannula extends</p> <p style="text-align: right;">Page 47</p>	<p>1 A Indeed, yes.</p> <p>2 Q And it didn't have a bellows between the</p> <p>3 inflow cannula and the pump; did it?</p> <p>4 A It didn't have a what?</p> <p>5 Q A bellows.</p> <p>6 A A bellows?</p> <p>7 Q Isn't that what you said could be there?</p> <p>8 A I think it had a flexible element of the whole</p> <p>9 inflow assembly, which was kind of bellows shaped. It's</p> <p>10 not illustrated here, but my recollection is that.</p> <p>11 Q Okay. So the inflow changes direction to go</p> <p>12 through the pump, and then when it comes out of the</p> <p>13 pump, it changes direction again; correct?</p> <p>14 A You said the inflow changes direction. Do you</p> <p>15 mean the blood flow changes direction to enter the pump</p> <p>16 and then exiting the pump?</p> <p>17 Q Yes.</p> <p>18 A That is correct.</p> <p>19 Q On the outflow side of the pipe, there appears</p> <p>20 to be -- I'm sorry -- on the outflow side of the pump,</p> <p>21 there appears to be an elbow; is that correct?</p> <p>22 A I'm trying to understand. On the outside --</p> <p>23 on the outflow side of the pump, there appears to be</p> <p>24 what?</p> <p>25 Q An elbow.</p> <p style="text-align: right;">Page 49</p>

<p>1 A Can you define what you mean? Elbow? I mean,</p> <p>2 this is an elbow, but it's movable. So what -- what do</p> <p>3 you exactly mean by "elbow"?</p> <p>4 Q Well, you used the term "elbow" --</p> <p>5 A Yes.</p> <p>6 Q -- in your declaration more than once when</p> <p>7 talking about the Bourque 2001 reference.</p> <p>8 A Okay. So you're using the term "elbow" in the</p> <p>9 same way I use it in my declaration?</p> <p>10 Q Yes.</p> <p>11 A Okay. In that case, yes. There is an elbow</p> <p>12 on the outflow side of the HeartMate II.</p> <p>13 Q And that's an axial flow pump; isn't it?</p> <p>14 A It is.</p> <p>15 Q If one were to replace that pump with a</p> <p>16 centrifugal pump in the same orientation, the blood</p> <p>17 would come out of the pump at a 90 degree angle compared</p> <p>18 to what we see in this figure; is that right?</p> <p>19 A Well, it depends on the orientation of the</p> <p>20 pump. If you put the pump in oriented so that the</p> <p>21 rotation axis is transverse to the pump, then the</p> <p>22 outflow of that pump could be exactly in the correct</p> <p>23 direction of the outflow tube, and the inflow of that</p> <p>24 pump would be exactly in the correct direction of the</p> <p>25 inflow tube. But that's only one of many possible</p> <p style="text-align: right;">Page 50</p>	<p>1 BY MR. CAHILL:</p> <p>2 Q And if and by other hand, I'm holding a</p> <p>3 centrifugal flow pump with the inlet oriented in the</p> <p>4 same direction, so the flow enters from above, the flow</p> <p>5 would exit laterally from the centrifugal flow pump; is</p> <p>6 that right?</p> <p>7 A Yes. In at least one direction.</p> <p>8 Q All right. I think you alluded to this a</p> <p>9 little while ago. Paragraph 52 of your report, you</p> <p>10 mention a device called the HVAD. Is that the HeartWare</p> <p>11 device?</p> <p>12 A The HVAD is the HeartWare device, yes.</p> <p>13 Q Do you know generally when the HeartWare</p> <p>14 device was FDA approved?</p> <p>15 A There were two clinical trials for two</p> <p>16 different indications in the U.S. One was for</p> <p>17 short-term implant, otherwise referred to as bridge to</p> <p>18 transplant, which is six months or less, and the other</p> <p>19 one is called destination therapy, which is long-term</p> <p>20 implant. My recollection -- and, gosh, it's going back</p> <p>21 a few years -- is the HVAD was approved for bridge to</p> <p>22 transplant around 2010 or thereabouts. I don't know if</p> <p>23 it ever obtained approval for long-term implant.</p> <p>24 Q Now, many patients received HeartWare</p> <p>25 implants; didn't they? Thousands of patients perhaps?</p> <p style="text-align: right;">Page 52</p>
<p>1 orientations of the pump. So there's no single answer</p> <p>2 to your question. Depends how the pump is oriented.</p> <p>3 Q Well, my question was based on the pump being</p> <p>4 oriented in the same place, the inflow in the same as</p> <p>5 the --</p> <p>6 A But it can't be. Because the inflow and</p> <p>7 outflow of the HeartMate II pump are generally on the</p> <p>8 same axis. The inflow and outflow of a centrifugal pump</p> <p>9 are not on the same axis. So you can't replace one with</p> <p>10 the other.</p> <p>11 Q So the outflow from a centrifugal pump is 90</p> <p>12 degrees offset from the inflow; is that right?</p> <p>13 A The axis of the outflow of a centrifugal pump</p> <p>14 is generally at about 90 degrees to the axis of the flow</p> <p>15 entering the pump along the center of the impeller, yes.</p> <p>16 Q So if I were to hold two pumps side by side,</p> <p>17 an axial flow pump and a centrifugal flow pump, and the</p> <p>18 inflow to both pumps came from above, the inflow came</p> <p>19 straight down, the outflow from the axial flow pump</p> <p>20 would go straight down; wouldn't it?</p> <p>21 MR. BORDER: Objection. Form.</p> <p>22 THE WITNESS: If -- if what you're saying</p> <p>23 is I hold an axial flow pump so that -- and I'm standing</p> <p>24 vertical, and the inflow is higher than the outflow, the</p> <p>25 outflow would be below the pump, yes.</p> <p style="text-align: right;">Page 51</p>	<p>1 A I understand so, yes.</p> <p>2 Q Do you know how big the HeartWare device was?</p> <p>3 A My recollection is it was about 12 centimeters</p> <p>4 in diameter or thereabouts, maybe three to four</p> <p>5 centimeters thick in a disc shape, with an inflow</p> <p>6 cannula maybe five to eight centimeters long and about</p> <p>7 15 millimeters in diameter. But that's really based on</p> <p>8 trying to remember holding it in my hand a decade ago,</p> <p>9 15 years ago.</p> <p>10 Q Do you know whether the HeartWare device was</p> <p>11 or larger or smaller than VentrAssist?</p> <p>12 A Than the VentrAssist?</p> <p>13 Q Yeah.</p> <p>14 A They were similar size. Slightly different</p> <p>15 shape, but similar size, similar volume, similar mass.</p> <p>16 Q Do you know whether the HeartWare device was</p> <p>17 bigger or smaller than the Bourque 2001 device?</p> <p>18 A The Bourque 2001 device, I don't know the</p> <p>19 exact dimensions of that, but just eyeballing the</p> <p>20 pictures in the publications of Bourque, the Bourque</p> <p>21 device looks to be a little bigger than the HeartWare</p> <p>22 device. That -- you're comparing a device in 2001 with</p> <p>23 a device in 2007. So of course they're going to be</p> <p>24 different.</p> <p>25 Q Do you know if the HeartWare device weighed</p> <p style="text-align: right;">Page 53</p>

<p>1 more or less than the Bourque 2001 device?</p> <p>2 A Gosh, this is really not part of my</p> <p>3 declaration. I -- I haven't studied that recently. I</p> <p>4 don't know the answers to those questions. I could</p> <p>5 speculate, but it's not part of my report. And, you</p> <p>6 know, I don't -- sitting here, I don't have an opinion</p> <p>7 today other than a speculation.</p> <p>8 Q Fair enough. I think you may have already</p> <p>9 touched on this, but what distinguishes a third</p> <p>10 generation device from a second generation device?</p> <p>11 A The generally accepted understanding is a</p> <p>12 third generation left ventricular assist device does not</p> <p>13 have mechanical bearings, whereas a second generation</p> <p>14 left ventricular assist device would be a rotary pump</p> <p>15 with mechanical bearings.</p> <p>16 Q Are there any other ways in which the industry</p> <p>17 distinguishes between second and third generation</p> <p>18 devices, or is it pretty much just the presence or</p> <p>19 absence of mechanical bearings?</p> <p>20 MR. BORDER: Object to form.</p> <p>21 THE WITNESS: My understanding is that</p> <p>22 the presence or absence of bearings is the primary</p> <p>23 distinguishing characteristic.</p> <p>24 BY MR. CAHILL:</p> <p>25 Q And do you know why that's important, that</p> <p style="text-align: right;">Page 54</p>	<p>1 Could you turn to figure three?</p> <p>2 A Three?</p> <p>3 Q Yes. Now, figure three, is that an artist's</p> <p>4 rendition of how a future version of the Bourque pump</p> <p>5 might be implanted?</p> <p>6 A It appears to be, yes, as it was envisaged in</p> <p>7 2001.</p> <p>8 Q Because the Bourque 2001 paper didn't report</p> <p>9 on implantation in humans; did it?</p> <p>10 A My recollection is no.</p> <p>11 Q It did have an animal study; is that right?</p> <p>12 A I certainly recall reading multiple papers of</p> <p>13 which Bourque was at least one author of animal studies</p> <p>14 of -- of this device or variations of it, yes. And in</p> <p>15 fact, it says on page 403, "Three sets of parts were</p> <p>16 fabricated from which three fully functional implantable</p> <p>17 LVADs were assembled, and all three have been implanted</p> <p>18 in calves."</p> <p>19 Q So it does report on an animal study using the</p> <p>20 --</p> <p>21 A Yes. It says it was implanted in calves, yes.</p> <p>22 Q Now, the illustration in figure three that</p> <p>23 shows the pump below the diaphragm, assuming the patient</p> <p>24 is standing up; correct?</p> <p>25 A Yes.</p> <p style="text-align: right;">Page 56</p>
<p>1 difference between having mechanical bearings or not?</p> <p>2 A Based on my experience of working in the</p> <p>3 ventricular assist device industry, mechanical bearings</p> <p>4 are subject to areas of stagnation of the blood, which</p> <p>5 can lead to coagulation of the blood and development of</p> <p>6 thrombus. And thrombus can be a real problem in LVADs.</p> <p>7 It can lead to clinical problems. So as an LVAD</p> <p>8 designer, one wants to eliminate areas of stagnant blood</p> <p>9 as much as possible, and one of the ways to do that is</p> <p>10 to eliminate bearings. Blood is a funny stuff. It's a</p> <p>11 liquid as long as it's flowing.</p> <p>12 Q We talked about some embodiments of Wampler</p> <p>13 having a thrust bearing. Would you consider a thrust</p> <p>14 bearing to be a mechanical bearing?</p> <p>15 A Yes.</p> <p>16 Q So then would that make -- that version of</p> <p>17 Wampler's pump in your mind, would that be a second</p> <p>18 generation device?</p> <p>19 A Under the definition I just offered, yes.</p> <p>20 Q Whereas the pump Wampler discloses, I think,</p> <p>21 in figures 11 through 16 that has hydrodynamic bearings,</p> <p>22 perhaps some magnetic bearings too, but no thrust</p> <p>23 bearing, would those be a third generation device?</p> <p>24 A Under the definition I just offered, yes.</p> <p>25 Q Could we turn to the Bourque 2001 reference?</p> <p style="text-align: right;">Page 55</p>	<p>1 Q And that pump would be located in a</p> <p>2 preperitoneal pocket; wouldn't it?</p> <p>3 A It's located below the diaphragm, yes.</p> <p>4 Q And this diagram shows transcutaneous energy</p> <p>5 transmission system; doesn't it?</p> <p>6 A It does.</p> <p>7 Q Now, the Bourque authors didn't have one of</p> <p>8 those in 2001; did they?</p> <p>9 A The Bourque what?</p> <p>10 Q The Bourque authors.</p> <p>11 A Yes.</p> <p>12 Q They didn't have a TET in 2001; did they?</p> <p>13 A I don't think anyone has one even today that</p> <p>14 -- that is commercialized.</p> <p>15 Q Now, transcutaneous energy transmission system</p> <p>16 transmits energy across the skin; doesn't it?</p> <p>17 A Well, it transmits at least energy. Usually,</p> <p>18 it's configured to transmit energy and information to</p> <p>19 control the pump -- to control the parameters of the</p> <p>20 pump.</p> <p>21 Q In 2001, were there TETS that could control</p> <p>22 parameters of the pump across the skin?</p> <p>23 A By 2001, I think people were conducting</p> <p>24 experiments with TET systems that could transmit both</p> <p>25 power and information. The challenge of a TET systems</p> <p style="text-align: right;">Page 57</p>

<p>1 is not the information. It's the heating of the skin</p> <p>2 transmitting that much power. To highlight that answer,</p> <p>3 in -- I worked on a -- for a company called Cochlear,</p> <p>4 which was developing a cochlear implant. I joined them</p> <p>5 in 1981, and we were using a TET system to transmit</p> <p>6 power and information across the skin in 1981 to an</p> <p>7 implantable cochlear implant. The problem was not the</p> <p>8 information.</p> <p>9 Q What kind of information was transferred in</p> <p>10 that case?</p> <p>11 A I beg your pardon?</p> <p>12 Q What kind of information was transferred in</p> <p>13 that case?</p> <p>14 A In that -- in that case, it was information to</p> <p>15 cause the implant to deliver electrical stimulation to</p> <p>16 the nerves of hearing, to reproduce the sensation of</p> <p>17 hearing in people who were profoundly deaf.</p> <p>18 Q Now, the orientation of the pump in figure</p> <p>19 three, Bourque and co-authors specifically intended that</p> <p>20 orientation; didn't they?</p> <p>21 A They did what to the orientation?</p> <p>22 Q They specifically intended that orientation;</p> <p>23 didn't they?</p> <p>24 A Well -- well, I'm not in their head, so I</p> <p>25 don't know what they intended. That's the orientation</p> <p style="text-align: right;">Page 58</p>	<p>1 long axis?</p> <p>2 A Approximately, yes. Depends on surgical</p> <p>3 vagaries, but yes.</p> <p>4 Q Now, the inflow to the Bourque 2001 device</p> <p>5 includes a flexible section; doesn't it?</p> <p>6 A Where are you reading that?</p> <p>7 Q Well, I'm looking, for example, at figure 1A.</p> <p>8 A Yes. It describes a flexible section or</p> <p>9 depicts a flexible section in that artist's illustration</p> <p>10 on figure 1A, yes.</p> <p>11 Q Are there any advantages to providing that</p> <p>12 flexible section on the inflow?</p> <p>13 A The -- can you point to me where the authors</p> <p>14 discussed the advantage of that in this paper?</p> <p>15 Q I don't know if I can.</p> <p>16 A Then I don't know if the authors described</p> <p>17 what the advantages were, if any, of that flexible</p> <p>18 section.</p> <p>19 Q Okay. But I was asking you if there were any</p> <p>20 advantages to having a flexible section there?</p> <p>21 A Well, I'm not the inventor of the HeartMate</p> <p>22 III, so I don't know what their thinking was of putting</p> <p>23 their flexible section in.</p> <p>24 Q Does the flexible section help with anatomical</p> <p>25 fit?</p> <p style="text-align: right;">Page 60</p>
<p>1 they described in their paper.</p> <p>2 Q Well, they gave reasons for selecting that</p> <p>3 orientation; didn't they?</p> <p>4 A Where are you referring to, please?</p> <p>5 Q So, for example, on page 402, the paragraph</p> <p>6 that starts in column one. So their plan was to orient</p> <p>7 the pump in the least obtrusive position.</p> <p>8 A At least as well as it was understood in 2001,</p> <p>9 yes.</p> <p>10 Q Now, they say they decided that the</p> <p>11 orientation -- that the rotational axis of the pump's</p> <p>12 rotor should be perpendicular to the body's long axis;</p> <p>13 right? That's what they say.</p> <p>14 A That's what the document says, yes.</p> <p>15 Q So looking at figure three, what is the long</p> <p>16 -- what is the body's long axis?</p> <p>17 A Well, it's from your head to your feet.</p> <p>18 Q So straight up and down on the page.</p> <p>19 A Straight up and down on the page.</p> <p>20 Q And then the rotational axis of the pump's</p> <p>21 rotor should be perpendicular to that axis. So in</p> <p>22 general, it looks to me like the rotational axis of this</p> <p>23 pump would be straight out of the page; is that fair?</p> <p>24 A In this configuration, yes.</p> <p>25 Q And that would be perpendicular to the body's</p> <p style="text-align: right;">Page 59</p>	<p>1 A It may. I don't see how, but it may.</p> <p>2 Q Does flexibility on the inflow side help to</p> <p>3 decouple the pump from cardiac motion?</p> <p>4 A I wouldn't see that as being relevant by 2007.</p> <p>5 People knew at that time that when you put an LVAD in a</p> <p>6 patient, particularly if the patient has cardiomyopathy,</p> <p>7 the heart doesn't move anyway, and the heart doesn't</p> <p>8 need to move. So a motivation to decouple the pump from</p> <p>9 heart motion doesn't seem to be relevant at all by the</p> <p>10 time we're talking about in 2007.</p> <p>11 Q Now, you're describing a circumstance where</p> <p>12 the LVAD takes over completely the pumping of blood;</p> <p>13 aren't you?</p> <p>14 A Well, generally, what an LVAD does, you</p> <p>15 replace most of the flow through the heart. Instead of</p> <p>16 going out the aortic valve, it goes through the LVAD,</p> <p>17 and it's a continuous flow pump. So you don't have a</p> <p>18 pulse.</p> <p>19 Q Sir, are you suggesting that anytime you</p> <p>20 implant an LVAD, you don't have a pulse?</p> <p>21 MR. BORDER: Object to form.</p> <p>22 THE WITNESS: Anytime you implant a</p> <p>23 second or third generation device that's a rotary pump,</p> <p>24 you don't have a pulse. In fact, there was a huge</p> <p>25 debate around the time of the Bourque article, the early</p> <p style="text-align: right;">Page 61</p>

<p>1 2000s, about whether there were any physiological</p> <p>2 disadvantages and/or disadvantages of having a pulse or</p> <p>3 not having a pulse.</p> <p>4 BY MR. CAHILL:</p> <p>5 Q But are you saying it's a fact that there is a</p> <p>6 -- there is never a pulse?</p> <p>7 MR. BORDER: Object to form.</p> <p>8 THE WITNESS: I didn't say there's never</p> <p>9 a pulse. It's most likely an LVAD patient would not</p> <p>10 have a pulse. In some cases where the heart may recover</p> <p>11 after being unloaded for a while, you may be able to</p> <p>12 detect a pulse. Generally, LVAD patients do not have a</p> <p>13 pulse, 'cause their heart doesn't move much. Certainly,</p> <p>14 the few hundred LVAD patients I've seen would often</p> <p>15 describe the wonder of being alive without a pulse.</p> <p>16 BY MR. CAHILL:</p> <p>17 Q Does the flexible section in figure 1A provide</p> <p>18 a point for clamping during pump explant?</p> <p>19 A For doing what? Sorry.</p> <p>20 Q Pump explant.</p> <p>21 A Does the flexible section help with that?</p> <p>22 Q Yes.</p> <p>23 A It may. Depends on the configuration.</p> <p>24 Generally, when I've seen pumps explanted, they just</p> <p>25 take the whole thing out and put another one in. The</p> <p style="text-align: right;">Page 62</p>	<p>1 at issue, that statement, I don't think, was anymore</p> <p>2 true.</p> <p>3 Q But at that time, there was experience with</p> <p>4 the HeartMate II; wasn't there?</p> <p>5 A There was experience with the HeartMate II,</p> <p>6 yes.</p> <p>7 Q And that's a rotary pump?</p> <p>8 A It is a rotary pump. But it doesn't talk to</p> <p>9 me here in this paragraph about which clinical</p> <p>10 experience it's referring to. And certainly by 2007,</p> <p>11 people understood, although that may have been the</p> <p>12 consideration in 2001, it -- it faded into obscurity by</p> <p>13 the time the field developed.</p> <p>14 And as I said, it doesn't really help you with</p> <p>15 a surgical explant, because if the main reason for</p> <p>16 surgical explant is infection, if you have an infection,</p> <p>17 you got to take it all out. You can't risk leaving any</p> <p>18 parts in the body that might be a continuing source of</p> <p>19 infection. So although that may have been true in 2001,</p> <p>20 by 2007, people would not have believed that.</p> <p>21 Q All right. Just to make sure I understand,</p> <p>22 the statement there about clinical experience, it's your</p> <p>23 opinion that by 2007 a person of ordinary skill in the</p> <p>24 art would not have believed that; is that right?</p> <p>25 A It's my opinion that by 2007, they would not</p> <p style="text-align: right;">Page 64</p>
<p>1 flexible section doesn't really make much difference in</p> <p>2 my view. If you're taking your pump out to replace it</p> <p>3 because of infection, you take it all out.</p> <p>4 Q On page 405 --</p> <p>5 A You're referring to Bourque?</p> <p>6 Q Yes. The second paragraph starts, "For</p> <p>7 example."</p> <p>8 A Four-oh-five. I see that.</p> <p>9 Q So it says there that "clinical experience has</p> <p>10 suggested that some freedom of movement between the</p> <p>11 native heart and the pump ameliorates stresses imposed</p> <p>12 on the heart by an imperfectly placed pump, and it</p> <p>13 subdues unnecessary pump motion." Do you see that?</p> <p>14 A I see that.</p> <p>15 Q Do you disagree with the clinical experience</p> <p>16 reported by Bourque and his co-authors?</p> <p>17 A Well, remember this is a paper from 2001. The</p> <p>18 only human clinical experience by that time was</p> <p>19 pulsatile left ventricular assist devices. For those</p> <p>20 type of pumps, it may have been important to retain some</p> <p>21 freedom of movement, because they were pulsatile pumps.</p> <p>22 There was very little, if any, clinical experience by</p> <p>23 that time with rotary pumps to suggest that that was</p> <p>24 important with rotary pumps. That was 2001. By 2007,</p> <p>25 which I understand as the priority date of the patents</p> <p style="text-align: right;">Page 63</p>	<p>1 have thought that was an important consideration. That</p> <p>2 is correct.</p> <p>3 Q Do you know whether the pump described in</p> <p>4 Bourque 2001 was ever implanted in humans?</p> <p>5 A I think you asked that before. I said I don't</p> <p>6 know.</p> <p>7 Q You're aware, aren't you, that Abbott markets</p> <p>8 a HeartMate III pump today?</p> <p>9 A I'm aware Abbott markets the HeartMate III</p> <p>10 Roman three today. This is labeled as the HeartMate</p> <p>11 III, I-I-I. So there are different pumps. Even though</p> <p>12 you might say them the same, they're different pumps.</p> <p>13 Q Okay. So the pump that's marketed today, but</p> <p>14 regardless -- I'm actually not sure the use of Roman</p> <p>15 numeral three or cursive three -- I'm not sure that's</p> <p>16 been consistent. But just so we're clear, the HeartMate</p> <p>17 III pump that Abbott markets today, recently, that's a</p> <p>18 different pump than the HeartMate III that appears in</p> <p>19 Bourque 2001?</p> <p>20 MR. BORDER: Objection. Form, outside</p> <p>21 the scope.</p> <p>22 MR. CAHILL: Is that correct?</p> <p>23 THE WITNESS: Well, I haven't examined</p> <p>24 the pump that Abbott manufactures and sells today, other</p> <p>25 than reviewing some of the documents in this case. It</p> <p style="text-align: right;">Page 65</p>

<p>1 is a centrifugal pump. Bourque is a centrifugal pump. 2 It is magnetically suspended. Bourque is magnetically 3 suspended. It has an inflow along the axis of rotation. 4 Bourque has an inflow along the axis of rotation. It 5 has an outflow at right -- right angles to the axis of 6 rotation. 7 Bourque has an outflow right angle to the 8 axis of rotation. So the fundamental characteristics of 9 the Bourque pump and the HeartMates III are, in my 10 opinion, the same. There are some differences in the 11 way those characteristics are engineered, but they're 12 basically the same. It's my understanding that. But 13 again, I'll caveat that with I haven't studied that 14 question. 15 BY MR. CAHILL: 16 Q Do you know whether the current HeartMate III 17 is larger or smaller than the pump illustrated in 18 Bourque 2001? 19 A I haven't studied that question. 20 Q Do you know -- well, you have reviewed the 21 infringement allegations. I think it's in Exhibit 1018; 22 is that right? 23 A 1018? 24 Q It's the last one in your -- 25 A Nineteen, I think.</p> <p style="text-align: right;">Page 66</p>	<p>1 A This is a patent by Bourque dated December 10, 2 2019, with a -- I'm just trying to figure out the 3 priority date. I think it's 2017; is that correct? 4 Q I don't know off the top of my head. My 5 question is, have you reviewed it before? 6 A I think I may have seen it. I think to say 7 reviewed it is probably too strong. 8 Q Have you formed any opinions about the pump 9 that's described in that patent as compared to the 10 Bourque 2001 pump? 11 A Do you know if I express any of those opinions 12 in my report? 13 Q You do not. 14 A Then I have not formed any opinions on it. 15 Q Very good. You can put that aside. Can you 16 turn to the Wampler patent publication, Exhibit No. 17 1008? 18 A Exhibit 1008 again? 19 Q Yes. And in particular, I'd like to ask you 20 about paragraph 76. 21 A Seventy-six? 22 Q Yes. 23 A I've read paragraph 76. 24 Q So there's a reference there, in a centrifugal 25 pump, a 90 degree redirection of the blood is affected.</p> <p style="text-align: right;">Page 68</p>
<p>1 Q -- Exhibit 7. 2 A Yes. I have it here. 3 Q Okay. It is Exhibit No. 1019; is that right? 4 A Yes, it is. It's marked as Exhibit 7 and 5 Exhibit 1019. So it's both, just to make it easier for 6 us all. 7 Q So based on your review of that, do you have 8 an understanding as to any of the engineering 9 differences between the pump that's illustrated in 10 Exhibit 1019 and the pump that's illustrated in Bourque 11 2001? 12 A I haven't studied it from that perspective, so 13 I don't really have an opinion on that today. 14 Q I am going to hand you, Mr. Crosby, Miracor 15 Exhibit No. 2009. 16 MR. BORDER: Thank you. 17 THE WITNESS: This is -- okay. 18 MR. CAHILL: Actually, could I check 19 that? There was one of these that I highlighted. No, 20 this one is fine. 21 MR. BORDER: I'm not seeing any 22 highlighting here. 23 BY MR. CAHILL: 24 Q Okay. Mr. Crosby, have you reviewed that 25 exhibit before?</p> <p style="text-align: right;">Page 67</p>	<p>1 Do you see that? 2 A Yes. 3 Q Now, that 90 degree redirection, is that what 4 we were talking about earlier where a centrifugal pump 5 -- the outflow will be perpendicular -- the axis of the 6 outflow will be perpendicular to the axis of the inflow? 7 A I think that's what it's referring to in 76, 8 yes. 9 Q Right. Because it says, "axial inflow and 10 radial outflow." 11 A I see that, yes. 12 Q So that means the outflow is at 90 degrees 13 from the inflow; is that right? 14 A That's a characteristic of all centrifugal 15 pumps. 16 Q And it says that that redirection is effective 17 without the necessity of a flow restrictive elbow 18 fitting. Do you see that? 19 A I see that. 20 Q Do you know what flow restrictive elbow 21 fitting Wampler is referring to? 22 A Well, I think he's referring to any flow 23 restricting elbow fitting. I don't think he's referring 24 to any one in particular. 25 Q Well, for example, when we talked about</p> <p style="text-align: right;">Page 69</p>

<p>1 HeartMate II, we saw an elbow on the outflow side.</p> <p>2 A In the outflow graph, yes.</p> <p>3 Q And if you could redirect the flow 90 degrees</p> <p>4 without --</p> <p>5 A But that doesn't make sense; does it? Because</p> <p>6 the outflow of the pump in Wampler is in exactly the</p> <p>7 same direction as the outflow of the HeartMate II. You</p> <p>8 still need to redirect the flow for the outflow graft to</p> <p>9 reach the aorta.</p> <p>10 Q But the Wampler pump is oriented differently</p> <p>11 with respect to the heart; isn't it?</p> <p>12 A But the outflow of the Wampler pump is in</p> <p>13 exactly the same direction of the outflow as the</p> <p>14 HeartMate II. We can go back to the illustration.</p> <p>15 You'll still need an elbow to go from the outflow of the</p> <p>16 Wampler pump up to the aorta exactly the same as you</p> <p>17 need in the HeartMate II.</p> <p>18 Q Figure five of Wampler, it doesn't show an</p> <p>19 elbow on the outflow side; does it?</p> <p>20 A But it -- it does show a 90 degree change in</p> <p>21 flow; doesn't it? The outflow of the pump 11 is at 90</p> <p>22 degrees from the inflow to the aorta 67. So somehow you</p> <p>23 have to change the blood 90 degrees, the blood flow.</p> <p>24 Q But there's not an elbow there; is there?</p> <p>25 A There's not a -- an elbow in the sense that</p> <p style="text-align: right;">Page 70</p>	<p>1 page? So it says, "Several enhancements to HeartMate</p> <p>2 III are presently being implemented."</p> <p>3 A All right. Let me read this if I --</p> <p>4 Q And the conclusion.</p> <p>5 A Yes. I read the conclusion.</p> <p>6 Q So several enhancements are being</p> <p>7 contemplated. One of them is incorporation of motor</p> <p>8 drive and control electronics within the pump. Do you</p> <p>9 know why they would do that?</p> <p>10 A Again, I'm not one of the authors of the</p> <p>11 paper, so I don't know the motivation here of why they</p> <p>12 might want to do that in 2001.</p> <p>13 Q And another enhancement would be the</p> <p>14 integration of a transcutaneous energy transmission</p> <p>15 system, as we've talked about before. Do you see that?</p> <p>16 A Yes.</p> <p>17 Q Now, it's your understanding, isn't it, that</p> <p>18 no one has implemented a TET system for an implantable</p> <p>19 LVAD?</p> <p>20 A I don't believe there's any commercially</p> <p>21 available TET system for an LVAD today. There have been</p> <p>22 commercially available TET system for a total artificial</p> <p>23 heart. There were two.</p> <p>24 Q Could you look at paragraph 471 of your</p> <p>25 declaration?</p> <p style="text-align: right;">Page 72</p>
<p>1 there's no hard sharp turn. That is correct. If you</p> <p>2 have a look at Bourque 2001 figure three, it also shows</p> <p>3 there's no elbow, because the orientation of the output</p> <p>4 of that particular device is exactly the direction you</p> <p>5 want it to flow towards the aorta. So Wampler would</p> <p>6 require some sort of change of direction of the outflow.</p> <p>7 Bourque 2001 would not.</p> <p>8 Q Because the outflow of the centrifugal pump is</p> <p>9 in the right direction; is that right?</p> <p>10 A In which device?</p> <p>11 Q In Bourque 2001.</p> <p>12 A In Bourque 2001, the outflow is oriented to be</p> <p>13 the direction that you want the outflow to go towards</p> <p>14 the aorta.</p> <p>15 Q So the outflow of the Bourque 2001 device</p> <p>16 doesn't need an elbow?</p> <p>17 A Doesn't need a --</p> <p>18 MR. BORDER: Objection. Form.</p> <p>19 MR. CAHILL: An elbow.</p> <p>20 MR. BORDER: Objection. Form.</p> <p>21 THE WITNESS: The Bourque 2001 device is</p> <p>22 illustrated without an elbow on the outflow.</p> <p>23 BY MR. CAHILL:</p> <p>24 Q Could we look back at the Bourque 2001</p> <p>25 reference, in particular the conclusion on the last</p> <p style="text-align: right;">Page 71</p>	<p>1 A Four-seventy-one?</p> <p>2 Q Yes.</p> <p>3 A You're certainly jumping around. It's hard to</p> <p>4 keep up.</p> <p>5 Q So in that paragraph, you talk about placement</p> <p>6 of LVADs in preperitoneal pocket position --</p> <p>7 A I'm sorry. I'm really having trouble hearing.</p> <p>8 Q Okay. In that paragraph, you talk about the</p> <p>9 placement of LVADs in the preperitoneal pocket position,</p> <p>10 and you talk about some of the disadvantages of that.</p> <p>11 Do you see that?</p> <p>12 A Yes.</p> <p>13 Q Now, the Bourque 2001 authors planned for</p> <p>14 their pump to be implanted in a preperitoneal pocket;</p> <p>15 didn't they?</p> <p>16 A That's what it said in 2001, yes.</p> <p>17 Q Right. And --</p> <p>18 A That was the state of the art of the day. No</p> <p>19 longer by 2007.</p> <p>20 Q Okay. So is it your opinion then that by 2007</p> <p>21 a person of ordinary skill in the art would have looked</p> <p>22 at Bourque 2001 and said, "Change the position," for</p> <p>23 this reason?</p> <p>24 A This paragraph is part of a large section on</p> <p>25 motivations to combine. And this is one set -- one</p> <p style="text-align: right;">Page 73</p>

<p>1 collection of reasons of a motivation to combine amongst 2 any -- excuse me -- amongst many. So it is my opinion 3 that by 2007 it would have been -- as it says in the 4 declaration, it would have been obvious to combine 5 Bourque 2001 with the actually aligned inflow tube of 6 Wampler 169. And a person would have been motivated to 7 do so based on the teachings at that time of the 8 placement of VADs.</p> <p>9 Q The teachings at what time?</p> <p>10 A By 2007.</p> <p>11 Q Mr. Crosby, I'm going to hand you Abbott 12 Exhibit No. 1018. Now, this is a patent belonging to 13 Thermo Cardiosystems; correct?</p> <p>14 A That's one of Vic Poirier's, yes.</p> <p>15 Q Now, the pump illustrated on the front page 16 and in figure one, that's an axial flow pump; isn't it?</p> <p>17 A Do I refer to this in my report somewhere?</p> <p>18 Q You do.</p> <p>19 A Can you tell me where, so I can just put it in 20 context of what I've said before?</p> <p>21 Q In paragraph 473.</p> <p>22 A Four-seventy-three.</p> <p>23 Q So the front page in figure one of Exhibit 24 1018 and the Poirier patent, that's an axial flow pump; 25 isn't it?</p> <p style="text-align: right;">Page 74</p>	<p>1 that right?</p> <p>2 A Yes. It says it can be attached to 3 conventional tubing adapters 403 and 427 to connect it 4 between the left ventricle and aorta to provide 5 ventricular assistance.</p> <p>6 Q And then in another embodiment, the pump 400, 7 which is the centrifugal pump of figures 4A, B, and C; 8 right?</p> <p>9 A I'm sorry. What's the question?</p> <p>10 Q It says, "In another embodiment of pump 400."</p> <p>11 A Yes.</p> <p>12 Q And I'm asking if you agree that pump 400 is 13 the centrifugal flow pump of figures 4A, 4B, and 4C?</p> <p>14 A It appears to be, yes.</p> <p>15 Q "May be implemented using various components 16 of pump ten." And would you agree with me that pump ten 17 is the axial flow pump of figure one?</p> <p>18 A Yes.</p> <p>19 Q So it says it may be modified to incorporate 20 inflow cannula adapter 40, inflow cannula elbow 43, 21 inflow cannula apical tube 45, outflow cannula elbow 49, 22 and outflow graft 52.</p> <p>23 A I see that, yes.</p> <p>24 Q Now, all four of those elements, 40, 43, 45, 25 49, and 52, those all appear in figure one; don't they?</p> <p style="text-align: right;">Page 76</p>
<p>1 A It is, yes.</p> <p>2 Q Does that pump look like HeartMate II?</p> <p>3 A It certainly looks similar. I haven't studied 4 a comparison of this and the actual device, but they 5 certainly look similar.</p> <p>6 Q Now, the pump illustrated in figures 4A, 4B, 7 and 4C --</p> <p>8 A Of the 975 patent?</p> <p>9 Q Yes.</p> <p>10 A I see that. What -- yes?</p> <p>11 Q That's a centrifugal flow pump; isn't it?</p> <p>12 A Yes.</p> <p>13 Q Do you recognize it as having some similarity 14 with Bourque 2001? I realize it's not the same, but 15 does it have some similar features?</p> <p>16 A It looks like it has a similar configuration, 17 yes.</p> <p>18 Q So in the paragraph in the Poirier patent, 19 Exhibit 1018, in the bottom of column six to the --</p> <p>20 A Which paragraph are you referring to?</p> <p>21 Q The bottom of column six to the top of column 22 seven.</p> <p>23 A Okay. Thank you.</p> <p>24 Q So that paragraph is talking about the tubing 25 and adapters for use with a centrifugal flow pump; is</p> <p style="text-align: right;">Page 75</p>	<p>1 A Yeah. They appear to, yes.</p> <p>2 Q So what this paragraph is saying is that you 3 can use those elements from the axial flow pump of 4 figure one on the centrifugal flow pump of figures 4A, 5 4B, and 4C; is that right?</p> <p>6 A Sure. The pump itself is the bit in the 7 middle. The cannula that connect to the heart and to 8 the aorta can be used with different types of pump. 9 That's basically what it's saying. Let's -- let's reuse 10 the parts we have that we know work. They look, by the 11 way, to be similar to the inflow and outflow graph shown 12 in the Bourque 2001 paper.</p> <p>13 Q Could you turn to paragraph 476 of your 14 declaration?</p> <p>15 A All right myself. Okay.</p> <p>16 Q So you say there that a PHOSITA would have had 17 a reasonable expectation of success that the Bourque 18 Wampler combination would fit well between the apex of 19 the heart and the adjacent diaphragm. Do you see that?</p> <p>20 A Yes.</p> <p>21 Q And then you suggest that the Bourque 2001 22 HeartMate III was already planned for enhancements, and 23 you said, for example, enhancements to make the device 24 smaller.</p> <p>25 A I see that, yes.</p> <p style="text-align: right;">Page 77</p>

<p>1 Q Now, I think it's the case that you don't know 2 how big the Bourque 2001 pump is; do you?</p> <p>3 A I -- I don't know.</p> <p>4 Q You don't know whether it's bigger or smaller 5 than the Wampler pump?</p> <p>6 A I don't know.</p> <p>7 Q You don't know whether it's bigger or smaller 8 than the Akamatsu pump?</p> <p>9 A Well, no. I don't know.</p> <p>10 Q Now, you say, "enhancements to make the device 11 smaller." What enhancements are discussed that would 12 make the device smaller?</p> <p>13 A Where are you referring?</p> <p>14 Q You cite to page 405 of Bourque 2001, and I 15 think that's the conclusion paragraph that talks about 16 enhancements.</p> <p>17 A Yes. It talks about various enhancements 18 there.</p> <p>19 Q Which enhancements does it -- which 20 enhancements will make the Bourque 2001 device smaller?</p> <p>21 A All of them could.</p> <p>22 Q So incorporation of motor drive and control 23 electronics within the pump, would that make the pump 24 smaller?</p> <p>25 A It could.</p> <p style="text-align: right;">Page 78</p>	<p>1 Q But you don't know what those ten things are; 2 do you?</p> <p>3 A Well, I don't know specifically for this 4 device, but I know from my 45 years of experience in 5 this industry that there's a drive to make things 6 smaller all the time, unless it's hips or joints.</p> <p>7 Q Okay. So there's a drive to make things 8 smaller.</p> <p>9 A Yes.</p> <p>10 Q But Bourque 2001 itself isn't proposing 11 changes to make the pump smaller; is it?</p> <p>12 A Well, it's -- it's proposing -- several 13 enhancements are presently being implemented, including 14 incorporation. A person of skill in the art would read 15 that and say, "Okay. That's one of the things they're 16 doing, and -- and they're trying to do all the other 17 enhancements, like reduce power, make it smaller, make 18 it easier to manufacture, make it lower cost."</p> <p>19 Q So a person of ordinary skill in the art would 20 understand that from Bourque's conclusion. That's your 21 opinion?</p> <p>22 A Well, I haven't discussed that particular 23 question in my report. So what I'm giving you is a 24 background of my experience in the medical device 25 industry that a person of skill in the art would look</p> <p style="text-align: right;">Page 80</p>
<p>1 Q If you're adding more parts to the pump, it's 2 going to make the pump smaller.</p> <p>3 A I designed pacemakers for many years. Today's 4 pacemakers have got about ten times as many parts as the 5 pacemakers designed in 1960, but they're one tenth the 6 size. The number of parts have got nothing to do with 7 the size.</p> <p>8 Q But if you're adding more parts, you're 9 reducing the size some other way; aren't you?</p> <p>10 A Well, you may. Adding parts will reduce size. 11 Sure.</p> <p>12 Q But adding parts will reduce size if you 13 actually engineer it to have a reduced size; isn't that 14 the case?</p> <p>15 A I'm sorry. I don't understand the question.</p> <p>16 Q Well, if you're adding parts to reduce the 17 size, you have to take the size away from someplace 18 else; don't you?</p> <p>19 A Well, the paragraph says, "Several 20 enhancements to HeartMate are presently being 21 implemented, including." It's not an exclusive list. 22 So it's including incorporation of motor drive and 23 control electronics within the pumps. There could be 24 another ten things that they're doing, which includes 25 that.</p> <p style="text-align: right;">Page 79</p>	<p>1 at this as a prototype device that's been designed for 2 use and has been experimented on in animals. And as 3 part of the progression -- I think it even talks about 4 -- these enhancements will continue the progression of 5 this VADs development as a compact, reliable device. So 6 a person of skill in the art would see this as being one 7 step in that progress.</p> <p>8 Q So then a person of ordinary skill in the art 9 would understand that the Bourque 2001 authors were 10 making other changes to the device that would make it 11 smaller, ones that aren't specifically enumerated here?</p> <p>12 MR. BORDER: Object to form.</p> <p>13 THE WITNESS: A person of skill in the 14 art reading this would understand -- as I said, this is 15 a first iteration of a device intended for use in 16 humans. It has been shown to work in animals to prove 17 the concepts, and part of the progression to develop a 18 compact, reliable device to treat chronic heart failure 19 in humans would be along multiple axes.</p> <p>20 BY MR. CAHILL:</p> <p>21 Q And do you know when HeartMate III was first 22 implanted in humans?</p> <p>23 A You mean this HeartMate III or the current 24 one?</p> <p>25 Q Well, any one. Any -- right. I think we've</p> <p style="text-align: right;">Page 81</p>

<p>1 talked a little bit about the current HeartMate III and 2 the Bourque 2001 HeartMate III. And now if I understand 3 you correctly, what you're saying is a person of 4 ordinary skill in the art would understand that they 5 would have been motivated to make changes all along. So 6 do you know if there was a time when the HeartMate III 7 device was ready to be implanted in humans? 8 A I haven't looked at that question. I don't 9 recall exactly the dates of the HeartMate III first 10 human chronic implantation. I don't know. 11 MR. CAHILL: Okay. Can we go off the 12 record? 13 THE OFFICER: Sure. It is 11:56 a.m. We 14 are now off the record. 15 (Off the record.) 16 THE OFFICER: We are now back on the 17 record. It is 12:32 p.m. 18 BY MR. CAHILL: 19 Q Mr. Crosby, we're going to change gears a 20 little bit now and talk about the Akamatsu reference. 21 So let's see. Could you turn to Akamatsu -- it's 22 Exhibit No. 1006. And this paper was published in 1999; 23 is that right? 24 A Yes. Received February 3, 1999, published in 25 1999.</p> <p style="text-align: right;">Page 82</p>	<p>1 Q Yeah. I guess, is -- does "seal" only refer 2 to mechanical bearings? 3 A I guess it may refer to something else, but my 4 understanding is, in the context of a blood pump, the 5 seal refers to the seal of the mechanical bearing. Of 6 course the whole assembly itself is sealed, so that the 7 blood can't leak out. In that sense, there are other 8 seals, but the concept of a seal-less pump means no seal 9 for mechanical bearings. That's my understanding. 10 Q Is -- that sentence, "We've developed a 11 seal-less centrifugal pump follows approaches to 12 mechanical reliability and non-thrombogenicity," does a 13 seal-less -- 14 A Okay. 15 Q Does the property of being seal-less -- does 16 it relate to both mechanical reliability and non- 17 thrombogenicity or one of them or neither of them? 18 A A little. I mean, mechanical -- any 19 mechanical bearing will have a reliability issue. And 20 even sealers bearings, like a pivot bearing in a 21 HeartMate II, will have thrombogenicity issues. Because 22 there is a point at which the blood is not flowing and 23 will form thrombus, a blood clot. 24 Q Other than not having mechanical bearings, 25 what are other general design parameters for an LVAD for</p> <p style="text-align: right;">Page 84</p>
<p>1 Q I want to ask you about a turn of phrase in 2 Akamatsu. I want to ask you about a turn of phrase in 3 Akamatsu. In his discussion on page six -- 4 A Page six? 5 Q Yes. 6 A There isn't a page six. Oh, sorry. That page 7 at the top, yes. Okay. 8 Q So near the top of the second column there, he 9 talks about approaches to mechanical reliability as well 10 as non-thrombogenicity. And he says, "We have developed 11 a seal-less centrifugal pump with a magnetically 12 suspended impeller." Do you know what he means by 13 "seal-less"? 14 A You're asking what seal-less means? 15 Q Yes. 16 A Well, a mechanical bearing will have a seal to 17 make sure the blood doesn't get into the bearing. So 18 seal-less usually refers to, in my experience at least, 19 a -- a pump that doesn't have seals. 20 Q So does that mean that all of the, sort of, 21 blood contacting surfaces will be continuous, and there 22 won't be seals? 23 A Well, what it -- in the context of this 24 discussion, it means there is no mechanical bearing with 25 the seal. Does that answer your question?</p> <p style="text-align: right;">Page 83</p>	<p>1 achieving non-thrombogenicity? 2 A I don't think I've opined on that in my 3 report. So you're asking, kind of, in general 4 engineering terms? 5 Q Yes. As someone who's experienced in the 6 field and contributed to blood pump designs. 7 A Sure. As I -- as I mentioned before, blood is 8 a funny fluid. It's only a fluid when it's flowing. If 9 it stops flowing, it turns into a solid. That's why you 10 have a scab when you hurt your knee. So one of the 11 things one needs to do in any blood pump is ensure that 12 there are no areas of stagnation where the blood is not 13 flowing. 14 One also -- it has to ensure that the shear 15 force applied to the blood is small enough that you 16 don't break apart any of the cells. One of the big 17 problems with early blood pumps was there was so much 18 shear force, it broke apart the red blood cells, which 19 leaked hemoglobin into the blood. Hemoglobin is 20 poisonous. It only does a useful function if it's 21 inside a cell wall. So there are multiple aspects to 22 ensure mechanical reliability and non-thrombogenicity. 23 Q What about the surfaces of the -- like, the 24 blood contacting the surfaces? 25 A What about the blood contacting surfaces?</p> <p style="text-align: right;">Page 85</p>

<p>1 Q Yeah. Would they be specially treated to</p> <p>2 prevent thrombus?</p> <p>3 A Some are. People have done work on special</p> <p>4 surfaces, blood contacting for reducing thrombogenicity.</p> <p>5 The earlier versions of the pumps -- any pump did not.</p> <p>6 But there have been a lot of work on different types of</p> <p>7 materials to reduce thrombogenicity in the blood</p> <p>8 contacting surfaces. In the VentrAssist pump we talked</p> <p>9 about today, we used what's called diamond like carbon,</p> <p>10 vitreous carbon to coat the surfaces. That's one method</p> <p>11 that people have used.</p> <p>12 Q In the Akamatsu pump, do you know what the</p> <p>13 housings and the impeller are made out of?</p> <p>14 A I -- I'm having trouble hearing. I'm sorry.</p> <p>15 Q I'm sorry. In Akamatsu, do you know what</p> <p>16 materials the housings and the impeller are made out of?</p> <p>17 A I don't know. There's a photograph figure</p> <p>18 five. It looks like it's some sort of polymer, but I</p> <p>19 don't know, unless you can point to me where it says in</p> <p>20 the paper.</p> <p>21 Q Okay. Could we look at figure one of</p> <p>22 Akamatsu? And this is a rendering of the Akamatsu pump</p> <p>23 as it might be implanted in a human; is that right?</p> <p>24 A It appears to be a rendering -- an artist's</p> <p>25 rendition, yes.</p> <p style="text-align: right;">Page 86</p>	<p>1 of work, and this pump became the Terumo DuraHeart,</p> <p>2 which was implanted in humans. I've held one in my hand</p> <p>3 a couple of times. I've actually met Dr. Nojiri, who's</p> <p>4 the first author of this paper. So whether it's this</p> <p>5 exact pump that was implanted in humans, it's the --</p> <p>6 this pump design has been implanted in humans is my</p> <p>7 understanding.</p> <p>8 Q Do you know when?</p> <p>9 A Are you asking for the first one?</p> <p>10 Q Yes.</p> <p>11 A I don't know exactly. I think it was during</p> <p>12 the time that I was at Ventracor they reported their</p> <p>13 first human implant. So it would have been in the 2005</p> <p>14 to 2009 frame -- timeframe.</p> <p>15 Q I'm looking at figure one. Can you tell how</p> <p>16 this pump is connected to the heart in the figure?</p> <p>17 A Well, it's difficult to see, because it's --</p> <p>18 this is a photocopy of the article. I'm not sure if the</p> <p>19 article would be easier to see, but it appears that the</p> <p>20 -- there's an inflow tube which is inserted into the</p> <p>21 apex of the heart, and the outflow graft from the pump</p> <p>22 goes to the ascending aorta.</p> <p>23 Q Can you tell whether the pump in figure one is</p> <p>24 implanted above or below a patient's diaphragm?</p> <p>25 A No. It doesn't describe that in the</p> <p style="text-align: right;">Page 88</p>
<p>1 Q It looks like the patient's heart is cut away</p> <p>2 in this figure. Do you see --</p> <p>3 A Okay.</p> <p>4 Q Well, do you see extending from the pump up</p> <p>5 into the left a little bit a partially white element?</p> <p>6 A That appears to be the outflow graft that</p> <p>7 connects the output of the pump to the aorta.</p> <p>8 Q So could I come over and just draw a couple</p> <p>9 circles?</p> <p>10 A Sure. What is that, are you asking? I have</p> <p>11 no idea.</p> <p>12 Q That makes two of us. So I've drawn a couple</p> <p>13 of circles about features that seem to appear inside the</p> <p>14 heart. And my question is, do you know what's being</p> <p>15 illustrated there?</p> <p>16 A No idea. It could be an anatomical structure</p> <p>17 in the heart.</p> <p>18 Q Now, in this paper, Akamatsu does not report</p> <p>19 on implanting his pump in humans; does he?</p> <p>20 A No.</p> <p>21 Q It's an animal study; isn't it?</p> <p>22 A This one is, yes.</p> <p>23 Q The pump that's illustrated here, was this</p> <p>24 pump ever implanted in humans?</p> <p>25 A As we talked about before, Akamatsu is a body</p> <p style="text-align: right;">Page 87</p>	<p>1 illustration.</p> <p>2 Q Now, I understand this article refers to three</p> <p>3 different models of Akamatsu's pump, four if you include</p> <p>4 modified model two. Do you agree with that?</p> <p>5 A Where are you referring to three different</p> <p>6 models?</p> <p>7 Q So in the abstract, it refers to model one,</p> <p>8 model two, and modified model two?</p> <p>9 A Model one, model two, and modified model two</p> <p>10 are the three you are referring to?</p> <p>11 Q And then the very last paragraph of the</p> <p>12 article refers to model three.</p> <p>13 A Are you talking about the abstract again?</p> <p>14 Q No. The very last paragraph of the Akamatsu</p> <p>15 reference.</p> <p>16 A Oh, I see. I see that -- that model three.</p> <p>17 Q So model one was a paracorporeal device; is</p> <p>18 that right?</p> <p>19 A Paracorporeal, yes, meaning outside of the</p> <p>20 body.</p> <p>21 Q And then model two was implanted in sheep but</p> <p>22 had issues with blood leakage; is that right?</p> <p>23 A Model two was intrathoracic, I said, I think.</p> <p>24 The implantable model two was evaluated ex vivo in two</p> <p>25 sheep and intra-thoracically implanted in one sheep. So</p> <p style="text-align: right;">Page 89</p>

<p>1 two different implant sites.</p> <p>2 Q And model two had problems with blood leakage;</p> <p>3 is that right?</p> <p>4 A The model two what? I'm still having trouble</p> <p>5 hearing.</p> <p>6 Q Model two had problems with blood leakage; is</p> <p>7 that right?</p> <p>8 A I think that's what it said, yes.</p> <p>9 Q And then modified model two was implanted in a</p> <p>10 sheep; is that right?</p> <p>11 A Yes. That's what it talks about in this</p> <p>12 paper. But remember, as we said before, when I say,</p> <p>13 "Akamatsu," I refer to a body of work of which Akamatsu</p> <p>14 is an author. The first author of this is Dr. Nojiri,</p> <p>15 not Akamatsu. But -- but -- and if you look at the</p> <p>16 whole body of work, there are many, many implants and</p> <p>17 many, many animals that they refer to.</p> <p>18 Q Okay. But those are referred to in other</p> <p>19 references.</p> <p>20 A Say the first?</p> <p>21 Q They're referred to in other references. Is</p> <p>22 that what you're saying?</p> <p>23 A Yes. I think I refer to the Akamatsu</p> <p>24 references in my report somewhere. All of them.</p> <p>25 Q And then model three is described as for the</p> <p style="text-align: right;">Page 90</p>	<p>1 Q Is that what's illustrated in figure one?</p> <p>2 A Well, I -- it doesn't refer to figure one in</p> <p>3 that paragraph. What does it say when I talk about</p> <p>4 figure one? I don't think the text refers to figure one</p> <p>5 at all. So I guess it could be, but I -- I don't think</p> <p>6 the text says that's what it is.</p> <p>7 Q Yeah. The reason I ask is because that is --</p> <p>8 I think that sentence is the only reference to a TET,</p> <p>9 and figure one does use a TET; doesn't it?</p> <p>10 A Yes.</p> <p>11 Q So do you know whether the Akamatsu pump is</p> <p>12 bigger or smaller than the VentrAssist pump?</p> <p>13 A I -- I think we've talked about this topic</p> <p>14 before. I don't know the actual size of the Akamatsu</p> <p>15 pump here or the weight, so I can't answer that</p> <p>16 question.</p> <p>17 Q So just for completeness of the record, do you</p> <p>18 know whether the Akamatsu pump is bigger or smaller than</p> <p>19 the Bourque 2001 pump?</p> <p>20 A I don't know the size and weight of either of</p> <p>21 those pumps, so I can't answer that question.</p> <p>22 Q Do you know whether the Akamatsu pump is</p> <p>23 bigger or smaller than the Schima pump?</p> <p>24 A Same answer. I don't know the size and weight</p> <p>25 of the Schima pump, so I can't answer that question.</p> <p style="text-align: right;">Page 92</p>
<p>1 next phase; is that right?</p> <p>2 A I didn't hear the question. Model three?</p> <p>3 Q Model three is developed for the next phase?</p> <p>4 A From this paper, yes.</p> <p>5 Q Okay. So model three has a pump with a</p> <p>6 sensor-less motor. Do you see that?</p> <p>7 A Sensor-less motor, yes.</p> <p>8 Q And an implantable controller?</p> <p>9 A I see that, yes.</p> <p>10 Q And then towards the bottom, it says,</p> <p>11 "Further" --</p> <p>12 A There's a picture of model three in figure</p> <p>13 seven --</p> <p>14 Q Yep.</p> <p>15 A -- where you can see the pump, the implantable</p> <p>16 controller, and a wire exiting that controller to the</p> <p>17 outside of the body with a AC to DC converter and a</p> <p>18 computer that controls the operation.</p> <p>19 Q Now, towards the very end -- in fact, I think</p> <p>20 it's the last sentence -- it says, "Further developments</p> <p>21 towards a totally implantable LVAS, including a</p> <p>22 transcutaneous energy and information transfer system</p> <p>23 and internal/external batteries are underway." Do you</p> <p>24 see that?</p> <p>25 A Yes.</p> <p style="text-align: right;">Page 91</p>	<p>1 Q Do you know whether Akamatsu's model three</p> <p>2 pump is bigger or smaller than the model two pump?</p> <p>3 A In this paper, there's no information about</p> <p>4 the size of the model three pump, so I don't know.</p> <p>5 There may be information in some of the other papers.</p> <p>6 Q Do you know if Akamatsu and his coworkers ever</p> <p>7 deployed a transcutaneous energy system?</p> <p>8 A I don't think a transcutaneous energy transfer</p> <p>9 system was deployed for the Terumo pump, which is the</p> <p>10 derivative of this one. So I don't think so.</p> <p>11 Q Now, this last sentence in Akamatsu that we've</p> <p>12 talked about, "Further developments toward a totally</p> <p>13 implantable LVAS." What makes an LVAS qualify as</p> <p>14 totally implantable?</p> <p>15 A In the context of this sentence, it means</p> <p>16 there will be no opening through the skin, no</p> <p>17 percutaneous lead. That term could mean that the LVAS</p> <p>18 itself is implantable but still have a percutaneous</p> <p>19 lead. In the context of this paper, I think they're</p> <p>20 referring to no percutaneous wire.</p> <p>21 Q Could I direct your attention, Mr. Crosby, to</p> <p>22 paragraph 603 of your declaration?</p> <p>23 A I think the answer to that question is yes.</p> <p>24 Q I'm glad. I'd hate it if you had said no.</p> <p>25 A Say again?</p> <p style="text-align: right;">Page 93</p>

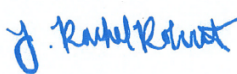
<p>1 Q I'd hate it if you had said no.</p> <p>2 A I wouldn't do that to you.</p> <p>3 Q Now, you quote Akamatsu in that paragraph</p> <p>4 where you talk about continuously measuring aortic</p> <p>5 pressure and pump flow rate. Does Akamatsu expressly</p> <p>6 use those measurements to control the pump?</p> <p>7 A I think I refer to Exhibit 1006 at page three</p> <p>8 -- four. Now I'm confused about which page number,</p> <p>9 'cause there are two lots of page numbers on this.</p> <p>10 Akamatsu 1999 says, "The pump was operated at a fixed</p> <p>11 rotational speed." So it's not clear if the aortic</p> <p>12 pressure and flow rate were used to control that fixed</p> <p>13 rotational speed. I can't tell from the way the paper's</p> <p>14 written.</p> <p>15 Q When you do an animal study, is it common to</p> <p>16 track parameters of the animal like these, like aortic</p> <p>17 pressure or other physiological parameters?</p> <p>18 A You mean -- you mean in -- in general or --</p> <p>19 Q Yes.</p> <p>20 A If you're conducting animal studies on an</p> <p>21 LVAD, you would monitor multiple physiological</p> <p>22 parameters. Some of those might be used to control the</p> <p>23 pump. You might want to adjust flow rate, for example.</p> <p>24 When I say, "flow rate," I mean volume of flow rate of</p> <p>25 blood, not the speed. So yes, you would try and monitor</p> <p style="text-align: right;">Page 94</p>	<p>1 THE WITNESS: I don't know how those</p> <p>2 parameters were used to control the speed of the pump.</p> <p>3 What it says is they measured multiple parameters,</p> <p>4 including aorta pressure and the flow rate, I think.</p> <p>5 And they operated the pump at a constant speed. So if</p> <p>6 the speed was not enough to keep the animal alive, they</p> <p>7 would have had to adjust the speed. And the way to know</p> <p>8 that is if the flow rate and aorta pressure are</p> <p>9 adequate.</p> <p>10 BY MR. CAHILL:</p> <p>11 Q Could I direct your attention to paragraph 612</p> <p>12 of your declaration?</p> <p>13 A The same answer. Yes.</p> <p>14 Q So there you quote Akamatsu as saying, "The</p> <p>15 electric current of the electromagnet is controlled by</p> <p>16 using three position sensors to maintain the impeller</p> <p>17 floating at the center of the pump housing." Do you see</p> <p>18 that?</p> <p>19 A That's correct.</p> <p>20 Q And does Akamatsu say that the signals from</p> <p>21 the position sensor are fed back to an external</p> <p>22 controller?</p> <p>23 A I think Akamatsu has no controller in the pump</p> <p>24 itself. So if there are signals from the position</p> <p>25 sensor that are used to control the free floating</p> <p style="text-align: right;">Page 96</p>
<p>1 as much -- much as you can. There's never so -- such a</p> <p>2 thing as too much data in a -- in an experiment.</p> <p>3 Q And if I understand you correctly, it's</p> <p>4 possible that some of those parameters could be used to</p> <p>5 adjust the operation of the pump.</p> <p>6 A Typically, you would use those parameters to</p> <p>7 -- to control the operation of the pump. If you have a</p> <p>8 75 kilogram calf, and you don't provide enough blood</p> <p>9 flow, the calf will die. So you need to monitor those</p> <p>10 to control the operation of the pump, so the animal</p> <p>11 lives through the experiment.</p> <p>12 Q So at this time in 1999, would -- so if you</p> <p>13 were measuring aortic pressure, like Akamatsu says,</p> <p>14 would there be some kind of feedback circuit that ran</p> <p>15 the pump, or would it be an engineer looking at the</p> <p>16 readings and changing the speed of the pump?</p> <p>17 A Well, I'm not going to speculate about how</p> <p>18 Akamatsu ran the experiment other than what's described</p> <p>19 here. So I don't know how I can answer that experiment</p> <p>20 -- that question.</p> <p>21 Q So then is it fair to say you don't know in</p> <p>22 this context --</p> <p>23 MR. BORDER: Objection. Form.</p> <p>24 MR. CAHILL: -- of Akamatsu?</p> <p>25 MR. BORDER: Objection. Form.</p> <p style="text-align: right;">Page 95</p>	<p>1 impeller, it must be from a controller which is external</p> <p>2 to the pump, certainly in versions one and two that he</p> <p>3 talks about. So by deduction, yes, those signals are</p> <p>4 fed back to an external controller.</p> <p>5 Q Okay. But Akamatsu doesn't say they're fed</p> <p>6 back to an external controller. You infer it.</p> <p>7 A Well, where else could it be? Can't be</p> <p>8 anywhere else.</p> <p>9 Q So what do these electromagnets do?</p> <p>10 A I think Akamatsu is pretty clear that the</p> <p>11 electromagnets maintain the impeller free floating at</p> <p>12 the center of the pump housing.</p> <p>13 Q So in real time, the electromagnets are</p> <p>14 adjusting the location of the rotor within the housing?</p> <p>15 A Well, let's see what Akamatsu says himself</p> <p>16 about that. It -- it says, "The electric current of the</p> <p>17 electromagnet is controlled by using three position</p> <p>18 sensors to maintain the impeller free floating at the</p> <p>19 center of the pump housing." That's the purpose.</p> <p>20 Q Right. And so my question for you is, doesn't</p> <p>21 that mean that the electromagnets are adjusting the</p> <p>22 position of the rotor in real time as it's spinning in</p> <p>23 the housing?</p> <p>24 A Well, technically, they're sensing. If</p> <p>25 there's a need for adjustment, it happens in real time.</p> <p style="text-align: right;">Page 97</p>

<p>1 If there's no need for an adjustment, there's no 2 adjustment. So the electromagnetics are sense -- excuse 3 me. The position sensors are sensing the position, and 4 if there's a need for an adjustment, then the power to 5 the electromagnets is adjusted to keep the rotor in the 6 right position. It doesn't mean that the currents 7 changing in real time all the time. 8 Q Not all the time, but -- 9 A Well, it's -- it's like the speed control of 10 your car, you know. You set the speed control to be 11 constant. Doesn't mean you adjust the motor speed all 12 the time. 13 Q Right. But this isn't about controlling the 14 speed of the rotor; right? There's a different motor 15 for that; right? 16 A It's about controlling the position of the 17 rotor. 18 Q Right. So if the rotor tilts or if the rotor 19 goes off center, in real time, the electromagnets have 20 to pull it back, so it stays centered; isn't that right? 21 A Sure. Then I'll use a different analogy. I 22 have a Tesla Model X. It's got full self-driving. If I 23 want to drive down the center of a lane, it keeps the 24 steering wheel so that it's at the center of the lane. 25 But it's not always changing the position of the</p> <p style="text-align: right;">Page 98</p>	<p>1 sensors to maintain the impeller free floating." Well, 2 that's exactly what it's doing. 3 BY MR. CAHILL: 4 Q Yes. It's controlled, but nothing about that 5 says it's an external controller. 6 A Well, there's no internal controller. So 7 we've talked about that before. It has to be external. 8 Q Certainly, there's some circuitry within the 9 implantable palm. 10 A Can you point that -- point me to that? 11 Q Can you point to something that says there 12 isn't any? 13 A You asked me to prove a negative. You just 14 said there's certainly -- I think you said, "Certainly, 15 there's an internal circuitry." I asked you to show me 16 where you -- you -- where that is and how you reached 17 that conclusion. 18 Q Yeah. I'm -- if you don't mind, I'll ask the 19 questions. Is there any place in Akamatsu where it says 20 no control takes place within the pump? 21 A I don't think Akamatsu uses those words, but 22 an engineer reading this paper would understand that if 23 there's no elements of a control circuitry within the 24 pump, and there's a wire that leads away from the pump, 25 then the only way that that pump position -- the</p> <p style="text-align: right;">Page 100</p>
<p>1 steering wheel. It only changes the position of the 2 steering wheel in response to deviation from that lane. 3 The same as this one. The electromagnetics only change 4 the power in response to the position sensors telling 5 the controller that there's a deviation. 6 Q Right. But when the position sensors detect a 7 deviation, those electromagnets have to operate in real 8 time. Otherwise, the rotor is going to bounce into 9 things; isn't it? 10 A Well, I'm trying to understand what you mean 11 by "operate in real time." The whole system operates in 12 real time. 13 Q So what I'm trying to get to is, are you 14 saying that the signals from the position sensors are 15 sent out to an external controller, some kind of 16 comparison or processing happens there, and then a 17 signal is sent back to the electromagnets in order to 18 prevent the rotor from getting too far out of position? 19 A Well, that's what Akamatsu says in this -- in 20 this paper, yes. 21 Q But he doesn't say that; right? You infer it. 22 A Well -- 23 MR. BORDER: Objection. Form. 24 THE WITNESS: "The electric current of 25 the electromagnet is controlled by using three position</p> <p style="text-align: right;">Page 99</p>	<p>1 impeller position could be controlled is with an 2 external controller. 3 Q Well, the wire could be there to control the 4 speed of the pump; couldn't it? 5 A The wire probably has multiple functions. 6 It's not a single conductor. 7 Q Akamatsu uses the passive voice about 8 controlling the electromagnets; right? 9 A You -- you're -- you're asking an opinion on 10 the use of the language in the paper? 11 Q The electromagnet is controlled; correct? 12 A Yes. The electromagnet is controlled. 13 Q It doesn't say what's doing the controlling; 14 does it? 15 A I'm -- I'm really struggling to understand 16 your questioning. 17 Q Akamatsu doesn't say what is doing the 18 controlling of the electromagnets; does it? 19 A Akamatsu says the electric current is 20 controlled. Even though that's passive voice, I think 21 anyone would understand that, if it's controlled, it 22 must be controlled by something. So presumably, it's 23 controlled by our controller. The controller uses the 24 three position sensors to maintain the impeller free 25 floating. That's what the -- one of the functions of</p> <p style="text-align: right;">Page 101</p>

<p>1 the controller is, at least for the position. 2 Q But Akamatsu doesn't say that about the 3 external controller; does he? 4 A Akamatsu didn't say what? 5 Q That it is the external controller that 6 controls the electromagnets. 7 A I'm not sure Akamatsu has to say that, because 8 anyone reading this would understand there has to be 9 something controlling it. There has to be a controller. 10 It's not part of the pump. There's a cable going from 11 the pump with multiple conductors, and it -- it doesn't 12 show an illustration of how the -- this particular pump, 13 model two, is implanted or connected. 14 So a person reading this, a person of skill in 15 the art, would understand this model two device is 16 implanted in a sheep. There is an external controller 17 which controls the free floating impeller in response to 18 signals from position sensors. That's what Akamatsu 19 describes. It says on the next paragraph, "The model 20 one and the modified model two had dual electric wires 21 separately connected to the motor and the 22 electromagnets." The wires have to go somewhere. 23 Q Right. 24 A They go to a controller 25 Q Or they go to a power source.</p> <p style="text-align: right;">Page 102</p>	<p>1 Q Do people use rotary pumps to move shear 2 sensitive liquids in an industrial setting? 3 A I'm not an industrial engineer, and I don't 4 think I've provided opinions on areas outside left 5 ventricular assist device in my report. I'm aware of 6 some applications of pump, but I'm not an expert on 7 that. 8 Q The Schima never describes its pump as being 9 connected to a heart; does it? 10 A If I go back to my report where I describe 11 where I refer to -- to Schima, can I just refer to that 12 again, please? I think it's in the -- 13 Q Yeah. It starts at paragraph 628. 14 A How much? Say again. 15 Q Six-twenty-eight. 16 A Six-twenty-eight. Yes. But I think there's 17 an earlier section. Ah, summary of Schima on page 83. 18 So he -- he, in his description, talks about addressing 19 problems with existing heart assist pumps and presenting 20 his invention as a way of addressing those problems of 21 existing heart assist pumps. So clearly, this has to do 22 with heart assist pumps. 23 Q Okay. Schima never describes its pump as 24 being connected to a heart; does it? 25 A Well, Schima describes an inlet 13 and an</p> <p style="text-align: right;">Page 104</p>
<p>1 A I don't think it's either/or. You have to 2 provide power to the pump, which is a power source, but 3 you also have to control the pump. That might be in the 4 same external box, or they could be in separate boxes. 5 He doesn't describe that. But the wires lead from the 6 pump to something that provides power and controls the 7 function of the pump, including keeping the impeller 8 free floating in the space. 9 Q Let's turn to Schima. 10 A Turn to? 11 Q Schima. So it's Exhibit 1005. So in 12 paragraph one of Schima -- 13 A Paragraph 20? 14 Q Paragraph one. 15 A Oh, one. I beg your pardon. 16 Q So it says, "The present invention relates to 17 a rotary pump for moving blood and other shear sensitive 18 liquids with a rotor journaled hydraulically and if 19 necessary magnetically in a housing." Do you see that? 20 A I see that. 21 Q Do you know what "other sheer sensitive 22 liquids" could refer to? 23 A I don't recall the Schima gives a list of 24 other shear sensitive liquids. So I don't know what 25 he's referring to.</p> <p style="text-align: right;">Page 103</p>	<p>1 inlet opening 36 that distributes the incoming liquid to 2 both sides of the rotor. And since he's describing this 3 as being -- solving some problems of previous versions 4 of heart assist devices, a person of skill in the art 5 would take that to mean that, if this was used for 6 pumping blood, that inlet port would have to be 7 connected to the heart. It's a blood pump. You take 8 blood from the heart; you -- you pump it out. Where 9 else could it be? 10 Q Well, it could be anywhere; couldn't it? 11 A As a blood pump? 12 Q Sure. So I'm going to ask one more time. 13 Schima never describes its pump -- Schima never says it 14 that its pump is connected to a heart; does it? 15 A I -- I haven't memorized all of the -- all of 16 the text in Schima. He -- he talks about this as being 17 a blood pump that solves some of the problems of left 18 ventricular assist devices, previous heart pumps. So if 19 it's talking about solving problems of other left 20 ventricular assist devices, which are connected to the 21 heart, and he says this is a better version of that, 22 than it must be connected to the heart. 23 I don't think he uses those words that "this 24 is connected to the heart" in the sense that you would 25 seem to be implying, but anyone reading this in the</p> <p style="text-align: right;">Page 105</p>

<p>1 field would understand that this is connected to the 2 heart. 3 Q Schima never describes its pump as being 4 implantable; does it? 5 A I -- I think the similar sort of answer 6 replies. He -- he talks about problems with previous 7 versions of implantable pumps, and he talks about this 8 as being a way of solving some of those problems. So 9 it's an implantable blood pump. 10 Q But Schima doesn't say it. 11 A Schima doesn't say what color it is either or 12 what material does there. Lots of things Schima doesn't 13 say. 14 Q Okay. But Schima doesn't say that its pump is 15 implantable; does it? 16 A Shall I read the whole Schima or see if I can 17 find that word, or you -- or you -- 18 Q Well, this one really shouldn't be hard. 19 Could you look to paragraph 780 of your declaration, 20 please? 21 A Seven-eighty? 22 Q Seven-eighty. All right. So you say, "Schima 23 is silent regarding implanting its pump in the body." 24 A I agree. I also say, "However, it would have 25 been readily apparent to a person of skill in the art</p> <p style="text-align: right;">Page 106</p>	<p>1 A He does, yes. 2 Q It says, "The Akamatsu pump is of complex 3 construction"; correct? 4 A That is Schima's opinion. I'm sure Akamatsu 5 would probably disagree with him. 6 Q Now, outside of this paragraph four, Schima 7 doesn't address Akamatsu again; does it? 8 A Again, I haven't read the whole thing right 9 now. If you present to me that he doesn't, I'll believe 10 you. 11 Q Do you know how big the Schima pump is? 12 A I don't recall that Schima talks about the 13 size in -- of this pump. There are multiple 14 embodiments, so I don't know which embodiment you're 15 referring to either. 16 Q Do you know whether the Schima pump is bigger 17 or smaller than the Akamatsu pump? 18 A It's smaller than the Akamatsu pump? 19 Q It bigger or smaller than the Akamatsu? 20 A I don't know. But going back to your earlier 21 questions about size, I noticed in the Akamatsu 22 reference that he did talk about the size and weight of 23 it. I missed that before. So I don't think Akamatsu 24 talks about the size and weight of the pump, so I don't 25 know.</p> <p style="text-align: right;">Page 108</p>
<p>1 for the reasons below that Schima's pump would be 2 implanted in the same way as Akamatsu's device. 3 Schima's inlet of the pump would be inserted into a 4 ventricle of the heart to collect blood from the left 5 ventricle." 6 Q There are extracorporeal blood pumps; aren't 7 there? 8 A There are some, yes. 9 Q And they sit outside the body and pump the 10 patient's blood; right? 11 A That's the definition of extracorporeal, yes. 12 Q The pump illustrated in Schima, do you know if 13 anyone has ever built this pump? 14 A I don't know. 15 Q Do you know if anyone has ever implanted this 16 pump? 17 A Well, if I don't know if anyone has built it, 18 I don't know if anyone has implanted it. 19 Q Now, in paragraph four of Schima, Schima is 20 discussing the Akamatsu pump there; isn't it? 21 A I read that. 22 Q I'm sorry. I didn't -- I didn't hear. 23 A Yes, I did read it. I apologize. 24 Q Okay. And Schima provides some criticisms of 25 Akamatsu; doesn't he?</p> <p style="text-align: right;">Page 107</p>	<p>1 Q Does the Schima pump have a different shape 2 than the Akamatsu pump? 3 A Well, yes, in the sense that the Schima pump 4 has a conical impeller, whereas the Akamatsu pump has a 5 circular flat torus impeller. 6 Q Are you aware of any other -- strike that. 7 Are you aware of any implantable left ventricular assist 8 pumps that have a similar shape to Schima? 9 A Yes. 10 Q What are they? 11 A The VentrAssist device had a similar shape to 12 Schima. It had a conical impeller. It implanted in 13 several hundred people. 14 Q Do you know whether the pump disclosed in 15 Schima is bigger or smaller than VentrAssist? 16 A Well, since the Schima reference doesn't 17 disclose, to my recollection, the size of the pump, then 18 I can't know if it's bigger or smaller than the 19 VentrAssist. 20 Q Does Schima disclose an external controller? 21 A Does Schima disclose a what? 22 Q An external controller. 23 A Schima's disclosure is directed towards the 24 pump itself. It is -- it has electrical requirements. 25 So presumably, there has to be a cable of some sort</p> <p style="text-align: right;">Page 109</p>

<p>1 leading away from the pump to a controller which 2 controls those electrical signals. But that's not the 3 focus of the Schima invention. A person of skill in the 4 art reading this would understand that if it uses 5 electromagnets to control the pump, then you have to 6 somehow have an electrical connection to a controller 7 that controls those electromagnets. 8 Q Schima doesn't say the control is external; 9 does it? 10 A External to what? 11 Q An external controller. 12 A The controller by definition is external to 13 the pump, 'cause it's not shown as being incorporated in 14 the pump. 15 Q Is that the definition of external controller 16 that you've used in forming your positions? 17 MR. BORDER: Object to form. 18 THE WITNESS: Where are you referring to 19 in my report where I used that? 20 BY MR. CAHILL: 21 Q I am not. You just said that anything outside 22 the pump is external, and I'm asking you, is that the 23 definition? That definition of external, is that what 24 you applied to the claim term external control unit in 25 forming your opinions?</p> <p style="text-align: right;">Page 110</p>	<p>1 with a controller, which is external to the pump but 2 internal to the body. 3 MR. CAHILL: No further questions. 4 MR. BORDER: All right. Why don't we 5 take a ten-minute break? 6 MR. CAHILL: Yep. 7 MR. BORDER: See if we have redirect. 8 THE OFFICER: It is 1:35 p.m. We are now 9 off the record. 10 (Off the record.) 11 THE OFFICER: We are now back on the 12 record. It is 1:44 p.m. 13 MR. BORDER: Petitioners have no 14 questions. 15 THE OFFICER: We can go off the record? 16 Okay. Mr. Border, would you like to purchase a copy of 17 the transcript? 18 MR. BORDER: Oh, I didn't -- what did we 19 decide? I wasn't paying attention. 20 MR. BOYLE: Yes. 21 THE OFFICER: Yes. Okay. 22 MR. BOYLE: Whatever the -- 23 MR. BORDER: Yes. Standard delivery. 24 We'll take a rough. No rush on the rough. We don't 25 need paper copies of anything.</p> <p style="text-align: right;">Page 112</p>
<p>1 MR. BORDER: Object to form. 2 THE WITNESS: I was responding to your 3 question, which I thought was difficult to respond to 4 with precision, because it didn't define the term 5 "external." So you asked if the Schima disclosed an 6 external controller. I asked you what external means, 7 and then I said, "Well, the controller is external to 8 the pump." 9 BY MR. CAHILL: 10 Q And my question for you is, is that the 11 definition you used in your report when you formed your 12 opinions? 13 A Where -- where in my report are you referring 14 to where I use the term "external controller"? Then 15 I'll answer that question. 16 Q It's a claim term. So just as one example, 17 page 789 or -- yeah, paragraph 789. 18 A Seven-eighty-nine? 19 Q Yeah. 20 A Well, in the context of Akamatsu, which is 21 referred to in paragraph 789, the external controller 22 is -- is something which is external to the body. In -- 23 in Schima, the controller is external to the pump and 24 probably external to the body as well. 'Cause it 25 doesn't disclose how it would be controlled with a --</p> <p style="text-align: right;">Page 111</p>	<p>1 THE OFFICER: Okay. And, Mr. Cahill, 2 would you like to purchase a copy of the transcript? 3 MR. CAHILL: Yes, please. 4 THE OFFICER: Okay. All right. It is 5 1:44 p.m. We are now off the record. 6 (Signature reserved.) 7 (Whereupon, at 1:44 p.m., the 8 proceeding was concluded.) 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p style="text-align: right;">Page 113</p>

<p>1 CERTIFICATE OF DEPOSITION OFFICER</p> <p>2 I, RUBY MORENO, the officer before whom the</p> <p>3 foregoing proceedings were taken, do hereby certify that</p> <p>4 any witness(es) in the foregoing proceedings, prior to</p> <p>5 testifying, were duly sworn; that the proceedings were</p> <p>6 recorded by me and thereafter reduced to typewriting by</p> <p>7 a qualified transcriptionist; that said digital audio</p> <p>8 recording of said proceedings are a true and accurate</p> <p>9 record to the best of my knowledge, skills, and ability;</p> <p>10 that I am neither counsel for, related to, nor employed</p> <p>11 by any of the parties to the action in which this was</p> <p>12 taken; and, further, that I am not a relative or</p> <p>13 employee of any counsel or attorney employed by the</p> <p>14  ally or otherwise interested</p> <p>15 on.</p> <p>16</p> <p>17 RUBY MORENO</p> <p>18 Notary Public in and for the</p> <p>19 State of California</p> <p>20</p> <p>21 ☒ Review of the transcript was requested.</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p style="text-align: right;">Page 114</p>	<p>1 SCOTT BORDER, ESQ.</p> <p>2 sborder@winston.com</p> <p>3</p> <p>4 September 17, 2025</p> <p>5 RE: Abbott Laboratories v. Miracor Medical SA</p> <p>6 9/4/2025, Peter Crosby, (#7565630).</p> <p>7 The above-referenced transcript has been</p> <p>8 completed by Veritext Legal Solutions and</p> <p>9 review of the transcript is being handled as follows:</p> <p>10 ☐ Per CA State Code (CCP 2025.520 (a)-(e)) – Contact Veritext</p> <p>11 to schedule a time to review the original transcript at</p> <p>12 a Veritext office.</p> <p>13 ☒ Per CA State Code (CCP 2025.520 (a)-(e)) – Locked .PDF</p> <p>14 Transcript - The witness should review the transcript and</p> <p>15 make any necessary corrections on the errata pages included</p> <p>16 below, notating the page and line number of the corrections.</p> <p>17 The witness should then sign and date the errata and penalty</p> <p>18 of perjury pages and return the completed pages to all</p> <p>19 appearing counsel within the period of time determined at</p> <p>20 the deposition or provided by the Code of Civil Procedure.</p> <p>21 ☐ Contact Veritext when the sealed original is required.</p> <p>22 ☐ Waiving the CA Code of Civil Procedure per Stipulation of</p> <p>23 Counsel - Original transcript to be released for signature</p> <p>24 as determined at the deposition.</p> <p>25 ☐ Signature Waived – Reading & Signature was waived at the</p> <p>time of the deposition.</p> <p style="text-align: right;">Page 116</p>
<p>1 CERTIFICATE OF TRANSCRIBER</p> <p>2 I, RACHEL ROBERTS, do hereby certify that this</p> <p>3 transcript was prepared from the digital audio recording</p> <p>4 of the foregoing proceeding, that said transcript is a</p> <p>5 true and accurate record of the proceedings to the best</p> <p>6 of my knowledge, skills, and ability; that I am neither</p> <p>7 counsel for, related to, nor employed by any of the</p> <p>8 parties to the action in which this was taken; and,</p> <p>9 further, that I am not a relative or employee of any</p> <p>10 counsel or attorney employed by the parties hereto, nor</p> <p>11 financially or otherwise interested in the outcome of</p> <p>12 this action.</p> <p>13</p> <p>14 </p> <p>15 RACHEL ROBERTS</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p style="text-align: right;">Page 115</p>	<p>1 ☐ Federal R&S Requested (FRCP 30(e)(1)(B)) – Locked .PDF</p> <p>2 Transcript - The witness should review the transcript and</p> <p>3 make any necessary corrections on the errata pages included</p> <p>4 below, notating the page and line number of the corrections.</p> <p>5 The witness should then sign and date the errata and penalty</p> <p>6 of perjury pages and return the completed pages to all</p> <p>7 appearing counsel within the period of time determined at</p> <p>8 the deposition or provided by the Federal Rules.</p> <p>9 ☐ Federal R&S Not Requested - Reading & Signature was not</p> <p>10 requested before the completion of the deposition.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p style="text-align: right;">Page 117</p>