

Page 1

1 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
 2 *****
 3 In the Inter Partes Review of:
 4 U.S. Patent No. 6,482,228,
 5 Filed: November 14, 2000
 6 Issued: November 19, 2002
 7 Inventor(s): Troy R. Norred
 8 Assignee: None
 9 Title: Percutaneous Aortic Valve Replacement
 10
 11 Trial Numbers: IPR2014-00110
 12 IPR2014-00111
 13 Attorney Docket No.: 058888/0000014
 14 058888/0000018
 15 *****
 16 DEPOSITION OF
 17 ALEXANDER J. HILL
 18
 19 DATE: Friday, December 5, 2014
 20 TIME: 9:30 a.m.
 21 PLACE: ROBINS, KAPLAN, MILLER & CIRESI, L.L.P.
 22 2800 LaSalle Plaza
 23 800 LaSalle Avenue
 24 Minneapolis, Minnesota 55402
 25 REPORTED BY: Lori Morrow, RMR, CRR, CLR, CCP

Page 3

1 APPEARANCES (CONTINUED):
 2 Also on Behalf of Troy R. Norred, M.D.:
 3 James J. Kernell, Esquire
 4 ERICKSON, KERNELL, DERUSSEAU & KLEYPAS, LLC
 5 8900 State Line Road
 6 Suite 500
 7 Leawood, Kansas 66206
 8 (913) 549-4700
 9 Fax (913) 549-4646
 10 jkernell@kcpatentlaw.com
 11
 12 ALSO PRESENT: Sean Edman, Medtronic
 13 Chad A. Hanson, Medtronic
 14 *****
 15 NOTE: The original transcript will be
 16 delivered to David Marcus, Esquire.
 17
 18
 19
 20
 21
 22
 23
 24
 25

Page 2

1 APPEARANCES:
 2 On Behalf of Medtronic, Inc.:
 3 Jack S. Barufka, Esquire
 4 PILLSBURY WINTHROP SHAW PITTMAN, LLP
 5 1650 Tysons Boulevard, 14th Floor
 6 McLean, Virginia 22102-4856
 7 (703) 770-7900
 8 Fax (703) 770-7901
 9 jack.barufka@pillsburylaw.com
 10
 11 On Behalf of Troy R. Norred, M.D.:
 12 David Marcus, Esquire
 13 BARTLE & MARCUS, LLC
 14 1100 Main Street
 15 Suite 2730
 16 Kansas City, Missouri 64105
 17 (816) 285-5888
 18 Fax (816) 222-0534
 19 dmarcus@bmlawkc.com
 20 -and-
 21
 22 (Appearances continued on the next page.)
 23
 24
 25

Page 4

1 INDEX
 2 WITNESS:
 3 Alexander J. Hill
 4
 5 EXAMINATION BY: PAGE:
 6 Mr. Marcus.....8
 7
 8 OBJECTIONS BY:
 9 Mr. Barufka.....10, 11, 12, 13, 14, 15, 16, 17,
 10 18, 19-20, 40, 46, 47, 48, 49, 51, 52, 53, 54, 55, 58, 59,
 11 60, 61, 62, 65, 66, 67, 70, 72, 73, 74, 75, 76, 77, 78, 79,
 12 80, 81, 82, 83, 84, 87, 88, 91, 96, 97, 101, 103, 104, 114,
 13 115, 116, 117, 118, 119, 120, 121, 123, 124, 125, 126, 127,
 14 128, 135, 137, 138, 139, 140, 141, 144, 145, 146, 147, 149,
 15 150, 151, 154, 155, 156, 158, 159, 161, 162, 163, 164, 166,
 16 167, 168, 169, 170, 171, 172, 174, 175, 176, 177, 178, 179,
 17 180, 182, 185, 186, 187, 188, 189, 190, 191, 192, 193, 197
 18
 19 INSTRUCTIONS NOT TO ANSWER BY:
 20 Mr. Barufka.....12, 13, 14, 15, 16, 17, 19-20,
 21 82, 83, 84, 91, 102, 103, 104, 118, 177
 22
 23 REQUESTS FOR PRODUCTION: (NONE)
 24
 25

Page 5			Page 7		
1	EXHIBITS: DESCRIPTION:	PAGE:	1	EXHIBITS (CONTINUED):	
2	Exhibit 2224 Article "Anatomy of the aortic		2	Exhibit 2141 Diagram	196
3	root: Implications for valve-sparing		3	Exhibit 2198 U.S. Patent No. 6,440,164,	
4	surgery" by Charitos and Sievers	41	4	DiMatteo	182
5	Exhibit 2225 Excerpt from book Heart Valves		5	Exhibit 2199 U.S. Patent No. 5,957,949,	
6	From Design to Clinical Implantation	45	6	Leonhardt	192
7	Exhibit 2226 Excerpts from book The Aortic		7	Exhibit 2213 U.S. Patent No. 4,030,142,	
8	Valve by Mano Thubrikar	65	8	Wolfe	131-139
9	Exhibit 2227 Medtronic Press Release		9	*****	
10	"Medtronic CoreValve® System Obtains Early		10	(REPORTER'S NOTE: Original exhibits are attached	
11	FDA Approval on Exceptional Clinical		11	to the original transcript.)	
12	Performance"	75	12		
13	Exhibit 2228 CoreValve US Important Safety		13		
14	Information	81	14		
15	Exhibit 2229 U.S. Patent No. 8,323,336 of		15		
16	Hill, Prosthetic Heart Valve Devices and		16		
17	Methods of Valve Replacement	96	17		
18	Exhibit 2230 Colored photocopy of photo		18		
19	labeled "Aortic Valve"	122	19		
20	Exhibit 2231 Colored photocopy of photo		20		
21	labeled "Aortic Valve" with cusps and		21		
22	annulus also labeled	123	22		
23	Exhibit 2232 Printout from University of		23		
24	Minnesota website of mitral and aortic		24		
25	valves	125	25		
Page 6			Page 8		
1	EXHIBITS (CONTINUED):		1	ALEXANDER JOHN HILL,	
2	Exhibit 2233 Printout from University of		2	duly sworn, was examined and testified as follows:	
3	Minnesota website of Chordae Tendineae	127	3	EXAMINATION	
4	Exhibit 2234 2014 ESC Guidelines on the		4	BY MR. MARCUS:	
5	diagnosis and treatment of aortic diseases	166	5	Q What's your name?	
6	Exhibit 2235 U.S. Patent No. 7,914,569, of		6	A Alexander John Hill.	
7	Nguyen, Heart Valve Prosthesis and Methods		7	Q What's your address?	
8	of Manufacture and Use	181	8	A Work address or home address?	
9			9	Q Let's do home address first.	
10	PREVIOUSLY MARKED EXHIBITS REFERRED TO HEREIN:		10	A 4430 - 118th Avenue Northeast in Blaine,	
11	Exhibit 1001 U.S. Patent No. 6,482,228 Norred	98-122	11	Minnesota.	
12	Exhibit 1009 U.S. Patent No. 6,454,799,		12	Q And your work address?	
13	Schreck	148-157, 171	13	A 8200 Coral Sea Street Northeast in Mounds View,	
14	Exhibit 1018 Declaration of Thomas		14	Minnesota.	
15	Vassiliades, Jr., M.D.	71	15	Q And you're presently employed?	
16	Exhibit 1026 Declaration of Alexander J.		16	A Yes.	
17	Hill, Ph.D.	11, 43, 82	17	Q By whom are you employed?	
18	Exhibit 2003 Hand drawn diagram of ascending		18	A Medtronic.	
19	and descending aorta	95	19	Q Is that Medtronic, Inc.?	
20	Exhibit 2129 Diagram of Schreck device	177	20	A Medtronic, Incorporated, yes.	
21	Exhibit 2130 Diagram of Schreck device	178	21	Q What's your position at Medtronic currently?	
22	Exhibit 2131 Diagram of Schreck device	180	22	A I'm a senior research manager.	
23	Exhibit 2133 Diagram	188	23	Q And is that in any particular department?	
24	Exhibit 2139 Diagram	195	24	A Yes. It's in Coronary and Structural Heart.	
25	Exhibit 2140 Diagram	196	25	Q And does that -- in Coronary and Structural	

Page 9	Page 11
<p>1 Heart, is that within any department, or is that a 2 stand-alone? 3 A It's within the Cardiac and Vascular Group. 4 It's a business unit within that group. 5 Q Okay. To whom do you report? 6 A Cindy Clague, C-1-a-g-u-e. 7 Q What is her title? 8 A Director Research. 9 Q And she is within your group? 10 A She's in the same business unit. 11 Q Okay. Do you report to anyone else? 12 A That's my direct line. I have other 13 dotted-line relationships with other people, but she's my 14 direct supervisor. 15 Q Okay. And who do you have dotted-line 16 relationships with? 17 A Senior director of Research and Innovation, 18 Matt Birdsall, and VP of Research and Innovation, 19 Mike Colson. 20 Q And do you have people who report to you? 21 A I do. 22 Q And who are they? 23 A Jason Quill, Ph.D., Brian McHenry, M.S., and 24 Mike Bateman, Ph.D. 25 Q Can you outline for us just in general terms</p>	<p>1 MR. BARUFKA: Objection, outside the scope of 2 direct, and it's privileged -- potentially 3 privileged information, so confidential, privileged 4 information. 5 Q You can answer. 6 A My current work does not directly involve 7 CoreValve. 8 Q Have you ever done any work in connection with 9 that product? 10 A I have. 11 Q Can you give me the years that you did work in 12 connection with that product? 13 A Let's see. 2009 to 2013, '12 and-a-half, '13, 14 around there. 15 Q And we'll go over your employment history in a 16 minute, and we can address that in more detail. Before 17 we do that, let me hand you a document marked 18 Exhibit 1026. You've seen this document prior to today? 19 A Yes. 20 Q This is a declaration that you prepared for 21 this matter? 22 A Yes. 23 Q And if you look at the back page of this, 24 page 22, there is your signature there on the line at the 25 bottom?</p>
<p>1 your current duties and responsibilities? 2 A Without going into too much confidential 3 information, I am the core team leader of a transcatheter 4 valve project, and I'm also the functional manager for a 5 small subset of research and technology which focuses on 6 anatomy and device characterization. 7 Q What sorts of things just generally do you do 8 in that position? 9 MR. BARUFKA: Objection, ambiguous. 10 Q Go ahead. 11 A So in the first role, the core team leader, I 12 lead the team, so I provide direction for the overall 13 team across all functions in the development of that 14 product. In the other role, I provide work direction and 15 career coaching and help develop employees essentially. 16 Q Do you currently have any role -- hands-on role 17 in research and development of the device? 18 A Yes. 19 Q And what's your role in connection with that? 20 A So I'm -- in terms of the research and 21 development specifically, I participate in brainstorming 22 sessions, participate in experiments to study the device 23 both on the bench and in other models. 24 Q Does your current work involve in any respect 25 the CoreValve product?</p>	<p>1 A Yes. 2 Q You were asked to prepare this by your 3 employer, Medtronic, Inc.? 4 A Yes. 5 Q Describe the manner in which you went about 6 preparing this document. 7 MR. BARUFKA: Objection, privileged. Instruct 8 the witness not to answer. 9 Q Okay. Did you draft this Exhibit 1026? 10 MR. BARUFKA: Objection, privileged. Instruct 11 the witness not to answer. 12 Q Did you -- are you going to follow your 13 attorney's instruction? 14 A Yes. 15 Q You say here on the last page -- look at the 16 "Conclusion" heading. It says, paragraph 72, "I hereby 17 declare that all statements made herein of my own 18 knowledge are true." Do you see that? 19 A Uh-huh. 20 Q That's a yes? 21 A I see it. 22 Q So I want to get a sense of what parts of this 23 are your knowledge. Let's look at the first -- well, 24 let's look at paragraph 3. Do you see paragraph 3? 25 A Yes, I do.</p>

Page 13

1 Q It says, "In forming my opinions, I understand
2 that the claims should be interpreted as they would be
3 understood by a person of ordinary skill in the art of
4 the subject matter of the patents." Did I read that
5 sentence correctly?
6 A Yes, you did.
7 Q Was that a sentence that you came up with?
8 MR. BARUFKA: Objection, privileged. Instruct
9 the witness not to answer.
10 Q And you won't answer that question?
11 A No.
12 Q The second sentence says, "I also understand
13 that claims are ordinarily construed based on the plain
14 meaning of the terms used in the claims, and also with
15 respect to the specification, the patent drawings, and
16 the prosecution history." Did I read that correctly?
17 A Yes.
18 Q Is that language that you came up with?
19 MR. BARUFKA: Objection, privilege. Instruct
20 the witness not to answer.
21 Q And you're going to follow your attorney's
22 instruction?
23 A Yes.
24 Q Is that information you knew prior to preparing
25 this Exhibit 1026?

Page 14

1 MR. BARUFKA: Objection -- I'm just going to
2 have a standing objection if that's okay.
3 Q The second -- well, and you're not going to
4 answer that question either?
5 A No, I'm not.
6 Q The next sentence says, "In addition, I
7 understand that although the specification should be
8 consulted to aid in the process of interpreting the
9 claims, the specific examples disclosed in the
10 specification generally do not limit the scope of the
11 claims." Did I read that correctly?
12 A Yes.
13 Q Is that language that you came up with?
14 MR. BARUFKA: David, are we going to -- can we
15 agree that we just have a standing objection here?
16 What do you want me to do? That's fine.
17 MR. MARCUS: No. That's fair. I think you
18 need to object just because I think you need to
19 make -- we'll need to make a record on this.
20 MR. BARUFKA: Okay. That's fine.
21 MR. MARCUS: I don't want to ask him something
22 you would have let him answer --
23 MR. BARUFKA: That's fine.
24 MR. MARCUS: -- and then assume he wouldn't
25 answer it, so.

Page 15

1 MR. BARUFKA: That's fine.
2 MR. MARCUS: With respect to that question, I
3 understand you're instructing him not to answer?
4 MR. BARUFKA: That's correct.
5 Q And you won't answer that?
6 A Correct.
7 Q Can you tell me what that sentence means where
8 you say, "In addition, I understand that although the
9 specification should be consulted to aid the process of
10 interpreting the claims, the specific examples disclosed
11 in the specification generally do not limit the scope of
12 the claims." What does that mean?
13 MR. BARUFKA: Just objection, privileged.
14 Instruct the witness not to answer.
15 Q You won't answer what that means?
16 A No.
17 Q Are these your words or your attorney's words?
18 MR. BARUFKA: Objection, privileged. Instruct
19 the witness not to answer.
20 Q You say here, "Finally, I also understand that
21 claim interpretation may be aided by reference to other
22 sources of information, such as dictionaries, textbooks,
23 and literature or other patents in related fields, in
24 order to determine the ordinary meanings of terms used in
25 the claims." Did I read that correctly?

Page 16

1 A Yes, you did.
2 Q Was that language that you came up with or that
3 your attorney came up with?
4 MR. BARUFKA: Objection, privileged. Instruct
5 the witness not to answer.
6 Q Tell me what you meant by that particular
7 sentence.
8 MR. BARUFKA: Objection, privileged. Instruct
9 the witness not to answer.
10 Q And you won't answer that?
11 A I'm not going to answer.
12 Q With respect to any of the content contained in
13 Exhibit 1026, are you willing to tell me whether this
14 content came from you or from your lawyer?
15 MR. BARUFKA: Objection, privileged. Instruct
16 the witness not to answer.
17 Q You say here, focusing still on paragraph 3, "I
18 further understand that for purposes of this inter partes
19 review, the claims should be given their broadest
20 reasonable interpretation when viewed in light of the
21 specification." Do you see that language?
22 A Uh-huh.
23 Q That's a yes?
24 A Yes.
25 Q Okay. What does that mean?

Page 17	Page 19
<p>1 MR. BARUFKA: Objection, privileged. Instruct</p> <p>2 the witness not to answer.</p> <p>3 Q And you won't answer that question?</p> <p>4 A No.</p> <p>5 Q You say here, "In addition, I understand that</p> <p>6 claims expressed as a 'means' for performing a recited</p> <p>7 function should be interpreted as covering the</p> <p>8 corresponding structure material or acts disclosed in the</p> <p>9 specification or equivalents thereof." Did I read that</p> <p>10 correctly?</p> <p>11 A Yes.</p> <p>12 Q What does that mean to you?</p> <p>13 MR. BARUFKA: Objection, privileged. Instruct</p> <p>14 the witness not to answer.</p> <p>15 Q And you won't answer that question?</p> <p>16 A Correct.</p> <p>17 Q With respect to the interpretation standards</p> <p>18 set forth in paragraph 3, did you apply those standards</p> <p>19 as you interpreted the claims set forth in the '228</p> <p>20 patent?</p> <p>21 MR. BARUFKA: You can answer that.</p> <p>22 A Yes.</p> <p>23 Q Okay. Describe then where it says, for</p> <p>24 example, "the specific" -- I'm focusing on paragraph 3</p> <p>25 again. It says, "the specific examples disclosed in the</p>	<p>1 guided by the principles set forth in paragraph 3?</p> <p>2 A Well, I was to look at the claims and interpret</p> <p>3 them as broadly as possible by one of ordinary skill in</p> <p>4 the art.</p> <p>5 Q You also say in here in paragraph 3 that you</p> <p>6 may be aided by "dictionaries, textbooks, and literature</p> <p>7 or other patents in related fields." That's correct?</p> <p>8 A Uh-huh.</p> <p>9 Q That language appears here?</p> <p>10 A Yeah, it's there. Uh-huh.</p> <p>11 Q Can you tell us what, if any, dictionaries,</p> <p>12 textbooks, or literature or other patents you considered</p> <p>13 as you interpreted the claims set forth in the '228</p> <p>14 patent?</p> <p>15 A Yeah. So there's some prior art that's</p> <p>16 disclosed elsewhere in my declaration that I reviewed, as</p> <p>17 well as other anatomy textbooks and publications as of</p> <p>18 the time of the publication of this patent, so Circa 2000</p> <p>19 and before.</p> <p>20 Q We talked about the CoreValve product a bit</p> <p>21 ago. You recall that testimony?</p> <p>22 A Yeah.</p> <p>23 Q There are patents covering that product, are</p> <p>24 there not?</p> <p>25 MR. BARUFKA: Objection. This is privileged</p>
Page 18	Page 20
<p>1 specification generally do not limit the scope of the</p> <p>2 claims." Describe how you applied that particular</p> <p>3 concept in interpreting the claims set forth in the '228</p> <p>4 patent.</p> <p>5 MR. BARUFKA: Objection as to form. It's</p> <p>6 ambiguous. If you want to ask a specific</p> <p>7 question --</p> <p>8 Q Yeah. Let me be straightforward with you. I</p> <p>9 want to understand what you understand by this language</p> <p>10 so I can get a feel for how you interpret these claims.</p> <p>11 Now, you say in this declaration paragraph number 3 that</p> <p>12 "the specific examples disclosed in the specification do</p> <p>13 not limit the scope of the claims." Do you see that</p> <p>14 there?</p> <p>15 A Uh-huh.</p> <p>16 Q That's a yes?</p> <p>17 A I do see that.</p> <p>18 Q And again, you won't -- can you -- you won't</p> <p>19 tell me if this is your language or your lawyer's</p> <p>20 language?</p> <p>21 MR. BARUFKA: That's -- objection.</p> <p>22 Q Okay. What I want to know is what you</p> <p>23 understood that to mean. In other words, when you went</p> <p>24 about interpreting the claims in the '228 patent, what</p> <p>25 did you have in your head you were supposed to do as</p>	<p>1 information. Instruct the witness not to answer.</p> <p>2 MR. MARCUS: Well, how is it -- patents are</p> <p>3 public, so you can acknowledge --</p> <p>4 MR. BARUFKA: He has no --</p> <p>5 MR. MARCUS: -- whether or not --</p> <p>6 MR. BARUFKA: He has no basis or foundation</p> <p>7 for --</p> <p>8 MR. KERNEL: That's not a proper objection.</p> <p>9 There's no proper objections --</p> <p>10 Q Let me try -- do you know whether there are</p> <p>11 patents covering the CoreValve product?</p> <p>12 A I don't know for sure if there are patents</p> <p>13 covering the CoreValve product.</p> <p>14 Q So then let me -- I'll ask this question, but I</p> <p>15 think I know the answer to it. Did you consider any of</p> <p>16 the patents covering the CoreValve product as you went</p> <p>17 about interpreting the '228 patent?</p> <p>18 A No, I did not.</p> <p>19 Q Okay. You yourself have been issued a couple</p> <p>20 of patents, have you not?</p> <p>21 A I have.</p> <p>22 Q Did you consider those patents as you went</p> <p>23 about interpreting the '228 patent?</p> <p>24 A I did not.</p> <p>25 Q Did you look at -- actually look at any</p>

Page 21	Page 23
<p>1 dictionaries in interpreting the language in the '228</p> <p>2 patent?</p> <p>3 A No, I did not.</p> <p>4 Q Let's go down to the section of your</p> <p>5 declaration that talks about work experience. Again,</p> <p>6 you're currently employed by Medtronic?</p> <p>7 A Yes.</p> <p>8 Q Receive a salary by Medtronic?</p> <p>9 A I do.</p> <p>10 Q And you're being -- you're receiving a salary</p> <p>11 as you sit here today?</p> <p>12 A Yes.</p> <p>13 Q Paragraph 11, it says, "In my current role at</p> <p>14 Medtronic, Inc., as a Senior Research Manager in the</p> <p>15 Cardiac and Vascular Group, Coronary and Structural</p> <p>16 Heart, I manage a group that conducts research focused on</p> <p>17 percutaneous, minimally invasive, and surgical heart</p> <p>18 valve replacement and repair including anatomical</p> <p>19 characterization, device research and design, image</p> <p>20 guided therapy development, and animal model development</p> <p>21 for testing of novel products." I read that correctly?</p> <p>22 A Yes, you did.</p> <p>23 Q Okay. "I also lead technical projects in</p> <p>24 Structural Heart product development." I read that</p> <p>25 correctly as well?</p>	<p>1 patient suffering from aortic stenosis?</p> <p>2 A I have not.</p> <p>3 Q Have you ever been involved in the treatment of</p> <p>4 a patient suffering from aortic stenosis?</p> <p>5 A I have not.</p> <p>6 Q Have you ever been involved in the treatment of</p> <p>7 any patient suffering any disease of the heart?</p> <p>8 A No.</p> <p>9 Q I think I asked this, but let me make sure.</p> <p>10 Have you ever worked with any doctors who have treated</p> <p>11 or -- strike that.</p> <p>12 Let me ask it this way. Have you ever assisted</p> <p>13 any doctors in treating patients suffering from diseases</p> <p>14 of the heart?</p> <p>15 A I have not.</p> <p>16 Q You agree -- I think we covered this, and I</p> <p>17 apologize if this is duplicative. But when we were</p> <p>18 talking about the standard for interpreting these claims,</p> <p>19 the claims of the '228 patent, you would agree that it is</p> <p>20 appropriate to look at other patents in this field and</p> <p>21 related fields?</p> <p>22 A Agree.</p> <p>23 Q It is appropriate to look at literature,</p> <p>24 textbooks, and dictionaries that may bear upon the</p> <p>25 interpretation of those claims?</p>
Page 22	Page 24
<p>1 A Yes.</p> <p>2 Q Can you tell us what products you're currently</p> <p>3 involved with?</p> <p>4 A It's a transcatheter heart valve.</p> <p>5 Q Does that have a particular name?</p> <p>6 A It does not. It's in the research stage.</p> <p>7 Q It says, "Over the past eight years, I have</p> <p>8 personally designed and tested numerous percutaneous</p> <p>9 heart valves, and have implanted heart valves into both</p> <p>10 live and isolated hearts." I read that correctly?</p> <p>11 A Yes.</p> <p>12 Q Now, you do not have a medical degree. Is that</p> <p>13 right?</p> <p>14 A I do not.</p> <p>15 Q And you have not -- and maybe you have. Let me</p> <p>16 ask it this way. Have you ever implanted an artificial</p> <p>17 valve in a live human patient?</p> <p>18 A I have not.</p> <p>19 Q Have you ever implanted a stent in a live human</p> <p>20 patient?</p> <p>21 A I have not.</p> <p>22 Q Have you ever rendered care to a live human</p> <p>23 patient suffering from any cardiac disease?</p> <p>24 A I have not.</p> <p>25 Q Have you ever provided care to a live human</p>	<p>1 A I agree.</p> <p>2 Q You said -- a moment ago you made reference to</p> <p>3 the broadest reasonable interpretation standard. Do you</p> <p>4 recall that?</p> <p>5 A I do.</p> <p>6 Q Okay. And what does that mean to you exactly</p> <p>7 to apply the broadest reasonable interpretation to the</p> <p>8 claims in the patent?</p> <p>9 A It means to look at the claims unless the means</p> <p>10 for language is used irrespective of the specifications</p> <p>11 and other language within the patent.</p> <p>12 Q Okay. When you say unless the means for</p> <p>13 language is used, what do you mean?</p> <p>14 A If the means for a language is used, then, as I</p> <p>15 understand it, by law you're supposed to be directed to</p> <p>16 the specifications in the patent and drawings.</p> <p>17 Q And then when you go to the specifications in</p> <p>18 the patent, you look at the corresponding structural</p> <p>19 material or acts disclosed in the specification?</p> <p>20 A Yes, as I understand it.</p> <p>21 Q Yeah. As well as equivalents of those,</p> <p>22 correct? You look at equivalents, too?</p> <p>23 A As equivalents, what do you mean by</p> <p>24 equivalents?</p> <p>25 Q Well, you look at both the corresponding</p>

Page 25	Page 27
<p>1 structure material or acts disclosed in the specification 2 and equivalents of those materials or acts, correct? 3 A Equivalents not disclosed in the patent? 4 Equivalents disclosed in another patent? 5 Q Yeah. I'm sorry. I'm reading from your 6 declaration. If you could look at paragraph 3 again -- 7 A Yeah. 8 Q -- the last sentence, it says, "In addition, I 9 understand that claims expressed as a 'means' for 10 performing a recited function should be interpreted as 11 covering the corresponding structure material or acts 12 disclosed in the specification." We talked about that 13 earlier, correct? 14 A Uh-huh. 15 Q And then you say "and equivalents thereof." 16 A Uh-huh. 17 Q That's a yes? 18 A That's what the declaration says. 19 Q Okay. Well, tell me what you meant by that, 20 what you meant by looking at equivalents thereof. 21 A Well, as you're interpreting the claims, 22 looking at -- let's see. What's the best way to phrase 23 this? A particular structure or material is disclosed, 24 and there's an equivalent structure that could perform 25 the same function. That's what I would interpret an</p>	<p>1 Q 1998. Okay. So for what period of time were 2 you in the Ph.D. program at the University of Minnesota? 3 A 1998 to 2004. 4 Q During the course of that program, it says you 5 received a -- is it a master's in biomedical engineering? 6 A Yes. 7 Q And that was in 2000? 8 A Yes. 9 Q And that was -- was that part of the program? 10 In other words, in the Ph.D. program, an intermediate 11 step is you received a master's degree? 12 A Yes. 13 Q Okay. And you received a minor in mechanical 14 engineering also in 2000? 15 A As part of that master's degree, yes. 16 Q Okay. And then you got your Ph.D. You alluded 17 to this earlier. But your Ph.D. was awarded to you in 18 2004 from the University of Minnesota, correct? 19 A Yes. 20 Q And you received also a minor in cellular and 21 integrative physiology? 22 A Yes. 23 Q Now, during that time period, that would be 24 '99 -- excuse me -- '98 through 2004, you also were 25 employed someplace?</p>
<p>1 equivalent as. 2 Q I would like to turn to your background, if I 3 could. It's set forth in your declaration but in a 4 reverse chronological order, and I would like to walk 5 through it chronologically if we could. You received a 6 bachelor's in biology in 1997? 7 A That is correct, yes. 8 Q And that was from Gustavus Adolphus College in 9 St. Peter, Minnesota? 10 A That is correct. 11 Q And after you got your bachelor's degree, did 12 you immediately enter the master's program, or what did 13 you do? 14 A No. I took a year off while applying to 15 graduate school. 16 Q Okay. Did you work in the medical industry 17 during that year? 18 A I did not. I volunteered in a hospital. 19 Q Okay. Then you entered a master's program? 20 A I entered a Ph.D. program at that point. 21 Q Okay. The Ph.D. program you entered, was that 22 the University of Minnesota? 23 A Yes. 24 Q And you entered it in 1999? 25 A 1998.</p>	<p>1 A Yes. 2 Q Where were you employed? 3 A So I was employed through the University as a 4 graduate assistant and a tech teaching assistant. 5 Q And what time period were you employed as a 6 teaching assistant through the University? 7 A That would have been 1999 through two 8 thousand -- September of 2003. 9 Q Okay. And you were a graduate teaching 10 assistant you said? 11 A Yes, and a graduate research assistant. It's 12 part of the program. 13 Q And what areas did you teach in or assist in 14 during that time period? 15 A So the research assistant was in the Visible 16 Heart Laboratory, which is the primary laboratory that I 17 worked in. And the teaching was in human physiology, an 18 undergraduate class, and then later into advanced cardiac 19 anatomy and physiology. 20 Q At some point during that time period, did you 21 begin work with Medtronic, or was that after you got your 22 Ph.D.? 23 A I did begin to work with Medtronic during that 24 time period. 25 Q Do you remember what year you began to work</p>

Page 29	Page 31
<p>1 with Medtronic? And you can reference your --</p> <p>2 A Yeah. I --</p> <p>3 Q -- declaration if you want. I just -- I'm</p> <p>4 trying to walk through it chronologically, so it's</p> <p>5 difficult for me to follow along.</p> <p>6 A Sorry. Let's see. So it was April of 2000 is</p> <p>7 when I started as an intern.</p> <p>8 Q April of 2000 you said?</p> <p>9 A Yeah.</p> <p>10 Q And you were an intern?</p> <p>11 A Yes.</p> <p>12 Q Was that a paid internship?</p> <p>13 A Yes, it was.</p> <p>14 Q And in what particular area were you an intern</p> <p>15 for Medtronic?</p> <p>16 A I was in Cardiac Rhythm Management at the time.</p> <p>17 Q Cardiac Rhythm Management, does that involve</p> <p>18 pacemakers?</p> <p>19 A Yes.</p> <p>20 Q What did you do as an intern for Medtronic in</p> <p>21 that time period? And just generally.</p> <p>22 A I analyzed the mechanics of pacing leads.</p> <p>23 Q Those would be leads placed into the heart to</p> <p>24 help regulate heart rhythm?</p> <p>25 A Yes.</p>	<p>1 A When I joined the vascular group, I began</p> <p>2 working on product development.</p> <p>3 Q Okay.</p> <p>4 A Early stage research product development.</p> <p>5 Q Was that your first introduction to stents and</p> <p>6 stent technology?</p> <p>7 A No.</p> <p>8 Q When was your first introduction to stents and</p> <p>9 stent technology?</p> <p>10 A It would have been while I was at the</p> <p>11 University as a research assistant.</p> <p>12 Q Do you remember the year?</p> <p>13 A I don't.</p> <p>14 Q How were you introduced to stents and stent</p> <p>15 technology as a research assistant?</p> <p>16 A The Visible Heart is an isolated heart</p> <p>17 preparation that we use cameras to visualize the internal</p> <p>18 structures while the heart is beating, and we deployed</p> <p>19 stents within the coronary arteries.</p> <p>20 Q When you say we deployed stents, did you</p> <p>21 personally deploy the stents?</p> <p>22 A Yes, I did.</p> <p>23 Q It was in a heart model?</p> <p>24 A No. It was in an actual heart, so --</p> <p>25 Q Okay. Was the actual heart in an actual live</p>
<p>1 Q Through what period of time did you do that?</p> <p>2 A That was from 2000 until 2003.</p> <p>3 Q I see. So you were in that same department as</p> <p>4 an intern for Medtronic through that time period?</p> <p>5 A Yes.</p> <p>6 Q In 2003, what did you do?</p> <p>7 A I began full-time employment.</p> <p>8 Q So that would be just before you received your</p> <p>9 Ph.D.?</p> <p>10 A Yes.</p> <p>11 Q And when you began full-term employment for</p> <p>12 Medtronic, where did you go to work? What department?</p> <p>13 A It's called the Physiological Research</p> <p>14 Laboratories.</p> <p>15 Q What did you do there?</p> <p>16 A I was a consultant -- an internal consultant on</p> <p>17 various animal studies, anatomy and imaging, image</p> <p>18 guidance.</p> <p>19 Q Through what period of time did you do that?</p> <p>20 A From 2003 to 2006, January of 2006, I believe.</p> <p>21 Yes.</p> <p>22 Q In January 2006, what did you do?</p> <p>23 A Then I joined the vascular group at Medtronic.</p> <p>24 Q Okay. And how did your work change, if at all,</p> <p>25 when you joined the vascular group at Medtronic?</p>	<p>1 human patient?</p> <p>2 A It was not in the patient. It's called an</p> <p>3 isolated or ex vivo apparatus.</p> <p>4 Q So that would be a heart that was excised from</p> <p>5 a patient?</p> <p>6 A Uh-huh.</p> <p>7 Q That's a yes?</p> <p>8 A Yes.</p> <p>9 Q And hooked up to some machinery that keeps it</p> <p>10 functional?</p> <p>11 A Yes.</p> <p>12 Q And then in that excised heart, you employed a</p> <p>13 stent to keep open -- well, why did you employ stents?</p> <p>14 A We deployed stents for educational purposes to</p> <p>15 for the first time visualize what a stent looked like</p> <p>16 inside of a beating heart with a direct visualization.</p> <p>17 Q During that time period, did you work with any</p> <p>18 artificial valve devices?</p> <p>19 A Yes.</p> <p>20 Q Which valve devices did you work with?</p> <p>21 A They were mechanical valves primarily.</p> <p>22 Q Do you remember what year that occurred?</p> <p>23 A I don't recall the exact year, but it would</p> <p>24 have been while I was a -- so from 1999 to 2003, in that</p> <p>25 time period.</p>

Page 33	Page 35
<p>1 Q Sometime in that time period. And did you 2 install those devices -- I think I asked you this, but 3 let me make sure. Did you install those devices in this 4 excised heart?</p>	<p>1 That's right. So from 2003 -- I believe 2003 is when you 2 started full-time there?</p>
<p>5 A I did not install the heart valves.</p>	<p>3 A Right.</p>
<p>6 Q How did you come to work with them then? In 7 what capacity?</p>	<p>4 Q From 2003 through 2006, you were with -- was it 5 Rhythm Management?</p>
<p>8 A Two capacities. So the hearts that we received 9 in the laboratory sometimes from human patients were 10 non-viable for transplant and already had a mechanical 11 valve or a tissue valve placed, and then we just took 12 pictures of it and video of it. And the second, I 13 assisted a cardiac surgeon as he was implanting one into 14 a pig heart to put on the same apparatus to do the same 15 visualization.</p>	<p>6 A I was with the Physiological Research Labs at 7 that point.</p>
<p>16 Q So you assisted the physician implanting an 17 artificial valve in a pig heart that was going to be then 18 hooked up to this apparatus?</p>	<p>8 Q Okay. Physiological Research Labs. And what 9 did you do there? I'm sorry. I don't think I asked that 10 question.</p>
<p>19 A Yes.</p>	<p>11 A So I served as a consultant. I worked with all 12 of the business units to conduct their research on their 13 devices within -- to satisfy FDA requirements.</p>
<p>20 Q Did you engage in that time period in the 21 development of the artificial valve?</p>	<p>14 Q Did you work on any -- well, the answer, I 15 think, is no to this. But during that period of time, 16 did you work with any artificial heart valves?</p>
<p>22 A I did not.</p>	<p>17 A I did not during that time period.</p>
<p>23 Q When did you begin work on the actual 24 development of an artificial valve?</p>	<p>18 Q Did you work with any stent technology at 19 Medtronic during that time period?</p>
<p>25 A That would be in 2006 when I joined Vascular.</p>	<p>20 A No, I did not.</p>
<p>Page 34</p> <p>1 Q Okay. And I'm just trying to catch up on your 2 information here. All right. So if I understand your 3 testimony then, you were -- as a student at the 4 University of Minnesota, you were involved in this 5 Visible Heart project --</p> <p>6 A Uh-huh.</p> <p>7 Q -- during which you implanted stents in these 8 excised hearts?</p> <p>9 A Uh-huh.</p> <p>10 Q That's a yes?</p> <p>11 A Yes.</p> <p>12 Q And also had the work -- as you described, had 13 some work with these mechanical valves implanted in these 14 hearts?</p> <p>15 A Yes.</p> <p>16 Q Your first experience with developing a heart 17 valve was in 2006 when you joined Medtronic?</p> <p>18 A Yes.</p> <p>19 Q And in the 2006 time period -- so now we're at 20 Medtronic. Walk me through -- well, let's begin in 2006. 21 What products were you involved with when you first 22 started at the company?</p> <p>23 A So I was already at Medtronic, but just a 24 different business unit, for clarity.</p> <p>25 Q No. I appreciate that. And let's back up.</p>	<p>Page 36</p> <p>1 Q With respect to the products designed to treat 2 the aortic valve, do you recall what those products were?</p> <p>3 A Yeah. They were very early stage transcatheter 4 valve products to treat the aortic valve, to treat aorta 5 stenosis primarily.</p> <p>6 Q Are any of those on the market today?</p> <p>7 A Yes, but not for aortic stenosis. It's on the 8 market for the pulmonary valve -- for the pulmonic valve.</p> <p>9 Q Can you -- and we'll get into valve physiology 10 in a bit. But can you describe for us what the 11 difference is between like a mitral valve and an aortic 12 valve?</p> <p>13 A I can.</p> <p>14 Q Okay. What is it?</p> <p>15 A Well, they're located in two different aspects 16 of the heart. One is leaving the ventricle going to the 17 aorta. That's the aortic valve. The mitral valve is 18 between the left atrium and the left ventricle. They 19 have principally different structures. One is a 20 semilunar valve, the aortic valve, controlled completely 21 by pressure changes across the valve. Mitral valve has 22 ancillary structures. So valvular apparatus is what it's 23 commonly termed.</p> <p>24 Q Is that like chordae tendineae?</p> <p>25 A Chordae tendineae are part of the subvalvular</p>

Page 37	Page 39
<p>1 apparatus, yes.</p> <p>2 Q That's part of the subvalvular apparatus?</p> <p>3 A Yes.</p> <p>4 Q What other subvalvular apparatus is associated</p> <p>5 with the mitral valve?</p> <p>6 A Papillary muscles and the leaflets.</p> <p>7 Q And are those on the -- is it correct to refer</p> <p>8 to that as the proximal side of the valve?</p> <p>9 A Depends on your perspective. They would be on</p> <p>10 the ventricular side.</p> <p>11 Q Okay. So let's use that. Those would be on</p> <p>12 the ventricular side of the valve?</p> <p>13 A Yes.</p> <p>14 Q That would be the side of the valve facing one</p> <p>15 of the ventricles?</p> <p>16 A It would be within the ventricle, yes.</p> <p>17 Q Is that the left ventricle?</p> <p>18 A Yes.</p> <p>19 Q So on the side of the valve facing the left</p> <p>20 ventricle, there are these subvalvular structures you</p> <p>21 described?</p> <p>22 A Supporting the mitral valve, yes.</p> <p>23 Q Is the mitral valve typically a bicuspid valve?</p> <p>24 A It's commonly referred to that as being a</p> <p>25 bicuspid valve. But if you studied in-depth, you'll</p>	<p>1 2007 -- or no. I'm sorry -- until 2008. So those were</p> <p>2 all as a senior scientist at that level working on the</p> <p>3 same types of products for the same types of valves.</p> <p>4 Q And then you said that was until 2008?</p> <p>5 A Yes.</p> <p>6 Q Then in 2008, what did you do?</p> <p>7 A Then I was promoted to principal scientist. So</p> <p>8 I began to take on more leadership and oversight but</p> <p>9 still conducted the same types of research. And about</p> <p>10 that time we focused more on aortic valve development.</p> <p>11 Q And that was for what time period?</p> <p>12 A From 2009 essentially, 2008, 2009, until about</p> <p>13 2013 --</p> <p>14 Q And it was --</p> <p>15 A -- for myself. The company still works on it</p> <p>16 obviously.</p> <p>17 Q And it was during that time period that you</p> <p>18 began working with the CoreValve product?</p> <p>19 A Yes.</p> <p>20 Q Can you just describe for us at a high level</p> <p>21 what your involvement was with that product?</p> <p>22 A With CoreValve?</p> <p>23 Q Yeah.</p> <p>24 A I was primarily responsible for understanding</p> <p>25 the use conditions of the device once implanted.</p>
<p>Page 38</p> <p>1 notice that it can have a wide variability in the number</p> <p>2 of leaflets.</p> <p>3 Q Typically, is it a bicuspid valve, or is there</p> <p>4 nothing typical about it? In other words, is it --</p> <p>5 A Typically, there are two leaflets, the anterior</p> <p>6 or aortic leaflet and the posterior or mural leaflet.</p> <p>7 But the posterior leaflet is commonly divided into three</p> <p>8 sections by scallops, which gives it the appearance of</p> <p>9 having three separate leaflets in that one leaflet --</p> <p>10 Q Okay.</p> <p>11 A -- so --</p> <p>12 Q Then again in 2006 you began working with these</p> <p>13 valves at Medtronic. Did your position then change at</p> <p>14 some point?</p> <p>15 A Yeah. So in 2006 I joined Vascular for about</p> <p>16 six months and then performed the same functions but</p> <p>17 within a different division, the Cardiac Surgery</p> <p>18 Division.</p> <p>19 Q So you did the same thing, but it was in a</p> <p>20 different division at Medtronic?</p> <p>21 A Yeah. Those two divisions were beginning to be</p> <p>22 merged essentially.</p> <p>23 Q And how long did you continue working in that</p> <p>24 capacity?</p> <p>25 A In that -- with those exact functions until</p>	<p>Page 40</p> <p>1 Q What does that mean?</p> <p>2 A It means how the device performs mechanically</p> <p>3 post implant, after implant.</p> <p>4 Q And did that remain your role in connection</p> <p>5 with that device throughout the time period you worked</p> <p>6 with that device?</p> <p>7 A That was the early portion. After that, I</p> <p>8 began to work on understanding the clinical performance</p> <p>9 as it related to the design.</p> <p>10 Q What did that involve?</p> <p>11 MR. BARUFKA: Objection, ambiguous.</p> <p>12 Q You used the term clinical performance --</p> <p>13 A Yeah.</p> <p>14 Q -- and I don't know what that means. So that's</p> <p>15 my question.</p> <p>16 A I was evaluating clinical outcomes of the</p> <p>17 device.</p> <p>18 Q So you were looking at patients in which the</p> <p>19 device had been implanted?</p> <p>20 A Yes.</p> <p>21 Q Was that patients -- were those patients who</p> <p>22 had undergone a clinical trial involving the device?</p> <p>23 A In some cases.</p> <p>24 Q And how long did you perform that task?</p> <p>25 A That would have been until about 2013.</p>

Page 41

1 Q And in 2013, you took the position you
2 currently hold?
3 A Yes.
4 Q Okay. I want to talk about some of these heart
5 structures, if I could. These are structures that you
6 mention in your declaration just so I make sure you and I
7 are on the same page. You've heard of, obviously, a
8 structure known as the aortic root?
9 A Yes.
10 Q The aortic root is the junction between the
11 left ventricular outflow tract and the ascending aorta?
12 A I would say it's the junction between the left
13 ventricular outflow tract and the aorta, the ascending
14 aorta being a portion of the aorta.
15 Q I want to -- I think I'll do this. I'm going
16 to show you a few documents, and then we'll talk about
17 them. But I want to identify them for the record first
18 so it's easier to discuss them in some detail. I'm going
19 to hand you this first document.
20 (Deposition Exhibit Number 2224
21 was marked for identification.).
22 Q I've marked it 2224, and I'll just show it to
23 you, if I could. Do you recognize the document I've
24 marked 2224?
25 A I do.

Page 42

1 Q This is an article mentioned, I believe, in
2 your declaration.
3 A It is.
4 Q And if we look at the second page -- it's
5 actually page 54 of the document -- or the article
6 itself, but it's page 2 of the exhibit. There's an
7 illustration up at the top?
8 A Yes.
9 Q And that illustration up at the top shows -- it
10 looks like it's got a picture of the aortic root.
11 A Uh-huh.
12 Q That's a yes?
13 A Yes.
14 Q And the reason I keep saying that is because
15 she has to write down your answer. And if you say
16 "uh-huh," she can't write that down. I'm not trying to
17 be rude. I just have to do that for her benefit.
18 A Okay.
19 Q The picture at the top left of the page is the
20 picture that shows the aortic root there at the bottom?
21 A Yes.
22 Q It shows the -- it looks like the annulus.
23 A Yes.
24 Q It looks like there's an arrow pointing to a
25 commissure.

Page 43

1 A Yes.
2 Q And then there's an arrow pointing to the sinus
3 of Valsalva?
4 A Yes.
5 Q Then we see above that -- that structure
6 identified as the aortic root directly above that, that
7 section is identified, at least in this drawing, as the
8 ascending aorta, correct?
9 A Correct.
10 Q Did you consult -- as I said, I believe this
11 document 2224 is referenced in your declaration. You
12 consulted this as you interpreted the claims of the '228
13 patent?
14 A Yes, also other literature from around the same
15 time as the claims --
16 Q Okay.
17 A -- or as the patent, I guess.
18 Q Well, yeah. Let's look at that. Your
19 declaration -- look at page 7 of your declaration, if you
20 would.
21 A Uh-huh.
22 Q There's a heading "Materials Reviewed."
23 A Yes.
24 Q It says here, "In preparing this declaration, I
25 have reviewed U.S. Patent No. 6,482,228 patent to

Page 44

1 Norred."
2 A Yes.
3 Q That's the '228 patent, correct?
4 A Yes.
5 Q Also "U.S. Patent No. 6,454,799 to Schreck"?
6 A Yes.
7 Q "U.S. Patent No. 4,030,142 to Wolfe," correct?
8 A Yes.
9 Q "U.S. Patent No. 6,440,164 to DiMatteo,"
10 correct?
11 A Yes.
12 Q "U.S. Patent No. 5,957,949 to Leonhardt"?
13 A Yes.
14 Q "The Declaration of Timothy Titus Catchings,
15 M.D."?
16 A Yes.
17 Q "The deposition testimony of Dr. Catchings."
18 Do you see that?
19 A Yes.
20 Q Okay. Did you review any other materials in
21 preparing to provide this declaration?
22 A Just other anatomy references.
23 Q What did you review?
24 A So this article and then --
25 Q When you say this article, that's 2224?

Page 45		Page 47	
1	A 2224. And other anatomy articles. I don't	1	Q Did you consult this book in preparing your
2	know the specific titles of them published by Professor	2	declaration?
3	Robert Andersen.	3	A I did not.
4	Q Anything else?	4	Q You were aware though of the substance of this
5	A Those would be the primary sources, yes.	5	book because you were one of the editors of it, correct?
6	Q Did you review the declaration provided by	6	A Yes.
7	Dr. Troy Norred?	7	Q And if we look at page 61 -- now, it's actually
8	A I skimmed it, but I did not review it with	8	page 18 of the exhibit, but it's page 61 of the original
9	respect to what I put in my testimony.	9	book. You see there's some highlighted language there
10	Q Did you review the deposition testimony of	10	under section 3.4.1.1?
11	Troy Norred?	11	A Uh-huh.
12	A No, I did not.	12	MR. BARUFKA: I'm going to object to this whole
13	Q Did you review the motion to amend filed by	13	line of questioning as to facts not in evidence and
14	Troy Norred in these proceedings?	14	also because it's beyond the scope of direct.
15	A No, I did not.	15	MR. KERNEL: That's not a proper objection.
16	Q Did you review the substitute claims offered by	16	Q Hold on. You've got in front of you now
17	Dr. Troy Norred in these proceedings?	17	page 18 of this Exhibit 2225, correct?
18	A No, I did not.	18	A Yes.
19	Q Let me hand you a document marked 2227.	19	Q The heading is "The Aortic Root," correct?
20	Actually, yeah. I don't want to mark it 2227. I'm	20	A Yes.
21	sorry. It's going to be 2225.	21	Q And it says, "When considering the anatomy of
22	(Deposition Exhibit Number 2225	22	the aortic valve, it is useful to examine the anatomy of
23	was marked for identification.)	23	the aortic root complex. The aortic root is the junction
24	MR. MARCUS: And I'll identify it for the	24	between the left ventricular outflow tract and the
25	record before I ask you questions about it so that	25	ascending aorta." I read that correctly?
Page 46		Page 48	
1	we all know what it is. Here, Jack, I'm going to	1	A Yes.
2	give this to you. This has 2227 on it. That's the	2	Q And you would agree that at least the aortic
3	wrong exhibit number. It should be 2225. I've got	3	root is the junction between the left ventricular outflow
4	multiple stickers. That's why.	4	tract and the aorta, correct?
5	MR. BARUFKA: I'm going to object to this as	5	A Yes.
6	being beyond the scope of direct.	6	Q It says, "Its primary component is the aortic
7	MR. MARCUS: That's fine. You can object.	7	valve, but it also contains the sinuses of Valsalva, the
8	Q You've got Exhibit 2225 in front of you?	8	membranous ventricular septum, and the coronary
9	A Yes.	9	arteries." Did I read that correctly?
10	Q That is an article that you were one of the	10	A Yes.
11	editors for -- a book that you were one of the editors	11	Q And you would agree that the aortic root does
12	for?	12	in fact contain those structures?
13	A A book, yes.	13	MR. BARUFKA: Objection, beyond the scope of
14	Q And the book itself, I believe, is like 400	14	direct.
15	plus pages. What I've handed you as Exhibit 2225 is a	15	A Yes, in general.
16	collection of excerpts from that book that might be	16	Q Okay. And then it says, "The aortic valve
17	relevant to your testimony, just so you know what's in	17	consists of three semilunar leaflets or cusps; each
18	front of you.	18	leaflet of the aortic valve is named for its respective
19	A Okay.	19	coronary artery." Do you see that sentence?
20	Q And this is a book -- it looks like it was	20	A Yes.
21	published just last year, 2013.	21	Q Now, you referred to the aortic valve earlier
22	A I believe so.	22	as a semilunar valve?
23	Q Did you consult this book -- it's entitled	23	A Yes.
24	Heart Valves from Design to Clinical Implantation.	24	Q And semilunar, where does that terminology come
25	A Yes.	25	from?

Page 49

1 MR. BARUFKA: Objection, beyond the scope of
2 direct.
3 A It's the shape of the leaflet.
4 Q And when you say it's the shape of the leaflet,
5 where the margin -- that's the shape that corresponds to
6 where the margin of the leaflet attaches to the aortic
7 wall?
8 A Yes.
9 Q Because that produces this half moon shape?
10 A Each leaflet has a half moon shape, yes.
11 Q And you say each leaflet because typically the
12 aortic valve is a trileaflet valve?
13 A Typically, yes.
14 Q There are instances where its a bileaflet or
15 bicuspid valve?
16 A Yes.
17 Q But in those instances typically then that
18 valve is associated with some sort of dysfunction or
19 stenosis?
20 A Not initially. It --
21 Q Ultimately, a bicuspid aortic valve is
22 associated with dysfunction or stenosis?
23 A Not in every patient.
24 Q Typically?
25 A It can lead to dysfunction, yes.

Page 50

1 Q Yeah. Take a look at 2224, the exhibit that --
2 A Uh-huh.
3 Q -- I marked earlier. This is that article
4 you --
5 A Uh-huh.
6 Q -- referred to in your declaration. You've got
7 2224 in front of you?
8 A Uh-huh.
9 Q And if we look at the second column of the
10 first page, you see there are three bullet points?
11 A Yes.
12 Q Below those bullet points, there's a sentence
13 that reads, "The aortic valve leaflets form the
14 hemodynamic junction and physical boundary between the
15 left ventricle and the aorta." I read that correctly?
16 A Yes, you did.
17 Q Then it says, "All the structures distal to the
18 hemodynamic junction are subject to arterial pressures,
19 whereas all the proximal parts are subjected to
20 ventricular hemodynamics." I read that correctly?
21 A Yes.
22 Q When it says "proximal parts," would that be
23 the parts that exist between the valve and the left
24 ventricle?
25 A As I'm reading this, yes.

Page 51

1 Q Okay. Then the next sentence says, "The
2 trileaflet design represents the optimal solution for low
3 resistance valve opening. No other valve configuration
4 can provide these characteristics, a fact prominently
5 demonstrated in the setting of a bicuspid aortic valve,
6 in which some kind of valve dysfunction or degree of
7 stenosis always co-exists depending on the
8 configuration." I read that correctly?
9 A Yes.
10 Q Do you agree with that sentence?
11 A That's the opinion of these authors.
12 Q Okay. And you attached or saw fit to attach
13 this particular article to the declaration you submitted
14 to the board, correct?
15 A Yes.
16 Q Take a look at this Exhibit 2225, if you would.
17 This is the excerpts from the book that you edited. Look
18 at page 31 of it. Yeah, you've got it right in front of
19 you.
20 A Okay.
21 Q We talked about the semilunar shape of the
22 aortic valve. That appears to be depicted in this
23 picture at the top. Is that what we're seeing?
24 MR. BARUFKA: Objection, beyond the scope of
25 direct.

Page 52

1 Q Do you see Figure 2.4?
2 A Yes. Can you show me?
3 Q Yeah. What this appears to be -- and tell me
4 if I'm wrong, but it appears that this is a picture of
5 the aortic valve with the arterial walls cut away, so all
6 we're seeing is the valve itself. And it appears there
7 there's this -- it looks like a U shape where that valve
8 would otherwise have been attached to the walls of the
9 aorta. Is that what this depicts?
10 MR. BARUFKA: Objection, assumes facts not in
11 evidence.
12 MR. KERNELL: Jack, I'm going to ask you one
13 more time not to interject with speaking objections.
14 Otherwise, we're going to get the board on the call
15 and end it. You have three objections that are
16 proper. Use those three objections.
17 MR. BARUFKA: I believe there are more than
18 just three. These are not speaking objections. We
19 can --
20 MR. KERNELL: This right now is a speaking
21 objection.
22 MR. BARUFKA: If you want to call the board, I
23 mean, that's --
24 MR. KERNELL: It's relevance, form, privilege.
25 MR. BARUFKA: I disagree that it's just those

Page 53	Page 55
<p>1 three.</p> <p>2 Q So you've got again Exhibit 2225 in front of</p> <p>3 you. We're looking at page 31 of that. And that</p> <p>4 picture, Figure 2.4, you've had a chance now to look at</p> <p>5 that picture and the description beneath that picture?</p> <p>6 A I've looked at the picture. I haven't read the</p> <p>7 description yet.</p> <p>8 Q And all my question is, I'm just simply trying</p> <p>9 to understand. When we talk about semilunar valve, are</p> <p>10 we seeing sort of that shape depicted here in Figure 2.4</p> <p>11 on page 31 of this book?</p> <p>12 MR. BARUFKA: Objection as to relevance.</p> <p>13 A Can you point to what you're referring to?</p> <p>14 Q Yeah. You see here there's -- this to me, to</p> <p>15 my eyes -- and I don't have your training, but this</p> <p>16 appears to be a half moon. These appear to be what we're</p> <p>17 seeing as the three leaflets of the aortic valve but with</p> <p>18 the arterial wall cut away. If you were to cut away the</p> <p>19 wall where these leaflets would attach, you would, I</p> <p>20 believe, be left with these semilunar shapes, which is</p> <p>21 where this valve gets its name, a semilunar valve.</p> <p>22 A Yes.</p> <p>23 Q And that's what we're seeing?</p> <p>24 A In that portion that you pointed to, yes.</p> <p>25 Q Okay. And if we look at the next page of</p>	<p>1 Q Now, this green ring that we see, that is a</p> <p>2 reference to the "sinutubular junction"?</p> <p>3 A Yes.</p> <p>4 Q And then this yellow color we see, this is</p> <p>5 the -- it says here the "coronet of aortic leaflet</p> <p>6 attachment."</p> <p>7 A Yes.</p> <p>8 Q So this is showing the semilunar shape of these</p> <p>9 trileaflets where they would attach to the arterial wall?</p> <p>10 MR. BARUFKA: I'm going to object to the</p> <p>11 relevance of this line of questioning. And I think</p> <p>12 we should call the board as to whether this is</p> <p>13 proper for this -- subject matter for this</p> <p>14 deposition. This is not within the scope of his</p> <p>15 testimony.</p> <p>16 MR. MARCUS: He's -- I'm not going to argue</p> <p>17 with you. If you want to call the board, call the</p> <p>18 board. You can make your objection. I'll keep</p> <p>19 asking the questions. I think I'm entitled to ask</p> <p>20 questions, and I think you can object, and I think</p> <p>21 you've got a right to move to exclude the testimony,</p> <p>22 but I think I get to ask the question. I mean,</p> <p>23 that's what the rules provide for.</p> <p>24 MR. BARUFKA: Let's see where this goes.</p> <p>25 MR. MARCUS: I didn't think it was a tricky</p>
<p>Page 54</p> <p>1 this -- and this particular article we're looking at,</p> <p>2 this is an article you were personally involved in</p> <p>3 putting together, were you not?</p> <p>4 A Uh-huh.</p> <p>5 Q Yes?</p> <p>6 A Yes.</p> <p>7 Q We see this illustration at the top. And I</p> <p>8 think I know what it is, but I want to confirm. Here</p> <p>9 we've got colors green, yellow, blue, and red?</p> <p>10 A Yes.</p> <p>11 Q And this is a schematic --</p> <p>12 MR. BARUFKA: Objection as to form; objection</p> <p>13 as to relevance.</p> <p>14 MR. MARCUS: I mean, I don't care if you</p> <p>15 object. I'm not going to complain. But I finish my</p> <p>16 question, then you object, and he answers --</p> <p>17 MR. BARUFKA: That's fine.</p> <p>18 MR. MARCUS: -- or she can't take it down.</p> <p>19 MR. BARUFKA: That's fine.</p> <p>20 Q Okay. The top of page 32, there's this</p> <p>21 schematic. You see?</p> <p>22 A Yes.</p> <p>23 Q And it's got a green color, a yellow color, a</p> <p>24 blue color, and a red color, correct?</p> <p>25 A Yes.</p>	<p>Page 56</p> <p>1 question. He's got more experience than I do. I'm</p> <p>2 not trying to trip him up. This is his article. He</p> <p>3 authored it. I think I get to ask him about it.</p> <p>4 MR. BARUFKA: Let's see where it goes.</p> <p>5 Q Okay. Let's ask some we all can -- the school</p> <p>6 that you got your doctorate from is probably one of the</p> <p>7 best schools in the country. Don't you think?</p> <p>8 A I like to think so, yes.</p> <p>9 Q I think so, too. See? We can agree on that.</p> <p>10 I went there.</p> <p>11 Okay. So page 32, top, we're looking at this</p> <p>12 schematic diagram. The green ring is the "sinutubular</p> <p>13 junction," and that is the border between the aortic root</p> <p>14 and the ascending aorta?</p> <p>15 A That's one way to describe it.</p> <p>16 Q Okay. And then the yellow color that we see,</p> <p>17 this shows where the three leaflets of the aortic valve</p> <p>18 would attach to the aortic wall?</p> <p>19 A Yes.</p> <p>20 Q Then this blue ring, it says, "Anatomical</p> <p>21 ventriculo-arterial junction." What is that?</p> <p>22 A That is the distinction between ventricular</p> <p>23 tissue and arterial tissue, anatomically speaking.</p> <p>24 Q And can you describe for a layperson, which I</p> <p>25 am, what that means?</p>

Page 57	Page 59
<p>1 A Ventricular tissue is on one side, and arterial 2 tissue is on the other side.</p>	<p>1 this is not my field. But there are sinuses associated 2 with the leaflets of the aortic valve?</p>
<p>3 Q And what's the difference between ventricular 4 tissue and arterial tissue?</p>	<p>3 A Yes.</p>
<p>5 A It's composed of different structures. So 6 ventricular tissue has one set of structures. Arterial 7 tissue has a different set of structures.</p>	<p>4 Q And within two -- are there three sinuses, one 5 for each of the leaflets?</p>
<p>8 Q Arterial tissue, does that have arteries?</p>	<p>6 A Commonly with the tricuspid valve --</p>
<p>9 A It is the tissue that surrounds the arteries.</p>	<p>7 Q Okay.</p>
<p>10 Q Okay. And then the bottom ring, that's the 11 virtual annulus defined by the basal attachments of the 12 valvular leafs -- of leaflets rather?</p>	<p>8 A -- configuration, yes.</p>
<p>13 A Leaflets, yes.</p>	<p>9 Q And within two of the three sinuses, there are 10 orifices for the right and left coronary arteries?</p>
<p>14 Q And basal attachments, is that simply the 15 bottom portion of the leaflets where they bottom out?</p>	<p>11 A Yes.</p>
<p>16 A Yes.</p>	<p>12 Q And on this Figure 2.9, we see where the -- we 13 see the "sinutubular junction" shown?</p>
<p>17 Q Okay. And so where they bottom out, that is 18 referred to as the -- typically as the aortic annulus?</p>	<p>14 MR. BARUFKA: Objection, relevance.</p>
<p>19 A That's one term for aortic annulus.</p>	<p>15 A Yes.</p>
<p>20 Q Now, within this aortic root, as we've looked 21 at before, there are the coronary arteries?</p>	<p>16 Q And that is defined by the -- is it the high 17 points of attachment for the valve leaflets?</p>
<p>22 A Yes.</p>	<p>18 A In some interpretations, yes. In others, it's 19 the portion where the sinuses become a tube. And that 20 may not correspond exactly with where the top of the 21 leaflets are.</p>
<p>23 Q And if we look at page -- it's 36 of your book, 24 but it's page 12 of this Exhibit 2225. There is a what I 25 believe to be a picture of the aortic root spread apart</p>	<p>22 Q Okay. And the top of the leaflets, is that the 23 structure typically referred to as a commissure?</p>
<p>24 A Commissure, yes.</p>	<p>24 A Commissure, yes.</p>
<p>25 Q And so if we were to draw a ring connecting all</p>	<p>25 Q And so if we were to draw a ring connecting all</p>
Page 58	Page 60
<p>1 and with the leaflets removed. Is that what that picture 2 shows at the top of that Figure 2.9?</p>	<p>1 the commissures, that ring would typically be the 2 sinutubular junction?</p>
<p>3 MR. BARUFKA: Objection, relevance.</p>	<p>3 A I wouldn't say typically. It can be below it; 4 it can be above it.</p>
<p>4 A Yes.</p> <p>5 Q And so here we see -- and you can -- I think, 6 and tell me if I'm wrong, but you can see here these 7 light U-shaped structures towards the top part of this 8 drawing. Is that where the leaflets would have been cut 9 away?</p>	<p>4 Q Is it right about that area?</p> <p>5 A It's around that area, yes.</p>
<p>10 MR. BARUFKA: Objection, relevance.</p>	<p>6 Q Okay. And then at the bottom, that red line, 7 that's the virtual annulus?</p>
<p>11 A I believe so. It looks like there may still be 12 some leaflets there, but.</p>	<p>8 A Yes.</p>
<p>13 Q Okay. And so what we can see is the left and 14 right coronary arteries appearing within these semilunar 15 shapes?</p>	<p>9 Q And that's -- we talked about earlier that's 10 also referred to sometimes as the aortic annulus?</p>
<p>16 MR. BARUFKA: Objection, relevance.</p>	<p>11 A Sometimes referred to that, yes.</p>
<p>17 A They're within the sinus.</p>	<p>12 Q And in this diagram, we see the membranous 13 septum?</p>
<p>18 Q Okay. When you say they're within the sinus, 19 what does that mean?</p>	<p>14 A Yes.</p>
<p>20 A The sinus is behind the leaflets in the aortic 21 group.</p>	<p>15 MR. BARUFKA: Objection, relevance.</p>
<p>22 Q Okay. And so within two of the three leaflets 23 of the aortic valve, two of the three sinuses, is it -- 24 and you'll have to excuse me. I'm trying to use the 25 correct terminology, and I struggle with this because</p>	<p>16 Q What is that?</p>
<p>25 Q Okay. And let me -- I want to direct your attention back to your book. 2225 is the exhibit number,</p>	<p>17 A The membranous septum is the portion of the 18 cardiac skeleton between the left ventricle and the right 19 atrium.</p>
<p>25 Q Okay. And let me -- I want to direct your attention back to your book. 2225 is the exhibit number,</p>	<p>21 Q What does it do?</p>
<p>25 Q Okay. And let me -- I want to direct your attention back to your book. 2225 is the exhibit number,</p>	<p>22 A It doesn't do anything. It's a part of the 23 cardiac skeleton.</p>
<p>25 Q Okay. And let me -- I want to direct your attention back to your book. 2225 is the exhibit number,</p>	<p>24 Q Okay. And let me -- I want to direct your 25 attention back to your book. 2225 is the exhibit number,</p>

Page 61	Page 63
1 and it's page 18 of the exhibit. It would be page 61 of 2 your book, and it's that section 3.4.1.1 that we looked 3 at earlier.	1 Q The leaflets of the aortic valve open and close 2 in response to pressure changes within the heart. Is 3 that a correct statement?
4 A Uh-huh.	4 A Yes.
5 MR. BARUFKA: Objection, relevance.	5 Q The aorta expands and contracts during each 6 cardiac cycle. Is that true?
6 Q And if we look at that highlighted language -- 7 and I think we've talked about these structures, but I 8 want to make sure we've covered this complete structure 9 here. If we go midway down, it says -- and I think we 10 read part of this language earlier. Do you see the word 11 "consequently"?	7 A The aorta?
12 A Yes.	8 Q The aorta.
13 Q "Consequently, there is a right coronary cusp, 14 a left coronary cusp, and a noncoronary cusp." Have I 15 read that correctly?	9 A Yes.
16 A Yes.	10 Q The commissures, they are attached to the 11 aorta?
17 Q And cusp and leaflet, are those used 18 interchangeably?	12 A Yes. 13 Q So is it true that as the aortic wall or the 14 aorta expands and contracts, the commissures move with 15 the aortic wall?
19 A Typically, yes.	16 A Yes.
20 Q And it says then, "The leaflets attach to the 21 left ventricular outflow tract in a semilunar fashion 22 creating triangular interleaflet spaces." Do you see 23 that?	17 Q And the valve leaflets are attached to the 18 commissures?
24 A Yes.	19 A The commissure is a portion of the valve 20 attachment -- the valve leaflet attachment.
25 Q What is a triangular leaflet space?	21 Q Okay. And so it would be a correct statement 22 the valve leaflets are attached to the commissures?
Page 62	23 A I guess I would say that the commissure is a 24 part of the valve leaflet attachment.
1 MR. BARUFKA: Objection, relevance.	25 Q Okay. And is it true that as the commissures
2 A The interleaflet spaces are the portion below 3 the commissure at the tip and the attachment of the 4 leaflet at the bottom.	1 move back and forth that the leaflets move back and 2 forth?
5 Q Then it says, "At the apex of these triangles 6 are the aortic valve commissures which are the highest 7 points of attachment of the aortic valve leaflets onto 8 the wall of the aorta." Have I read that correctly?	3 A The leaflets moving back and forth and --
9 MR. BARUFKA: Objection, relevance.	4 Q Yeah.
10 A Yes. That's what it says.	5 A Can you identify that a bit?
11 Q And we talked about that earlier, correct? The 12 commissures are the highest points of attachment of the 13 leaflets to the aortic wall?	6 Q Let me ask you more plainly. We talked about 7 earlier the fact that the aorta moves with the 8 contractions of the heart, correct, the aorta?
14 A Yes.	9 A The aorta moves with -- because of pressure 10 changes due to contractions in the heart.
15 Q And then it says here, "This junction, where 16 the aortic valve commissures are hinged, is referred to 17 as the sinotubular junction or ridge. It is a transition 18 point from the aortic root to the ascending aorta."	11 Q Okay. And the commissures are attached to the 12 aortic wall?
19 MR. BARUFKA: Objection to relevance.	13 A Yes.
20 A Yes.	14 Q And the commissures move in response to the 15 aortic wall moving?
21 Q And you agree with that?	16 A Due to the pressure change.
22 A I think that's one interpretation.	17 Q Right. And the leaflets -- the commissures are 18 an attachment point for the leaflets to the aortic wall?
23 Q And it's interpretation set forth in a book on 24 which you served as one of the four editors?	19 A They are a part of the attachment.
25 A Yes.	20 Q Okay. And when the commissures move, that 21 causes movement of the leaflets?
	22 A No. The commissures move because of the 23 pressure change, as do the leaflets. 24 Q Okay. Let me show you something to see if you 25 can --

Page 65		Page 67	
1	(Deposition Exhibit Number 2226	1	A In general, that seems to be mostly true, yes,
2	was marked for identification.)	2	as I would understand it.
3	Q Take a look at Exhibit 226, if you would -- I'm	3	Q The leaflets, do they contain any musculature?
4	sorry. 2226. What I've handed you are excerpts from a	4	A I'm not sure.
5	book entitled The Aortic Valve by Mano Thubrikar. Did	5	Q You don't know one way or the other?
6	you consult this book in preparing the affidavit -- or	6	A I don't know.
7	the declaration rather than that you submitted to the board in	7	Q Are they -- you said that they move in response
8	this case?	8	to pressure changes. Is that right?
9	A I did not.	9	A Yes.
10	Q I want to ask you to take a look at page 48 of	10	Q And I believe you said or agreed that the
11	the book. So these pages are at the top here. There are	11	aortic valve is generally regarded as a passive
12	not individual page numbers on this, but we'll put those	12	structure?
13	on this. Do you see page 48?	13	A Yes.
14	A I do see page 48.	14	Q The aortic valve opens during systole?
15	Q There's a heading that says, "The Mechanism of	15	A Yes.
16	Opening of the Aortic Valve." Do you see that heading?	16	Q Am I pronouncing that right?
17	A I do.	17	A Systole, yes.
18	Q It says, "The aortic valve is generally	18	Q And during systole, ventricular pressure rises
19	regarded as a passive structure changing mainly in	19	and exceeds pressure in the arteries?
20	response to hemodynamic forces." Did I read that	20	A Pressure in the aorta directly above it, yes.
21	correctly?	21	Q Okay. And that is what causes the aortic valve
22	MR. BARUFKA: Objection, relevance.	22	to open?
23	A Yes.	23	A The leaflets open, yes.
24	Q What's a hemodynamic force?	24	Q And when the leaflets open, then blood is
25	A That would be the pressures that I was	25	forced out of the left ventricle through the aorta?
Page 66		Page 68	
1	referring to.	1	A Yes.
2	Q And so do you agree with the sentence that I	2	Q And then during diastole, that's when the
3	just read?	3	aortic valve closes?
4	MR. BARUFKA: Objection, relevance.	4	A Yes.
5	A I would agree with that statement in general.	5	Q So the ventricles relax, and blood flows back
6	Q Okay. Then it says, "For the most part this is	6	against the cusps of the aortic valve to force them
7	true; however, there are active components to valve	7	closed?
8	behavior. For example, there is interaction between the	8	A Yes.
9	commissures and the leaflets, as noted in the previous	9	Q And at that time during diastole, blood is also
10	section. Classically, the aortic valve is thought to	10	directed through the right and left coronary arteries?
11	open when blood ejected from the ventricle pushes the	11	A Yes.
12	leaflets open. This would be true if the leaflets were	12	Q And that is how the blood -- or that is how the
13	attached to a nonexpansile structure. However, the	13	heart receives its blood?
14	leaflets are attached to an expansile structure and the	14	A In general, yes.
15	expansion of that structure alone can open the valve.	15	Q And would you agree that that's one of the most
16	The leaflets are attached to the aortic wall at the	16	critical functions of the aortic root is to allow that
17	commissures, which move outward during each cardiac	17	process to happen so that the heart is supplied with
18	cycle." Did I read that sentence correctly?	18	blood?
19	MR. BARUFKA: Objection, relevance.	19	A Yes.
20	A Yes. You read that.	20	Q And if blood flow to the heart is restricted,
21	Q Do you agree with what's stated?	21	that can have significant consequences to the person
22	MR. BARUFKA: Objection, relevance.	22	whose heart that is?
23	A I apologize. This is the first time I've seen	23	A Could, yes.
24	this. (Perusing document.)	24	Q The patient could die?
25	Q No. That's fine.	25	A The patient could die, yes.

Page 69	Page 71
1 Q The valves of the heart are designed to allow	1 you evaluated patients who had the Medtronic valves
2 blood flow in only one direction?	2 implanted?
3 A Yes.	3 A That was one of the concerns, yes.
4 Q It flows from the left ventricle through the	4 MR. MARCUS: We've been going for about an
5 aortic valve to the arterial system?	5 hour. Do you want to take a brief break?
6 A Yes.	6 MR. BARUFKA: Sure.
7 Q And again, that would be during the part of the	7 MR. MARCUS: Let's do that. And I try to do
8 cardiac cycle known as systole when the aortic valve is	8 that like every hour.
9 open?	9 (Break, 10:49 a.m. until 10:57 a.m.)
10 A Systolic ejection, yes.	10 Q I'm going to hand you a document marked 1018.
11 Q Okay. And then during diastole, the aortic	11 This is a Declaration of Thomas Vassiliades. Did you
12 valve closes to prevent blood from flowing the other way	12 look at Exhibit 1018 in preparing your declaration in
13 back from the direction of the aorta into the left	13 this matter?
14 ventricle?	14 A I did not.
15 A Yes.	15 Q Have you ever met Dr. Vassiliades?
16 Q Would you agree that in order for that	16 A I have.
17 process -- that cardiac cycle to work effectively and	17 Q And who is he?
18 efficiently, it is important that the aortic valve not	18 A He serves as our chief -- or let's see.
19 leak to allow blood to flow back into the left ventricle	19 Medical Affairs -- chief of our Medical Affairs Office
20 from the aorta?	20 for Structural Art. We just merged, so I'm not sure his
21 A As much as possible, yes. Some small leaks can	21 exact title, but --
22 be tolerated.	22 Q Where is he in relation to you? I mean, is he
23 Q But leaks can result in something known as	23 someone that you regularly interact with, or do you ever
24 regurgitation?	24 interact with him? Or what is that relationship?
25 A The leak is regurgitation.	25 A I do interact with him with respect to the
Page 70	Page 72
1 Q And that can have significant consequences for	1 project I'm leading now. I haven't interacted with him
2 the patient?	2 previously to a large extent.
3 A It could.	3 Q If we look at this declaration, I want to
4 Q Can cause the heart to fail?	4 direct your attention to paragraph 21.
5 A It could.	5 A Okay.
6 Q In fact, that's one of the most serious	6 MR. BARUFKA: Objection as to relevance.
7 concerns in connection with replacement valves such as	7 Q Paragraph 21 says, "During each cardiac cycle,
8 the valves that you worked on at Medtronic?	8 the natural heart valves alternatively open to allow
9 A It's one of them, one of the concerns.	9 blood to flow through them and then close to block blood
10 Q One of the most significant concerns?	10 flow. During systole, the aortic and pulmonary valves
11 A I think that's debatable. But yes.	11 open to allow blood flow into the aorta and pulmonary
12 Q Well, hasn't -- I mean, you know people at	12 arteries. Conversely, during diastole, the aortic and
13 Medtronic have said that, haven't they?	13 pulmonary valves close to prevent reverse blood flow from
14 A I don't know what everyone at Medtronic has	14 the aorta and pulmonary arteries into the ventricle."
15 said.	15 Did I read that correctly?
16 Q You've heard that at Medtronic that --	16 A Yes.
17 MR. BARUFKA: Objection, relevance.	17 Q And do you agree with that statement by
18 Q You've heard during your time at Medtronic that	18 Dr. Vassiliades?
19 one of the most significant concerns in relation to these	19 MR. BARUFKA: Objection, relevance.
20 replacement valves is whether these replacement valves	20 A Yes.
21 allow perivalvular leaks?	21 Q Then paragraph 22 says, "Natural heart valves
22 MR. BARUFKA: Objection, relevance.	22 open and close passively in response to blood pressure
23 A I don't know if the term significant is there.	23 changes operating against the valves' leaflet structure.
24 It is a concern for the valves.	24 Specifically, the valve leaflets open when the forward
25 Q Is that one of the concerns you looked at as	25 pressure gradient urges blood flow forward and close when

Page 73	Page 75
1 the forward pressure gradient reverses and urges blood	1 Q Let me hand you an exhibit marked 2227.
2 flow backward." Do you agree with that statement by	2 (Deposition Exhibit Number 2227
3 Dr. Vassiliades?	3 was marked for identification.)
4 MR. BARUFKA: Objection, relevance.	4 Q This is a Medtronic press release stating the
5 A Some of the wording in general, yes.	5 "Medtronic CoreValve® System Obtains Early FDA Approval
6 Q Then paragraph 23, Dr. Vassiliades says, "A	6 on Exceptional Clinical Performance." Did I read that
7 prosthetic heart valve must necessarily function in the	7 correctly?
8 same manner as the natural heart valve it replaces.	8 MR. BARUFKA: Objection, relevance.
9 Thus, passive prosthetic valves, both of mechanical and	9 A That's the title.
10 tissue design (including prosthetic tissue heart valves	10 Q And down here in the body of this, if you go
11 that incorporate pig heart valves), utilize the pressure	11 one, two, three -- four paragraphs down, you'll see some
12 gradient created during systole and diastole to open and	12 highlighted language saying, "'The low rates of stroke
13 close the prosthetic valve such that the blood flow	13 and valve leakage with the CoreValve System - two of the
14 controlling function of the natural valve is replaced."	14 most concerning complications of valve replacement
15 Do you agree with that statement by Dr. Vassiliades?	15 because they increase the risk of death and have a
16 MR. BARUFKA: Objection, relevance.	16 dramatic impact on quality of life - set a new standard
17 A Yes.	17 for transcatheter valves,' said Jeffrey J. Popma, M.D.,
18 Q We talked several moments ago about the	18 director of Interventional Cardiology at the Beth Israel
19 condition known as aortic regurgitation, correct?	19 Deaconess Medical Center, Boston, and co-principal
20 A Yes.	20 investigator of the Trial." Did I read that correctly?
21 Q And that is the condition where blood flows	21 MR. BARUFKA: Objection, relevance.
22 backward from the aorta or -- yeah, from the aorta to the	22 A Yes.
23 left ventricle through the aortic valve?	23 Q Did you work with Dr. Popma while you were in
24 A Yes.	24 Medtronic working on this project?
25 Q And that can be caused by the failure of the	25 MR. BARUFKA: Objection, relevance.
Page 74	Page 76
1 valve leaflets to coapt?	1 A I have worked with Dr. Popma in limited
2 A Yes.	2 exposures.
3 Q And the problem with regurgitation is that if	3 Q Okay. Are you aware of the commentary that he
4 blood is allowed to flow back into the ventricle from the	4 offers here in this press release? Is that something you
5 arterial system, that can overload the ventricles and	5 were generally aware of while you worked on the CoreValve
6 potentially cause chronic heart failure?	6 product at Medtronic?
7 A It can.	7 MR. BARUFKA: Objection, relevance.
8 Q Do you agree that for a replacement valve to	8 A His specific comments, no, I wasn't aware of
9 effectively replace the native valve, it must control	9 this and this press release.
10 perivalvular leakage?	10 Q Were you aware that one of the features of the
11 A I think an ideal state would be to have	11 CoreValve product being touted was the low rates of valve
12 minimization of perivalvular leakage.	12 leakage?
13 Q If the replacement valve allows blood to freely	13 MR. BARUFKA: Objection, relevance.
14 leak from the aorta back into the left ventricle, that	14 A From this trial? From reading this, I am aware
15 valve would not be an acceptable replacement for the	15 now.
16 natural valve?	16 Q The people who design replacement valves are
17 A Depends on the degree of leakage.	17 often very specific about where their valves are supposed
18 Q What degree of leakage is tolerable?	18 to be placed within the human anatomy, correct?
19 A I think a minimal amount to minimize the	19 A I think that's -- I don't know that that's
20 leakage.	20 always true.
21 Q The CoreValve device that you worked on at	21 Q In the case of the CoreValve product as an
22 Medtronic is designed in part to minimize perivalvular	22 example, in the case of that valve, it is true that there
23 leakage?	23 is a specific guideline for where that valve ought to be
24 MR. BARUFKA: Objection, relevance.	24 placed?
25 A Yes.	25 MR. BARUFKA: Objection, relevance.

Page 77		Page 79	
1	A Within our instructions for use? Or, I mean,	1	Q Do you know what Medtronic told the FDA as it
2	what are you looking for in terms of guidelines?	2	was applying for investigational device exception for
3	Q Anything. I mean, are you aware -- and you may	3	that product?
4	not be aware, and if you're not aware, just tell me that.	4	MR. BARUFKA: Objection, relevance.
5	But are you aware that the maker of that valve,	5	A I don't know exactly. But I believe it
6	Medtronic, provides specific guidance to doctors as to	6	probably stated annulus. I haven't reviewed the IFU or
7	where the CoreValve devices be placed within the human	7	clinical protocol.
8	anatomy?	8	Q Take a look at Exhibit 2225 again, this book
9	MR. BARUFKA: Objection, relevance.	9	that you helped edit.
10	A I believe there is specific guidance provided	10	A Okay.
11	by Medtronic for how to place and where to place that	11	Q Look at page 237 of that book, if you would.
12	valve.	12	It's page 37 of the exhibit.
13	Q And is that true with respect to the other	13	A Okay.
14	valves that you've been involved with --	14	Q On that page, does there appear a picture of
15	MR. BARUFKA: Objection, relevance.	15	the CoreValve device?
16	Q -- that there has been specific guidance to the	16	MR. BARUFKA: Objection, relevance.
17	doctor as to where the valve ought to be placed within	17	A There does.
18	the human anatomy?	18	Q And at the top of the page, you'll see there's
19	A Most of the valves that I've been involved with	19	a label for inflow portion, constrained portion, and
20	have -- are in the early stages, so haven't been released	20	outflow portion?
21	to humans, so we don't have guidance yet.	21	MR. BARUFKA: Objection, relevance.
22	Q Is the CoreValve product the only valve you've	22	A Yes.
23	been involved with that has been released for human	23	Q And it says here, the inflow portion is
24	trials?	24	"intra-annular anchoring." Did I read that correctly?
25	A No. The Melody Transcatheter Pulmonary Valve	25	MR. BARUFKA: Objection, relevance.
Page 78		Page 80	
1	is another one.	1	A Yes.
2	Q In the case of that valve, was there guidance	2	Q What does "intra-annular anchoring" mean?
3	given to physicians as to where the valve ought to be	3	MR. BARUFKA: Objection, relevance.
4	placed?	4	A Per this statement, I would assume it means
5	MR. BARUFKA: Objection, relevance.	5	within the annulus.
6	A Yes.	6	Q Okay. And then if you look at the outflow
7	Q And in the case of both of those valves,	7	portion, it says, "sits in ascending aorta," correct?
8	misplacement would be a complication of the procedure for	8	MR. BARUFKA: Objection, relevance.
9	implantation?	9	A It does.
10	MR. BARUFKA: Objection, relevance.	10	Q So at least in the case of this valve, there is
11	A I don't know that I can speak to misplacement,	11	guidance given to the physician as to where the valve
12	off-label use of the product, or at the discretion of the	12	ought to be placed?
13	physician.	13	MR. BARUFKA: Objection, relevance.
14	Q Well, when you talk about the discretion of the	14	A Yes.
15	physician in relation to the CoreValve product, that	15	Q And you looked at -- we'll get into these in a
16	product is designed so that the proximal end of it fits	16	minute. But you said in your declaration you looked at
17	within the aortic annulus --	17	several patents in preparing the declaration, correct?
18	MR. BARUFKA: Objection, relevance.	18	A Yes.
19	Q -- correct?	19	MR. BARUFKA: Objection, relevance.
20	A It's designed to fit within the lower portion	20	Q And in those patents, did you see guidance
21	of the aortic root, yes.	21	given as to where those devices would be placed within
22	Q Specifically, the aortic annulus, correct?	22	the human anatomy?
23	A Depending on who you talk to. I mean, it --	23	A I don't remember specifically. Generally, they
24	the physician -- there's lots of debate around physicians	24	would refer to a valve or valves. But I don't know. I
25	and how they interpret placement of that device.	25	would have to look back at the specific references.

Page 81	Page 83
<p>1 Q Okay. I'm going to hand you Exhibit 2228 if I 2 could. 3 (Deposition Exhibit Number 2228 4 was marked for identification.) 5 Q This is a document that we pulled from the 6 internet. But I'm only handing it to you for one 7 purpose. If you could turn to the -- it's actually the 8 third page under "Potential Adverse Events." 9 A Okay. 10 Q I've highlighted, there's a bullet point right 11 there in the center. It says, "prosthetic valve 12 dysfunction including, but not limited to, fracture, 13 bending." Do you see where I'm reading from? 14 A I do. 15 Q And one of the dysfunctions listed is 16 "malposition (either too high or too low)/malplacement." 17 MR. BARUFKA: Objection, relevance. 18 A Yes, I see that. 19 Q So at least in the case of this valve, 20 malplacement is in fact an adverse event associated with 21 the device? 22 MR. BARUFKA: Objection, relevance. 23 A According to this document, yes. 24 Q And is that something that you in fact know to 25 be true based on your involvement with the product?</p>	<p>1 person of ordinary skill in the art? In other words, is 2 that what that means where you say "the ordinary person 3 in that field"? 4 MR. BARUFKA: Objection, privileged. Instruct 5 the witness not to answer. 6 Q And you won't answer that? 7 A No. 8 Q What I want to know is, with respect to 9 paragraph 31, are you defining there what it means to be 10 a person of ordinary skill in the art? I'm asking that 11 question because that language itself does not appear in 12 paragraph 31. Will you tell me that? 13 MR. BARUFKA: Objection, privileged. Instruct 14 the witness not to answer. 15 Q You say there now in paragraph 32, "I 16 understand that the relevant time frame for the person of 17 ordinary skill in the art" -- now, here that language 18 does appear -- "is around the time the '228 Patent was 19 filed, i.e., November 14, 2000. Thus, any comments I 20 make regarding the knowledge of the ordinary person are 21 in reference to that time frame." Did I read that 22 correctly? 23 A Yes. 24 Q Is that language that you came up with or that 25 your attorney or Medtronic's attorney provided to you?</p>
Page 82	Page 84
<p>1 MR. BARUFKA: Objection, relevance. 2 A Yes. 3 Q Your declaration, this was Exhibit 1026. If 4 you could turn back to it for just a moment, please. 5 A Okay. 6 Q You say -- there's a heading. It's on page 8. 7 "Level of Skill In the Art," do you see that heading? 8 A I do. 9 Q It says, "Based on my experience with the 10 design, development, and manufacture of percutaneous 11 heart valves, the ordinary person in that field would 12 typically have a bachelor's level degree in mechanical or 13 biomedical engineering (or gained such knowledge by 14 equivalent experience), and have had direct experience 15 developing heart valves." Did I read that correctly? 16 A Yes. 17 Q Is that language that you came up with or that 18 was given to you by Medtronic's attorneys? 19 MR. BARUFKA: Objection, privileged. Instruct 20 the witness not to answer. 21 Q And you will not answer that question? 22 A No. 23 Q Then it says -- well, let me ask you about that 24 language where there's a reference to "the ordinary 25 person in that field." Are you using that to mean a</p>	<p>1 MR. BARUFKA: Objection, privileged. Instruct 2 the witness not to answer. 3 Q If you look at that first -- or not first 4 paragraph, but paragraph 31, you're saying, or whoever 5 came up with this language is saying, "the ordinary 6 person in that field would typically have a bachelor's 7 level degree in mechanical or biomedical engineering." I 8 read that sentence correctly so far? 9 A Yes. 10 Q Okay. So is it true that, in your opinion, 11 there is no need for a person to have any sort of medical 12 education at all? 13 A For what purpose? 14 Q To be, as you state here, an "ordinary person 15 in that field," whatever that terminology means? 16 A I think part of mechanical and biomedical 17 training includes some medical education depending on how 18 you define it and how -- 19 Q Well, if you have -- I'm sorry. If you are in 20 the bachelor's program of mechanical engineering at the 21 school you went to, was there a requirement that you have 22 specific medical training of any kind? 23 A How do you define medical training? As in 24 becoming a medical doctor or -- 25 Q No. You don't have to take -- and we can look</p>

Page 85

1 it up if you want. I've got an internet connection. But
 2 it's true you do not have to take any classes in
 3 physiology or human anatomy or anything of that nature in
 4 order to get a bachelor's level degree in mechanical
 5 engineering, correct?
 6 **A I would agree with that in general, yes.**
 7 **Q Okay.**
 8 **A It probably changes per program depending on**
 9 **what school you're at, but in general.**
 10 **Q Okay. And as for biomedical engineering, do**
 11 **you know, is it required that you take classes in human**
 12 **anatomy, that sort of thing, to get that degree?**
 13 **A Typically.**
 14 **Q But as part of that, is it required that you**
 15 **take classes involving specifically the aorta or human**
 16 **circulatory system?**
 17 **A I think those would be covered in human anatomy**
 18 **and physiology requirements generally.**
 19 **Q So if you are a person that has that degree, a**
 20 **bachelor's in biomedical engineering, if you have that**
 21 **degree, then you might have had classes involving human**
 22 **anatomy, correct?**
 23 **A Right.**
 24 **Q But in the case of someone who's got a**
 25 **bachelor's level degree in mechanical engineering, that**

Page 86

1 person would not necessarily have those sort of classes,
 2 correct?
 3 **A They may not.**
 4 **Q Okay. Now, you say here that that person also**
 5 **have had -- should have had direct experience developing**
 6 **heart valves. Did I read that correctly?**
 7 **A Yes.**
 8 **Q And so is it sufficient for a person -- say a**
 9 **person with a bachelor's level degree in mechanical**
 10 **engineering, for that person to be working in his or her**
 11 **garage hammering out a rudimentary valve, is that**
 12 **sufficient experience developing heart valves to qualify**
 13 **as a person in the field?**
 14 **A It depends. Developing a heart valve or**
 15 **developing a valve for a pipe? What type of valve?**
 16 **Q Yeah. I mean, if I'm sitting in my garage, and**
 17 **I've got a bachelor's degree in mechanical engineering**
 18 **but no medical training at all, but I'm sitting in my**
 19 **garage, and I've got in front of me a book, say, the book**
 20 **that you helped edit, and I'm hashing out with chicken**
 21 **wire a mock-up of a heart valve, would I qualify, as**
 22 **you've defined it, as a person -- say, a person of**
 23 **ordinary skill in the art?**
 24 **A I think that would constitute, because I think**
 25 **the book -- the heart valve book or other book would be**

Page 87

1 **considered a part of education in the anatomy.**
 2 **Q Okay. Regardless of what book it is? I mean,**
 3 **what if it's a book -- say, a pamphlet I picked up at my**
 4 **physician's office? I mean, if I've got that pamphlet I**
 5 **picked up at my physician's office, I'm sitting in my**
 6 **garage, I've got chicken wire out there, and I'm working**
 7 **with tools to fashion a rudimentary valve, is that**
 8 **sufficient to qualify as a person of ordinary skill in**
 9 **the art?**
 10 **A I would say that would probably be a bit low in**
 11 **terms of ordinary skill in the art. But it's hard to**
 12 **deal in generalities. I don't know what the pamphlet**
 13 **states. I don't know what their --**
 14 **Q So the example I gave you, that person could**
 15 **qualify, but you don't have enough facts in front of you**
 16 **to know that?**
 17 **A Sure.**
 18 **Q Then you say, "I understand that the relevant**
 19 **time frame for the person of ordinary skill in the art is**
 20 **around the time the '228 Patent was filed, i.e.,**
 21 **November 14, 2000," correct?**
 22 **A That's what it says.**
 23 **Q Now, at that time, you were not involved in**
 24 **developing heart valves, correct?**
 25 **MR. BARUFKA: Objection, relevance.**

Page 88

1 **A I was not involved in developing heart valves.**
 2 **Q So as of the relevant time period, you would**
 3 **not have qualified, as you defined it, as a person of**
 4 **ordinary skill in the art, correct?**
 5 **MR. BARUFKA: Objection, relevance.**
 6 **A At that time period.**
 7 **Q Yeah. So you weren't -- as of November 14,**
 8 **2000, you weren't involved in developing, fashioning, or**
 9 **exploring these artificial valves?**
 10 **MR. BARUFKA: Objection, relevance.**
 11 **A Exploring the valves. As I mentioned, we were**
 12 **looking at them in the Visible Heart Laboratory and**
 13 **understanding them.**
 14 **Q But you had no direct experience developing**
 15 **them at that time, correct?**
 16 **A Correct.**
 17 **Q And you had not seen or treated any patients**
 18 **requiring a replacement valve?**
 19 **A I'm not a medical doctor.**
 20 **Q You have no experience with the condition of**
 21 **aortic stenosis, which typically gives rise to the need**
 22 **for the valve, correct?**
 23 **A Well, what do you mean by no experience?**
 24 **Q Well, let me focus the question. As of**
 25 **November 14, 2000, you hadn't treated, cared for, helped**

Page 89

1 treat or care for any patients suffering from any
 2 condition requiring use of a replacement valve?
 3 **A Other than the stuff that we did on the Visible**
 4 **Heart. So those patients that had the valves implanted,**
 5 **the excised hearts, would have likely been patients with**
 6 **aortic stenosis.**
 7 Q You didn't care for the patients at that
 8 time --
 9 **A I did not care for the patients.**
 10 Q -- because those patients were pretty much
 11 dead, right?
 12 **A I did not care for the patient.**
 13 Q Have you had any training at all in treating
 14 aortic stenosis, the condition?
 15 **A No. I'm not a medical doctor.**
 16 Q Okay. You didn't -- as of November 14, 2000,
 17 you hadn't yet obtained your doctorate, correct? You
 18 were still in the program at the University of Minnesota?
 19 **A Yes.**
 20 Q Had you gotten your master's degree at this
 21 point?
 22 **A I believe so. I'm not sure exactly on the**
 23 **timing. It would have been right around there.**
 24 Q Okay.
 25 **A It might have been 1999. I'm not exactly sure.**

Page 90

1 Q Look at paragraph 34, if you would, of your
 2 declaration. It says, "Placement and positioning of
 3 prosthetic aortic valves within the aorta is typically
 4 within the discretion of the physician." Did I read that
 5 correctly?
 6 **A Yes.**
 7 Q But it's true, as we've discussed, that valve
 8 manufacturers often tell a physician where they need to
 9 put the valve, right?
 10 **A Typically, based on interactions with**
 11 **physicians.**
 12 Q I mean, the CoreValve is designed again so that
 13 the proximal part of it goes within the aortic annulus,
 14 correct?
 15 **A Yes.**
 16 Q And then you say -- so to the extent a
 17 physician has any discretion, that discretion is
 18 controlled by what the design of the valve is?
 19 **A Physicians are able to do what they want with**
 20 **devices. It's protected. So they could put it wherever**
 21 **they want outside or within the instructions for use, as**
 22 **I understand it.**
 23 Q But they're told where the valve is supposed to
 24 go, correct?
 25 **A Within the instructions for use, yes.**

Page 91

1 Q And if they put it elsewhere, is that
 2 considered an off-label use?
 3 **A Yes.**
 4 Q And is an off-label use -- you say here, "It is
 5 well known by those skilled in the art that aortic valves
 6 can be placed at different positions within the aorta,
 7 such as the lower portions of the aortic root or more
 8 upwardly in the ascending aorta." Did I read that
 9 correctly?
 10 **A Yes.**
 11 Q Is that language you came up with, or did your
 12 attorneys give that to you to say?
 13 MR. BARUFKA: Objection, privileged. Instruct
 14 the witness not to answer.
 15 Q You won't answer that?
 16 **A No.**
 17 Q What would a person who's got a bachelor's in
 18 mechanical engineering but absolutely no medical
 19 training, what would that person know about the placement
 20 of an aortic valve within a live human patient?
 21 **A That is difficult to say for what a general**
 22 **person would know. I would have to look at their**
 23 **training to understand classes they took and so forth and**
 24 **experiences they have had.**
 25 Q Well, you're saying, "It" -- I think there's a

Page 92

1 typo here, but you're saying, "It is well known by those
 2 skilled in the art that aortic valves can be placed at
 3 different positions within the aorta." What's your basis
 4 for saying that?
 5 **A My basis for saying that is looking at valves**
 6 **that were and had been developed at the time. So I would**
 7 **assume that a person with a bachelor's in mechanical**
 8 **engineering that was going to develop a mechanical valve**
 9 **would look at literature, would look at other valves.**
 10 So --
 11 Q You said -- go ahead.
 12 **A So it can't be true for everyone. But by**
 13 **looking at what historical surgical valves were placed,**
 14 **you would say that they would be -- possible to be placed**
 15 **anywhere in the aorta.**
 16 Q You said you would assume that, correct? That
 17 was the language you used?
 18 **A Yeah.**
 19 Q That's an assumption you're making?
 20 **A Uh-huh.**
 21 Q That's correct?
 22 **A Yes.**
 23 Q That's not something you verified through
 24 conversations with people who were placing these valves
 25 at this time period, correct?

Page 93	Page 95
<p>1 A No. I did not converse with physicians placing 2 these valves.</p>	<p>1 place. So I didn't trust myself. And I don't do</p>
<p>3 Q And in fact, in this time period, the relevant 4 time period, November 2000, there were not percutaneous 5 valves available for placement within live human 6 subjects?</p>	<p>2 this. I mean, they make us put all this language on 3 these labels. This would not be my choice. I would 4 just put one, two, three, four, but we can't do that 5 here, so.</p>
<p>7 A I'm not sure if the Melody valve was in 8 development at that time if you're talking specifically 9 aortic. I'm not sure on the timing as well when the 10 first aortic valves were placed, the percutaneous aortic 11 valves.</p>	<p>6 Q Okay. Take a look at this Exhibit 2003, if you 7 would. Did you look at this Exhibit 2003 in preparing 8 your declaration or assisting your attorney to prepare 9 your declaration?</p>
<p>12 Q But when you say, "It is well known by those 13 skilled in the art that aortic valves can be placed at 14 different positions within the aorta," you were making 15 that assumption based upon your review of valves that 16 were in development during the 2000 time period?</p>	<p>10 A I believe this was in the declaration of 11 Dr. Norred.</p>
<p>17 A That were released.</p>	<p>12 Q And you skimmed, you said --</p>
<p>18 Q What valves were released during that time 19 period that support your assumption?</p>	<p>13 A Skimmed that.</p>
<p>20 A There were typically mechanical valves and 21 tissue valves. I don't know the specific names and when 22 they came out, but --</p>	<p>14 Q -- that declaration?</p>
<p>23 Q Is your assumption based upon consideration of 24 any percutaneously placed aortic valves?</p>	<p>15 A Yeah.</p>
<p>25 A Based on the time period of this patent, no.</p>	<p>16 Q If you look at the diagram shown in 17 Exhibit 2003, there are the words "aortic valve." Do you 18 see those words there?</p>
	<p>19 A On the left and -- yes.</p>
	<p>20 Q And it's pointing to this figure. It looks 21 like a ring with three intersecting lines in it. Do you 22 see that figure?</p>
	<p>23 A Yeah. This circle here?</p>
	<p>24 Q Correct. And can you tell me, is that a 25 typical way to represent a tricuspid valve in a schematic</p>
Page 94	Page 96
<p>1 Q So your assumption is based on surgically 2 placed mechanical valves?</p>	<p>1 drawing?</p>
<p>3 A Yes.</p>	<p>2 A Outside of the rest of the aorta, yes. 3 (Deposition Exhibit Number 2229 4 was marked for identification.)</p>
<p>4 Q Okay. With respect to placement of the valve 5 as you referenced in paragraph 34, it's correct that the 6 valve cannot be placed in a manner which would block the 7 coronary artery.</p>	<p>5 Q And in fact, take a look at 2229, if you would. 6 MR. BARUFKA: Objection, relevance.</p>
<p>8 A That would be less than ideal to place a valve 9 to block the coronary artery, yes.</p>	<p>7 Q 2229 is a patent issued to you and other 8 inventors and then assigned to Medtronic, correct?</p>
<p>10 Q It would kill the patient, wouldn't it?</p>	<p>9 MR. BARUFKA: Objection --</p>
<p>11 A If it completely blocked it, potentially.</p>	<p>10 A Yes.</p>
<p>12 Q And so in the case of the natural valve, when 13 the natural valve closes, blood still flows and is 14 allowed to flow backwards into the aortic root and 15 through the coronary arteries in order to supply the 16 heart, correct?</p>	<p>11 MR. BARUFKA: I'm sorry. Objection, relevance.</p>
<p>17 A Yes.</p>	<p>12 Q And if we look at the second page of that, 13 there are some figures depicted?</p>
<p>18 Q If you were to place that valve -- an 19 artificial valve in a position where when it closed it 20 prevented the backflow of blood in the coronary arteries, 21 that would be fatal to the patient?</p>	<p>14 A Yes.</p>
<p>22 A Typically, yes.</p>	<p>15 MR. BARUFKA: Objection, relevance.</p>
<p>23 MR. MARCUS: I don't have this many exhibits.</p>	<p>16 Q And one of the figures depicted there, 17 Figure 2, that is a schematic drawing of a tricuspid 18 valve?</p>
<p>24 I had her make me multiple copies because I realized</p>	<p>19 MR. BARUFKA: Objection, relevance.</p>
<p>25 I would burn many of these putting them in the wrong</p>	<p>20 A A trileaflet valve, yes.</p>
	<p>21 Q Is there a difference? And I don't know the 22 answer. That's why I'm asking. Is there a difference 23 between tricuspid and trileaflet?</p>
	<p>24 A Anatomically, when you use the term 25 "tricuspid," you usually refer to the right</p>

Page 97	Page 99
<p>1 atrioventricular valve.</p> <p>2 Q I see.</p> <p>3 A So that's why I keep saying trileaflet.</p> <p>4 Q Okay. But in terms of a valve that has three</p> <p>5 leaflets, what we're seeing in Figure 2, that's what</p> <p>6 Figure 2 depicts --</p> <p>7 A Yes.</p> <p>8 Q -- a valve with three leaflets?</p> <p>9 A Yes.</p> <p>10 Q Are these drawings we see on this page, page 3,</p> <p>11 are these to scale?</p> <p>12 MR. BARUFKA: Objection, relevance.</p> <p>13 A I would have to review the patent. I know it's</p> <p>14 my patent, but it's been a while. Would you like me to</p> <p>15 review it?</p> <p>16 Q Yeah. I mean, if you think you can tell me if</p> <p>17 these drawings are to scale, I would like you to tell me</p> <p>18 that. I mean, if you can't, then that's fine, too. But</p> <p>19 see if that's something you can answer.</p> <p>20 MR. BARUFKA: Objection, relevance.</p> <p>21 A (Perusing document.) I don't see anything in</p> <p>22 here that says one way or the other that they're drawn to</p> <p>23 scale.</p> <p>24 Q Is it correct that even if a drawing is not to</p> <p>25 scale, it can still be useful in helping illustrate how</p>	<p>1 second open end displaced therefrom, said means moving</p> <p>2 said membrane second end between a first open position to</p> <p>3 allow a blood flow therethrough and a second closed</p> <p>4 position to preclude a blood flow therethrough." Did I</p> <p>5 read that correctly?</p> <p>6 A Yes.</p> <p>7 Q And so I want to ask you about your</p> <p>8 interpretation of this claim. You see the first section</p> <p>9 where it refers to a ring member?</p> <p>10 A Yes.</p> <p>11 Q This is column 8.</p> <p>12 A Yes.</p> <p>13 Q So you would interpret this claim to include a</p> <p>14 ring member?</p> <p>15 A Uh-huh.</p> <p>16 Q That's a yes?</p> <p>17 A Yes.</p> <p>18 Q And specifically one that is adapted to seat</p> <p>19 about an aortic wall?</p> <p>20 A Yes.</p> <p>21 Q Did you construe this to mean that the ring</p> <p>22 member must be in contact with the aortic wall?</p> <p>23 A Yes.</p> <p>24 Q This also refers to a membrane. Do you see</p> <p>25 that reference to a membrane?</p>
<p>Page 98</p> <p>1 an invention is intended to function?</p> <p>2 A I would agree with that.</p> <p>3 Q One of the things you looked at for certain in</p> <p>4 preparing your declaration is the '228 patent, correct?</p> <p>5 A Yes.</p> <p>6 Q Let me hand you a copy of that if I could.</p> <p>7 This is Exhibit 1001. And you looked at in particular</p> <p>8 claims 16 and -- well, you looked at claim 16 for sure.</p> <p>9 You looked at 17, 18, 19, and 20 as well? Or what other</p> <p>10 claims did you look at?</p> <p>11 A With respect to my declaration, I commented on</p> <p>12 claims 16 and 20.</p> <p>13 Q Okay. And if we look at claim 16, this is</p> <p>14 on -- it's column 7, if you could find that in the</p> <p>15 document. It's page 12 of the document. It says, "An</p> <p>16 aortic valve for regulating a blood flow through an</p> <p>17 aortic channel surrounded by an aortic wall upon</p> <p>18 placement therein, said valve comprising: a ring member</p> <p>19 having a circumference adapted to seat about an aortic</p> <p>20 wall surrounding an aortic channel, said ring including</p> <p>21 an aperture for blood flow therethrough; a membrane</p> <p>22 having first and second spaced-apart open ends, said</p> <p>23 membrane made of a material resistant to a fluid flow</p> <p>24 therethrough; and means for mounting said first open end</p> <p>25 of said membrane about said ring aperture with said</p>	<p>Page 100</p> <p>1 A Yes.</p> <p>2 Q It says, again, "a membrane having first and</p> <p>3 second spaced-apart open ends." Do you agree with me</p> <p>4 that the dictionary definition of the term "membrane"</p> <p>5 would include a tissue membrane?</p> <p>6 A A dictionary definition?</p> <p>7 Q Correct.</p> <p>8 A Yes.</p> <p>9 Q Have you heard -- I mean, did you look at the</p> <p>10 dictionary definition of membrane when you drafted your</p> <p>11 declaration?</p> <p>12 A I did not.</p> <p>13 Q Have you heard in your experience the term</p> <p>14 "membrane" to be defined as a thin, soft, pliable sheet</p> <p>15 or layer?</p> <p>16 A I believe so. I'm not sure exactly where.</p> <p>17 It's in this patent or one of the other patents that I</p> <p>18 reviewed.</p> <p>19 Q And you would agree with me that the claim</p> <p>20 term, the term "membrane" must be given its broadest</p> <p>21 reasonable interpretation?</p> <p>22 A Yes.</p> <p>23 Q Do you believe the broadest reasonable</p> <p>24 interpretation of the term "membrane" includes tissue?</p> <p>25 A If we go outside of the patent, yes, as you</p>

Page 101	Page 103
<p>1 mentioned the dictionary term. I think within this</p> <p>2 patent they're used distinctly.</p> <p>3 Q Is it true -- in this patent there are several</p> <p>4 embodiments of the invention, are there not?</p> <p>5 A Yes.</p> <p>6 Q Is it true that each of the embodiments we see,</p> <p>7 for example, in Figures -- there's Figures 6, 7, 8, 9,</p> <p>8 10, 11, 12, 13. Each of these embodiments could be</p> <p>9 constructed utilizing tissue?</p> <p>10 A 6, 7, 8, 9.</p> <p>11 MR. BARUFKA: Objection, relevance.</p> <p>12 A They could be.</p> <p>13 Q You could use, in fact, tissue to produce any</p> <p>14 of the embodiments referenced in the '228 patent, any of</p> <p>15 the embodiments of the invention?</p> <p>16 MR. BARUFKA: Objection, relevance.</p> <p>17 A Any of the valve embodiments?</p> <p>18 Q Correct.</p> <p>19 A There's more than just valves embodied here.</p> <p>20 Q No. And that's a good clarification. With</p> <p>21 respect to the valve embodiments, the specific part of</p> <p>22 the device that's the valve itself, those structures --</p> <p>23 all of the structures shown in the '228 patent could be</p> <p>24 manufactured utilizing tissue?</p> <p>25 MR. BARUFKA: Objection, relevance.</p>	<p>1 MR. BARUFKA: Objection, privileged. Instruct</p> <p>2 the witness not to answer.</p> <p>3 Q Were you told that the board defined "membrane"</p> <p>4 broader than simply an artificial membrane?</p> <p>5 MR. BARUFKA: Objection, privileged. Instruct</p> <p>6 the witness not to answer.</p> <p>7 Q Were you told that the board interpreted the</p> <p>8 term "membrane" such that it would encompass a tissue</p> <p>9 membrane?</p> <p>10 MR. BARUFKA: Objection, privileged. Instruct</p> <p>11 the witness not to answer.</p> <p>12 Q And I take it with respect to those</p> <p>13 instructions, you will follow them, correct?</p> <p>14 A Yes.</p> <p>15 Q Do you believe that as you were being asked to</p> <p>16 prepare your declaration, you should have been told what</p> <p>17 the board's definition of the term "membrane" was?</p> <p>18 MR. BARUFKA: Objection, form; objection,</p> <p>19 relevance.</p> <p>20 A I don't know how to answer that. I don't know</p> <p>21 if -- I apologize. This is my first deposition. I don't</p> <p>22 understand the process --</p> <p>23 Q Yeah.</p> <p>24 A -- and what the important aspects are.</p> <p>25 Q I mean, you were asked by your employer --</p>
<p>Page 102</p> <p>1 A I think if I look at Figures 18 and 19, those</p> <p>2 are the ones I would question. The figures are a bit</p> <p>3 confusing as to how the tissue would work in that</p> <p>4 configuration. But I think the others, it's likely that</p> <p>5 they could function with tissue.</p> <p>6 Q If we look at how Figure 19 is described -- and</p> <p>7 that's column 2. Do you see column 2 in the '228 patent?</p> <p>8 A Uh-huh.</p> <p>9 Q Figure 18 is described as a "diagrammatic view</p> <p>10 of a cadaver/porcine incorporated valve and stent</p> <p>11 system," correct?</p> <p>12 A Yes.</p> <p>13 Q Figure 9 [sic] is a "plan view of the</p> <p>14 cadaver/porcine valve of Figure 18," correct?</p> <p>15 A Figure 19?</p> <p>16 Q Correct.</p> <p>17 A That is what the text says, yes.</p> <p>18 Q And you're aware the board -- were you provided</p> <p>19 with the order where the board -- the patent board</p> <p>20 defined each of the terms set forth or certain of the</p> <p>21 terms set forth in the '228 patent?</p> <p>22 A I don't recall if I was provided that.</p> <p>23 Q Were you told how the board -- the Patent Trial</p> <p>24 and Appeal Board defined the term "membrane" in the '228</p> <p>25 patent?</p>	<p>Page 104</p> <p>1 A Uh-huh.</p> <p>2 Q -- to submit a declaration, right?</p> <p>3 A Yes.</p> <p>4 Q And a declaration that you were being asked to</p> <p>5 affix your signature to, correct?</p> <p>6 A Yes.</p> <p>7 Q And to say what was in the declaration was</p> <p>8 truthful to the best of your knowledge, correct?</p> <p>9 A Yes.</p> <p>10 Q And one of the things that you offered or</p> <p>11 purported to offer an opinion on was what the term</p> <p>12 "membrane" meant, correct?</p> <p>13 A Yes.</p> <p>14 Q And in offering that opinion, do you think</p> <p>15 it would have been helpful to know how the Patent</p> <p>16 Trademark [sic] and Appeal Board interpreted that</p> <p>17 exact same term?</p> <p>18 MR. BARUFKA: Objection, relevance.</p> <p>19 A It may have been helpful.</p> <p>20 Q So as you sit here, can you tell me, were you</p> <p>21 told how the Patent Trademark [sic] and Appeal Board</p> <p>22 interpreted that same term?</p> <p>23 MR. BARUFKA: Objection, privilege. Instruct</p> <p>24 the witness not to answer.</p> <p>25 Q Let me ask you this. Each of the valve</p>

Page 105

1 structures shown in the '228 patent in the embodiments,
 2 are they all passive structures?
 3 **A Can I have some time to re-read?**
 4 **Q Sure.**
 5 **A (Perusing document.) So it describes not**
 6 **directly in figures -- the description of the figures to**
 7 **the umbrella valve, that it would open based on pressure**
 8 **as we described earlier. It doesn't say it's passive**
 9 **directly.**
 10 **Q But when it says it would open based on**
 11 **pressure, would you interpret that to mean that it's a**
 12 **passive valve?**
 13 **A I would think so, yes.**
 14 **Q So that what is causing it to open and close**
 15 **are pressure changes within the aorta, correct?**
 16 **A It's pressure changes within the ventricle and**
 17 **the aorta.**
 18 **Q Okay. Yeah. I mean, there are pressures**
 19 **within the ventricle and the aorta. And the changes in**
 20 **pressure between those two compartments caused the aortic**
 21 **valve to open and close?**
 22 **A Yes.**
 23 **Q And that would be true with both the natural**
 24 **valve and the umbrella valve depicted in these figures in**
 25 **the '228 patent?**

Page 106

1 **A I would think so.**
 2 **Q What about the other valves we see here**
 3 **depicted in the embodiments in the '228 patent,**
 4 **Figures 10 -- I think Figures 10 through 13. That's one**
 5 **valve structure. Is that also a passive structure?**
 6 **A I would believe so. I don't -- again, I don't**
 7 **know for sure if it says it here, but I would imagine**
 8 **that it would open and close based on pressure.**
 9 **Q And is the same true with Figures 14 through**
 10 **17?**
 11 **A Yes.**
 12 **Q So what's causing those valves to function,**
 13 **meaning open and close, are changes in the pressure**
 14 **gradient between the left ventricle and the aorta?**
 15 **A Yes.**
 16 **Q Now, in the case of the natural valve, it works**
 17 **the same way, does it not, in the sense that pressure**
 18 **changes between the left ventricle and the aorta cause**
 19 **the leaflets to open and close?**
 20 **A Yes.**
 21 **Q And in the natural valve, those leaflets,**
 22 **they're tissue leaflets, correct?**
 23 **A Yes.**
 24 **Q That's three soft tissue leaflets which come**
 25 **together or coapt in the center of the valve?**

Page 107

1 **A In the normal valve they would be -- that's**
 2 **exactly what they do, yes.**
 3 **Q And these tissue leaflets, when the pressure**
 4 **gradient changes between the left ventricle and the**
 5 **aorta, that causes them to, as we discussed earlier, open**
 6 **or close depending upon whether the cardiac cycle is in**
 7 **systole or diastole, correct?**
 8 **A Yes.**
 9 **Q And those tissues, the three tissue leaflets,**
 10 **those tissues attach to the aortic wall in the semilunar**
 11 **pattern that we talked about earlier?**
 12 **A In the native valve?**
 13 **Q Correct.**
 14 **A Yes.**
 15 **Q Okay. There is no separate structure within**
 16 **the leaflets which facilitate them opening and closing,**
 17 **correct?**
 18 **A Not to my knowledge.**
 19 **Q The tissue itself in the native valve acts as a**
 20 **hinge for the leaflet to swing open and closed?**
 21 **A Which tissue?**
 22 **Q The tissue that comprises the leaflets -- each**
 23 **of the three leaflets of the valve?**
 24 **A The tissue acts as a hinge?**
 25 **Q Yeah. The tissue connects directly to the**

Page 108

1 aortic wall, correct?
 2 **A The leaflets connect to the aortic wall.**
 3 **Q I'm sorry. Yeah. Let me back up because I**
 4 **want to make sure we're describing this correctly.**
 5 **A Okay.**
 6 **Q The leaflets are made of tissue, correct?**
 7 **A In the native valve.**
 8 **Q Correct.**
 9 **A Yes.**
 10 **Q And we're talking about the native valve. And**
 11 **the tissue of the leaflets connects to the aortic wall,**
 12 **correct?**
 13 **A Yeah. You can say that, yes.**
 14 **Q Yeah. And it connects in the semilunar fashion**
 15 **as we talked about earlier, correct?**
 16 **A Uh-huh.**
 17 **Q That's a yes?**
 18 **A Uh-huh. Sorry. I was drinking. Yes.**
 19 **Q No. That's fine. And the high point of the**
 20 **connection is known as the commissure, correct?**
 21 **A Yeah. The commissure -- there's different**
 22 **definitions. I would say that's the highest point where**
 23 **the leaflets meet, yes.**
 24 **Q Where the leaflets coapt on that end?**
 25 **A Adjacent leaflets come together, yes.**

Page 109	Page 111
<p>1 Q Okay. And so when the pressure changes, those 2 leaflets -- each of the leaflets swing either open or 3 closed depending upon where the pressure is within the 4 aorta and the ventricle?</p>	<p>1 well.</p>
<p>5 A Yes. They open and close based on pressure 6 differences.</p>	<p>2 Q Well, what structures would you have to remove? 3 I mean, if you remove the valve itself and then cut away 4 that section of the aortic wall, then if you did that, 5 what you would be left with is a porcine valve that has 6 the semilunar attachments around its outer circumference.</p>
<p>7 Q Okay. There's no separate structure within any 8 of the leaflets causing them to do that. It's the 9 pressure changes that cause that motion?</p>	<p>7 A Which parts of the aortic wall are you 8 removing? Are you removing only within the sinus or 9 everything? I think you need to maintain some of it to 10 maintain that structure.</p>
<p>10 A There -- I mean, I don't fully understand the 11 microstructure of the leaflets. But I have heard that 12 there are different bands of collagen that are arrayed 13 within the leaflets that do aid in the opening and 14 closing, but I'm not --</p>	<p>11 Q Yeah. You would have to remove the part 12 encompassing where the attachment is, right? Wherever 13 the semilunar attachment is on the wall, you would have 14 to remove that whole part of the wall if you want to 15 maintain that same semilunar attachment?</p>
<p>15 Q That's not something you're --</p>	<p>16 A I think, yeah. I mean, I think you would have 17 to leave -- there would have to be some residual 18 structure to maintain the semilunar. I think if you cut 19 it out too far, it would flatten out.</p>
<p>16 A -- exactly well-versed in that. No.</p>	<p>20 Q But if you did that, and you cut that out and 21 maintained the structure so you had the semilunar 22 structure and these tissue valves, then if that was 23 installed in a system where you had the same pressure 24 gradients, would that valve open and close as the native 25 valve does?</p>
<p>17 Q That's not something you're offering an opinion 18 on here today, correct?</p>	
<p>19 A No.</p>	
<p>20 Q Okay. So if you take then an artificial valve 21 comprised of tissue leaflets, and those tissue leaflets 22 in the artificial valve were arranged in the same fashion 23 as they are in the native valve in the sense that they 24 are attached to a ring structure and then coapt in the 25 center of the valve, would that not function the same way</p>	
Page 110	Page 112
<p>1 if it was exposed to the same pressure gradient?</p>	<p>1 A Depends on what those structures are attached.</p>
<p>2 A What is the ring structure? Is it planar, or 3 is it the same semilunar that we've just described as the 4 attachment in the native leaflets?</p>	<p>2 Q But it could?</p>
<p>5 Q Yeah. I mean, does it matter?</p>	<p>3 A If it was attached correctly, yeah.</p>
<p>6 A It does.</p>	<p>4 Q There would be no need in the case of that 5 structure to include another component to cause the valve 6 to open and close so long as the valve was exposed to the 7 changes in pressure from the ventricle to the aorta?</p>
<p>7 Q And how does it matter?</p>	<p>8 A I think it would need to be attached to a ring 9 member that is of a semilunar shape. I think you need to 10 recreate the structure that you removed when you removed 11 the valve for those to work.</p>
<p>8 A I think the attachment of the native leaflets 9 in that semilunar fashion is what allows them to open and 10 close and reduce stresses across those --</p>	<p>12 Q Yeah. Maybe we're not communicating. If you 13 pull out the valve -- I mean, if I'm doing the surgery 14 and I go in and I cut out the porcine valve and I really 15 just snip out the circumference of the valve --</p>
<p>11 Q And you've --</p>	<p>16 A Including the wall or just only --</p>
<p>12 A -- leaflets during the cycles.</p>	<p>17 Q No. Including --</p>
<p>13 Q You've had experience with porcine valves?</p>	<p>18 A -- the valve leaflets?</p>
<p>14 A Like porcine heart valves that are removed or 15 other porcine tissue used to create valves?</p>	<p>19 Q -- the wall.</p>
<p>16 Q Have you had experience with both or either?</p>	<p>20 A Okay.</p>
<p>17 A Yes.</p>	<p>21 Q I'd include it. I snip that whole thing apart, 22 so I get the semilunar attachment. I remove the 23 entire --</p>
<p>18 Q And in the case of a porcine valve that's 19 removed, that valve attaches also in a semilunar fashion?</p>	<p>24 A Are you removing the entire aortic root?</p>
<p>20 A If the structures are maintained upon removal.</p>	<p>25 Q Let me back up because you don't need the root.</p>
<p>21 Q Yeah. If you remove that porcine valve in one 22 piece, it's going to show an attachment that's also 23 semilunar in shape for each of the three leaflets?</p>	
<p>24 A Yeah. If you remove the valve in its entirety, 25 yes, it would still -- with the surrounding structures as</p>	

Page 113

1 I mean, the whole root, it doesn't attach -- well, let me
 2 back up and ask the question. Would you have to remove
 3 the root in its entirety to preserve the semilunar shape?
 4 **A** If you aren't going to attach it to something
 5 else.
 6 **Q** If you attached it to a -- you remove the
 7 valve, and you attach it to a ring that because of the
 8 manner of attachment preserved the semilunar shape of the
 9 attachment, would you end up with a valve that opened and
 10 closed in response to pressure changes?
 11 **A** Again, is it a planar ring, so is it on a
 12 table? Is that what we're referring to?
 13 **Q** When you say planar ring --
 14 **A** I mean on a plane.
 15 **Q** -- I don't know what that means.
 16 **A** On a plane, so like would the ring sit down on
 17 this table?
 18 **Q** Well, I mean, if it sat on a table, you
 19 wouldn't have pressure -- changes in pressure gradient.
 20 So I don't -- I mean --
 21 **A** Well, a plane is defined by any three points.
 22 You can define a plane. So is that ring on a plane in
 23 space? Doesn't matter what plane.
 24 **Q** Okay. If you had a ring that was of sufficient
 25 depth, so now you've got a root, but it's of sufficient

Page 114

1 depth to allow the porcine valve to be attached to it in
 2 a manner that preserved the semilunar shape of the
 3 attachments, would that valve when installed in the human
 4 system open and close?
 5 **A** So there -- pardon my questions. But so the
 6 ring spans the height of the attachment from the bottom
 7 of the leaflet to the commissures?
 8 **Q** Yeah. The ring --
 9 **A** Is that what you're suggesting?
 10 **Q** Yeah. The ring is sufficient to allow the
 11 semilunar shape of the attachment to be maintained.
 12 That's the ring we're talking about.
 13 **MR. BARUFKA:** Objection as to form.
 14 **A** Okay. I can envision that that would work.
 15 There may be other challenges with it as well, though.
 16 **Q** But you could envision that that would work?
 17 **A** I could envision that it could support the
 18 valve leaflets. I don't know that it would work in the
 19 patient without covering the coronaries or causing other
 20 problems.
 21 **Q** Yeah. It's important if you have any -- this
 22 valve or any artificial valve that you not block the
 23 coronaries, right?
 24 **A** Uh-huh.
 25 **Q** So when you place this valve or any other

Page 115

1 valve, you need to place it where you're not going to
 2 cause that obstruction.
 3 **A** Yeah. So I guess, as I understand it, what
 4 we're talking about with our ring is rather than it being
 5 this thin, it's this tall, and it surrounds the entirety
 6 of the valve, so I would find it hard to understand how
 7 that would be placed within the aortic root without
 8 blocking the coronaries.
 9 **Q** You would have to place it where it didn't
 10 block the coronaries, correct?
 11 **A** Right. But just thinking about it
 12 anatomically, I don't know where that placement would be.
 13 **Q** But if you did place it where it didn't block
 14 the coronaries, you would have an operable valve that
 15 would open and close in responses to changes in pressure?
 16 **A** Potentially, yes.
 17 **Q** Just if you could go back to Exhibit 2229 for a
 18 second.
 19 **A** Okay.
 20 **MR. BARUFKA:** I'm going to object as to
 21 relevance.
 22 **Q** Are the valves shown in this exhibit -- the
 23 trileaflet valves shown in this exhibit, is this in a
 24 planar configuration?
 25 **A** The valve leaflets were intended to be planar,

Page 116

1 I believe, in this configuration, yes.
 2 **Q** Would these -- would this open and close in
 3 response to changes within the arterial and ventricle
 4 system -- ventricular system?
 5 **MR. BARUFKA:** Objection, relevance.
 6 **A** I would have to read through the entirety of
 7 the patent again to fully answer that question. Would
 8 you like me to do that?
 9 **Q** Do you know sitting here -- I may want you to
 10 do that. But do you know sitting here whether the valves
 11 you've depicted in your patent, Exhibit 2229, do you know
 12 whether those valves will open and close?
 13 **MR. BARUFKA:** Objection, relevance.
 14 **A** The reason for the invention was that they
 15 would open and close. It was a different way to support
 16 the valve leaflets, I believe.
 17 **Q** You don't show -- at least I don't see here,
 18 but tell me. I may be wrong. You don't show
 19 preservation of a particular shaped attachment, do you?
 20 **MR. BARUFKA:** Objection, relevance.
 21 **A** No. But this is replacing that attachment with
 22 other structures to mitigate the loss of that structure
 23 as I understand the patent. I would have to review it to
 24 be more specific.
 25 **Q** Do you see anywhere in Exhibit 1001, the '228

Page 117	Page 119
<p>1 patent, where Dr. Norred excludes the preservation of a 2 semilunar attachment? And this is in reference to 3 Figures 18 and 19.</p> <p>4 A Figures 18 and 19, again, it looks planar to 5 me. Additionally, the connecting rods look like they 6 connect across where the leaflets tissue membrane would 7 be. So I'm not sure how this valve would work.</p> <p>8 Q Did you read Dr. Norred's description of how 9 this valve would work in his deposition?</p> <p>10 A In his deposition, no. I think I read his 11 declaration. I don't believe I read his deposition.</p> <p>12 Q If Dr. Norred provided in his deposition a 13 description of how this valve would work, would that be 14 something you would want to have before you as you opined 15 about its operability?</p> <p>16 MR. BARUFKA: Objection to form; objection, 17 relevance.</p> <p>18 A I think it could help shed light on it, but I 19 was instructed to look at prior art and what's in the 20 patent as I understood this.</p> <p>21 Q Do you think -- were you made aware that 22 Dr. Norred's deposition had been taken in this matter?</p> <p>23 A I don't know actually if I was aware that he 24 had a deposition. I know he had a declaration. I know 25 that Dr. Catchings had a declaration and a deposition.</p>	<p>1 used, you would look both at the structures in the claim 2 but also at equivalents of those structures, correct?</p> <p>3 A Yes.</p> <p>4 Q And so in the case of Figures 18 and 19, those 5 figures specifically call out a cadaver/porcine valve and 6 stent system?</p> <p>7 A That is what the description says.</p> <p>8 Q And you could look to both those particular 9 structures as well as equivalents to those structures in 10 determining what the scope of claim -- or what the scope 11 of the patent is?</p> <p>12 MR. BARUFKA: Objection as to form.</p> <p>13 A Can you repeat that one more time?</p> <p>14 Q Yeah. I mean, Figures 18 and 19 specifically 15 call out a cadaver/porcine valve, correct?</p> <p>16 A That's what the description says, yes.</p> <p>17 Q And you know from your experience what a 18 cadaver/porcine valve looks like, correct?</p> <p>19 A Yes.</p> <p>20 Q And you know from your preparation for your 21 deposition and your declaration that in interpreting a 22 claim that contains a means language -- means plus 23 function language, in interpreting that claim, you look 24 both to the structure set forth in the patent but also to 25 equivalents of those structures?</p>
<p>Page 118</p> <p>1 I'm not sure about Dr. Norred.</p> <p>2 Q Okay.</p> <p>3 A I take that back. Yes, I do know. I found out 4 last night.</p> <p>5 Q That his deposition was taken?</p> <p>6 A That he had a deposition, yes.</p> <p>7 Q Did you ask at that point whether you could 8 review Dr. Norred's deposition in preparation for your 9 testimony today?</p> <p>10 MR. BARUFKA: Objection, privileged. Instruct 11 the witness not to answer.</p> <p>12 Q Were you given -- at the time you became aware 13 that the inventor's deposition had been taken, were you 14 given a copy of the deposition so you could look at it in 15 preparation for your deposition here today?</p> <p>16 A No, I was not.</p> <p>17 Q And to get back to my other question -- and 18 before I do that, you would agree, and I think you said 19 at the outset of your deposition and in your declaration 20 that the embodiments depicted in the patent do not limit 21 the scope of the claim, correct?</p> <p>22 MR. BARUFKA: Objection as to form; objection 23 as to relevance.</p> <p>24 A Unless the means for language is used.</p> <p>25 Q And in the case where the means for language is</p>	<p>Page 120</p> <p>1 MR. BARUFKA: Objection as to form.</p> <p>2 A Yes.</p> <p>3 Q And so claim 16 would encompass what we see 4 here depicted in these figures as well as any equivalents 5 to what we see here depicted in these figures?</p> <p>6 A I would say that's correct, yes.</p> <p>7 MR. MARCUS: Let's go ahead and go off the 8 record. (Lunch break, 12:13 p.m. until 1:23 p.m.)</p> <p>9 BY MR. MARCUS:</p> <p>10 Q I want to pick up on where we left off when we 11 broke, if I could. The '228 patent has been marked 12 Exhibit 1001, and I see you've got that in front of you.</p> <p>13 A Yes.</p> <p>14 Q And we looked at claim 16 earlier. Do you 15 recall looking at that claim as we went through your 16 deposition testimony this morning?</p> <p>17 A Yes.</p> <p>18 Q And as you interpret that claim, that claim 19 includes a structure called out as a ring member?</p> <p>20 A Yes.</p> <p>21 Q And that ring member is seated against the 22 aortic wall?</p> <p>23 A Yes.</p> <p>24 Q And then attached to that ring member is a</p>

Page 121

1 membrane?

2 **A Yes.**

3 **Q And we looked at Figures 18 and 19 earlier**

4 **today, did we not?**

5 **A Yes.**

6 **Q And those figures that we looked at are**

7 **specifically described in the text of the patent in the**

8 **specification?**

9 **A Yes -- is that a question? Yes.**

10 **MR. BARUFKA: Object to the form.**

11 **Q If we look at the text of the patent, there's a**

12 **heading under column 2 "Brief Description of the**

13 **Drawings"?**

14 **A Yes.**

15 **Q And in the description for Figure 18, it says,**

16 **"Figure 18 is a diagrammatic view of a cadaver/porcine**

17 **incorporated valve and stent system," correct?**

18 **A That's what it says.**

19 **Q Likewise, for Figure 19, it says that's "a plan**

20 **view of the cadaver/porcine valve of Figure 18," correct?**

21 **A Yes.**

22 **Q And a cadaver/porcine valve -- let's just**

23 **focus, I suppose, on the cadaver valve for a moment. A**

24 **cadaver valve, that has a defined structure, does it not?**

25 **A Depends -- I mean, the structure could be**

Page 122

1 **different depending on how it was extracted, but yes.**

2 **Q If you looked -- you said you participated in**

3 **the Visible Heart project?**

4 **A Yeah.**

5 **Q And so in that project, you were able to look**

6 **at a natural valve in a human heart, correct?**

7 **A Yes.**

8 **Q And as you observed that valve -- would that**

9 **be -- let me ask it this way. Would that be considered a**

10 **cadaver valve?**

11 **A It's tough to say. We've reanimated the heart.**

12 **I mean, I think in this respect, the way I would**

13 **interpret this would be that it's a cadaver tissue that's**

14 **preserved to be used in an application such as this. The**

15 **Visible Heart specimens aren't preserved to be used for**

16 **reuse. They're reused for education and research.**

17 **Q The language in the patent itself simply refers**

18 **to "a cadaver/porcine" --**

19 **A Sure.**

20 **Q -- "incorporated valve and stent system"?**

21 **A It does.**

22 **MR. MARCUS: Are we at 2230?**

23 **(Deposition Exhibit Number 2230**

24 **was marked for identification.)**

25 **Q Let me hand you Exhibit 2230 if I could. Do**

Page 123

1 you recognize that as an aortic valve?

2 **A As it being labeled that, yes. It's -- it**

3 **could be the pulmonic valve as well.**

4 **Q It has a label "aortic valve," does it not?**

5 **A Yes.**

6 **Q And the aortic valve is a tricuspid valve?**

7 **A Trileaflet, yes.**

8 **Q And the valve we're looking at as Exhibit 2230**

9 **is a trileaflet valve?**

10 **A Yes.**

11 **Q And if you were to extract a valve out of a**

12 **cadaver, this is what that valve could look like?**

13 **A Could if you retained all the tissue around it,**

14 **yes.**

15 **Q And you'll agree with me that this patent,**

16 **1001, does not contain any reference as to how the valve**

17 **is to be extracted?**

18 **A Don't recall that it does.**

19 **Q And just for completeness' sake, let me hand**

20 **you 2231.**

21 **(Deposition Exhibit Number 2231**

22 **was marked for identification.)**

23 **Q Does 2231 appear to be a --**

24 **MR. BARUFKA: Objection, relevance. Sorry.**

25 **Q Does 2231 appear to be a picture of the aortic**

Page 124

1 valve?

2 **A It's labeled as such.**

3 **Q And are the structures there labeled correctly,**

4 **the left coronary cusp, right coronary cusp, non-coronary**

5 **cusp, and aortic valve annulus?**

6 **MR. BARUFKA: Objection, relevance.**

7 **A It's difficult to say with this single picture.**

8 **I can't see the coronaries to know for sure if those are**

9 **the correct labels.**

10 **Q Do you know whether these pictures -- can you**

11 **tell from this whether these pictures were taken from the**

12 **University of Minnesota Visible Heart project?**

13 **MR. BARUFKA: Objection, relevance.**

14 **A They look very similar to what we've taken**

15 **there, yes.**

16 **Q And so what you would do in that project is you**

17 **would reanimate the heart, and then you would go in and**

18 **take pictures such as that depicted in 2231 of the heart**

19 **structures?**

20 **A Yes.**

21 **Q And in fact, if you look on this document, you**

22 **can see in faint writing "copyright University of**

23 **Minnesota"?**

24 **A Yes.**

25 **MR. BARUFKA: Objection, relevance.**

Page 125	Page 127
1 Q You talked in your declaration about placement 2 of the replacement valve. Do you recall talking about 3 that in your declaration?	1 A If you're interfering with portions of the 2 valve, yes, that could happen.
4 A Yes.	3 Q And that could have a negative impact on the 4 patient?
5 Q One thing that you would need to do in placing 6 a prosthetic aortic valve is to avoid subvalvular 7 structures?	5 A It could.
8 MR. BARUFKA: Objection as to form.	6 Q And that impact could include death of the 7 patient?
9 Q Yeah. Let me restate the question. The mitral 10 valve has associated with it certain subvalvular 11 structures, does it not?	8 A It depends on the degree of interaction with 9 the mitral valve and the degree of disruption. But yes, 10 it potentially could include death.
12 A Yes, it does.	11 Q Those chordae tendineae, which are on the 12 ventricular side of the mitral valve, they are numerous, 13 are they not?
13 Q Those structures include the chordae tendineae?	14 A They are -- there are -- I don't know the exact 15 number, but there are more than one, yes.
14 A Yes.	16 (Deposition Exhibit Number 2233 17 was marked for identification.)
15 Q And the mitral valve in the heart is adjacent 16 to the aortic valve?	18 Q I mean, if we look at this Exhibit 2233 -- 19 MR. BARUFKA: I'll object as to relevance.
17 A Yes.	20 Q You've got Exhibit 2233 in front of you?
18 Q And in placing a prosthetic valve -- a 19 prosthetic aortic valve in the heart, you would want to 20 avoid the subvalvular structures associated with the 21 mitral valve?	21 A I do.
22 A Yes.	22 Q And this is --
23 Q And let me hand you Exhibit 2232, if I could. 24 (Deposition Exhibit Number 2232 25 was marked for identification.)	23 MR. BARUFKA: Can we go off the record for one 24 minute? 25 (Discussion was held off the record.)
Page 126	Page 128
1 MR. BARUFKA: Objection as to relevance.	1 Q You've got 2233 in front of you?
2 Q You can now tell from 2232 that this picture 3 derives from the University of Minnesota website, can you 4 not?	2 A Yeah.
5 MR. BARUFKA: Objection, relevance.	3 Q And that 2233 depicts the chordae tendineae, 4 which exist on the ventricular side of the mitral valve?
6 A I can see that, yes.	5 MR. BARUFKA: Objection as to relevance.
7 Q And this depicts both the area where the aortic 8 valve is located as well as the mitral valve adjacent to 9 it?	6 A According to the labels on the picture, yes.
10 MR. BARUFKA: Objection, relevance.	7 Q Do you have any reason to doubt that that's 8 what's depicted in the picture?
11 A Yes.	9 MR. BARUFKA: Objection as to relevance.
12 Q And we can see in this picture the chordae 13 tendineae, which are -- is it proximal -- are there on 14 the ventricular side of the mitral valve, correct?	10 A I don't. It could be mislabeled. It could be 11 the tricuspid valve. That's possible.
15 A Yes.	12 Q And assuming these are the chordae tendineae on 13 the ventricular side of the mitral valve, these are 14 structures that a person placing a prosthetic aortic 15 valve would need to avoid during the placement procedure?
16 Q And what happens -- and if you don't know, tell 17 me you don't know. But what happens if you were to 18 interfere with the subvalvular structures associated with 19 the mitral valve?	16 MR. BARUFKA: Objection as to relevance.
20 A Depends on the degree of interference, but you 21 could interfere with the functioning of that valve.	17 A During the placement procedure?
22 Q You could disrupt the rhythm of the heart?	18 Q Yeah. While someone is attempting to place a 19 prosthetic aortic valve in a patient, in placing that 20 valve, that person would have to avoid the chordae 21 tendineae which are on the proximal or ventricular side 22 of the mitral valve?
23 A I don't know that that would be true.	23 MR. BARUFKA: Objection as to form.
24 Q You could at a minimum interfere with the 25 functioning of the mitral valve?	24 Q Let me reask the question to respond to the 25 form objection. We've been talking today about

Page 129	Page 131
<p>1 prosthetic valves in part, correct?</p> <p>2 A Yes.</p> <p>3 Q And prosthetic valves are designed to be placed</p> <p>4 in patients, correct?</p> <p>5 A Yes. There are some that are designed to be</p> <p>6 placed in animals as well, but.</p> <p>7 Q Sure. But one of the purposes of these valves</p> <p>8 is to put them inside patients who require a replacement</p> <p>9 valve for one reason or another, correct?</p> <p>10 A Yes.</p> <p>11 Q And in placing -- and your declaration talks</p> <p>12 about placement of prosthetic valves, does it not?</p> <p>13 A It does.</p> <p>14 Q And talks about, among other things, the</p> <p>15 discretion that a physician has in placing the valve,</p> <p>16 correct?</p> <p>17 A Yes.</p> <p>18 Q That discretion is limited in part by the</p> <p>19 structures that surround the area where the prosthetic</p> <p>20 valve is to be placed, correct?</p> <p>21 A I think they would take the structures that</p> <p>22 surround the location to be placed into their view. I</p> <p>23 mean, I can't put words in their mouth, but --</p> <p>24 Q Sure.</p> <p>25 A -- they would take those structures into</p>	<p>1 description. So it wouldn't avoid them completely. I</p> <p>2 don't know that that's completely necessary, but you</p> <p>3 would want to minimize the impact to those structures.</p> <p>4 Q Yeah. Because if you disrupt them to a</p> <p>5 significant enough degree, you're going to impact the</p> <p>6 mitral valve and possibly kill the patient?</p> <p>7 A Yes.</p> <p>8 Q And have you done any research as to the degree</p> <p>9 that you can impact the chordae tendineae and still avoid</p> <p>10 harm to the patient?</p> <p>11 A No. I have not done any research to that</p> <p>12 effect.</p> <p>13 Q Take a look at Exhibit 2213, if you would.</p> <p>14 You've got Exhibit 2213 in front of you?</p> <p>15 A Yes.</p> <p>16 Q This is the Wolfe patent, is it not?</p> <p>17 A Yes.</p> <p>18 Q This is one of the patents you considered in</p> <p>19 preparing your declaration, correct?</p> <p>20 A Yes.</p> <p>21 Q What is the ring member in this device?</p> <p>22 A The ring member consists of two parts. Let's</p> <p>23 see which it would be here. So if we look at Figure 2A,</p> <p>24 it consists of a combination of this soft outer part,</p> <p>25 number 14, I believe, which is the Dacron, and the inner</p>
<p>1 account when deciding where to place it.</p> <p>2 Q Sure. I mean, you can't put words in their</p> <p>3 mouth because you've never been in the position of</p> <p>4 placing one of these valves inside a live human patient,</p> <p>5 correct?</p> <p>6 A Right.</p> <p>7 Q But you know -- from your education and</p> <p>8 experience, you know that there are structures</p> <p>9 surrounding the area where the aortic valve is located,</p> <p>10 correct?</p> <p>11 A Yes.</p> <p>12 Q Amongst those structures are the chordae</p> <p>13 tendineae which exist on the ventricular side of the</p> <p>14 mitral valve, correct?</p> <p>15 A Yes.</p> <p>16 Q And so in placing the prosthetic aortic valve,</p> <p>17 the person placing the valve would have to avoid the</p> <p>18 chordae tendineae if he or she wanted to avoid disrupting</p> <p>19 operation of the mitral valve?</p> <p>20 A I don't know that you would need to avoid them</p> <p>21 completely. I think it would -- I mean, there's vary --</p> <p>22 I think it's a variable -- there's a range. So you could</p> <p>23 impact some chordae and probably not impact the valve.</p> <p>24 People have some chordae that rupture and the valve still</p> <p>25 continues to function fine. So I think it's a relative</p>	<p>1 portion, which is a soft sealing cuff. I believe that's</p> <p>2 number 26. So those two. There's also a rigid member</p> <p>3 that's inside the Dacron in combination with 56, the ring</p> <p>4 at the bottom. Those parts constitute the ring member.</p> <p>5 Q Now, if we take a look at 14, 14 is what's</p> <p>6 referred to as the valve seat assembly, correct?</p> <p>7 A Yes.</p> <p>8 Q That includes a soft seating ring, which is</p> <p>9 number 16, correct?</p> <p>10 A Yes.</p> <p>11 Q And then a hard, rigid, cast supporting ring,</p> <p>12 which is 18?</p> <p>13 A Yes.</p> <p>14 Q That hard, rigid, cast supporting ring is</p> <p>15 surrounded by Dacron?</p> <p>16 A I believe so. Fixation cover, Dacron mesh,</p> <p>17 yes.</p> <p>18 Q The purpose of that Dacron is to allow that</p> <p>19 device to be sutured into the patient?</p> <p>20 A (Perusing document.) According to the diagram</p> <p>21 here -- or the description in the specifications.</p> <p>22 Q Now, that structure -- you said there were</p> <p>23 different structures. The structure I've described, is</p> <p>24 that the ring, or is there another ring also that you're</p> <p>25 referring to?</p>

Page 133	Page 135
<p>1 A That's part of it. The other part is 56, I 2 believe.</p>	<p>1 replacing the aortic valve, correct?</p>
<p>3 Q Okay. Now, 56, if we look at that, that is 4 part of this device referred to as an occluder. Do you 5 see that?</p>	<p>2 MR. BARUFKA: Objection as to form. 3 A Can you show me where it says that -- 4 Q Sure.</p>
<p>6 A Where do you see the description of occluder?</p>	<p>5 A -- in the article -- or in the patent?</p>
<p>7 Q If you look at Figure 2A, there's an arrow, and 8 I think it's number 12.</p>	<p>6 Q If we look at page 4 of Exhibit 2213, 7 column 1 -- let me know when you're there.</p>
<p>9 A Number 12. Okay.</p>	<p>8 A Column 1. Okay.</p>
<p>10 Q So do you understand with respect to the -- 11 let's focus first on this structure you've defined with 12 numbers 16 and 18. You understand that structure to be 13 in contact with the aortic wall when this device is 14 placed?</p>	<p>9 Q And there's a heading "Summary of the 10 Invention," correct?</p>
<p>15 A Yes.</p>	<p>11 A Yes.</p>
<p>16 Q With respect to the structure that is defined 17 with number 12, does number 12, that structure, the 18 occluder, contact the aortic wall?</p>	<p>12 Q It says, "This invention relates to 13 improvements in center-flow occluders of prosthetic heart 14 valve assemblies. The heart valve assemblies of this 15 invention are especially designed for implantation in the 16 human heart to replace the natural mitral valve; however, 17 the valve assemblies of this invention also can be 18 adapted to replace the tricuspid and/or aortic valves."</p>
<p>19 A I don't believe so.</p>	<p>19 Did I read that correctly?</p>
<p>20 Q What is -- in this design, the Wolfe design, 21 what objects are you defining as the membrane?</p>	<p>20 A Yes.</p>
<p>22 A The material that goes over the occluder. So 23 if you look at Figure 4, they have the membrane removed, 24 and they have the arms, I believe, of the occluder.</p>	<p>21 Q And so you would agree that this says that the 22 invention disclosed can be adapted to replace the aortic 23 valve?</p>
<p>25 Q You're looking at Figure 4?</p>	<p>24 A That's what it says.</p>
<p>Page 134</p>	<p>25 Q Does this patent disclose anywhere what</p>
<p>1 A Yeah.</p>	<p>Page 136</p>
<p>2 Q Okay.</p>	<p>1 adaptations would be necessary in order to enable this 2 device to replace the aortic valve?</p>
<p>3 A So those arms coming up would be essentially 4 the fingers. The membrane covers those fingers so that 5 the first open portion is at the bottom and the second 6 open portion is at the left and the right in that figure.</p>	<p>3 A I don't know. I would have to re-read it to 4 find out specifically.</p>
<p>7 Q And so this occluder -- the portion of the 8 occluder that covers these arms you're defining as the 9 membrane?</p>	<p>5 Q Okay. Go ahead.</p>
<p>10 A Yes.</p>	<p>6 A Would you like me to do that?</p>
<p>11 Q Okay. Is that -- what you've defined as the 12 membrane, is that attached to number 18?</p>	<p>7 Q Yes.</p>
<p>13 A No. It's not directly attached to 18.</p>	<p>8 A (Perusing document.) I don't see any specific 9 mention of adaptation for the aortic position in here.</p>
<p>14 Q This device, there's a statement in your 15 declaration. And I'm having trouble finding it. Give me 16 just one second here. You say in your declaration -- 17 this is paragraph 63. You say, "I have also reviewed 18 Dr. Catchings' testimony, where he states that the Wolfe 19 invention relates to mitral valves, and not to aortic 20 valves. This is incorrect, as Wolfe expressly explains 21 that the disclosed valve can be used to replace aortic 22 valves." Did I read that correctly?</p>	<p>10 Q When you were reading this patent, did you 11 notice a reference to clots?</p>
<p>23 A You did.</p>	<p>12 A I don't remember that. I was just looking -- 13 scanning it again looking for specific words.</p>
<p>24 Q The reality, though, is that what the Wolfe 25 patent says is that this device can be adapted for use in</p>	<p>14 Q Let me help you with that. Look at page 5, 15 column 3.</p>
	<p>16 A Okay.</p>
	<p>17 Q And this is the last paragraph, last --</p>
	<p>18 A I'm on the wrong page. Sorry.</p>
	<p>19 Q Yeah. It's column 3.</p>
	<p>20 A Okay.</p>
	<p>21 Q If we look at that last paragraph, last 22 sentence, it says, "After the fixation cover 20 has been 23 sutured to the heart tissue, thrombosis, which is the 24 formation of clots, is relied upon to retain the valve 25 seat assembly 14 in its proper position within the</p>

Page 137

1 heart." Did I read that correctly?

2 **A That's what it says.**

3 Q Now, you know sitting here today that the

4 formation of clots is something that is disapproved of by

5 persons of ordinary skill in the art, correct? Strike

6 that. Let me ask a better question.

7 The Wolfe patent specifically refers to

8 reliance on clots in order to retain the valve seat

9 assembly in place, correct?

10 **A That's what it says at the end of that**

11 **paragraph, yes.**

12 Q A person of ordinary skill in the art as of

13 2000 would never rely upon the formation of clots to

14 maintain a device in place, would they?

15 MR. BARUFKA: Object as to form.

16 A I wouldn't say they would never. I would say

17 it would be ideal.

18 Q Well, a person of ordinary skill in the art

19 would know that clots are something to be avoided for the

20 health and well-being of the patient, correct?

21 **A I think clots are the beginning of the natural**

22 **healing process, so they can be construed in multiple**

23 **ways.**

24 Q Well, in the Wolfe patent, it's actually trying

25 to or attempting to rely upon clots to maintain the

Page 138

1 device in place, right?

2 **A That's what it says.**

3 Q But a person of ordinary skill in the art would

4 fashion the device in such a manner as to avoid clots if

5 that was possible, correct?

6 **A If it was possible.**

7 Q Because clots, or thrombosis, can lead to

8 complications within the heart, correct?

9 **A They could.**

10 Q Including stroke, correct?

11 **A They could.**

12 Q And in your patent we looked at earlier -- this

13 is 2229. Do you still have that?

14 **A Yes.**

15 Q Look at column 2 of your patent.

16 **A Okay.**

17 MR. BARUFKA: Objection as to relevance.

18 Q You say -- and I'll just read this in entirety

19 to get the context. You say here -- can you see where

20 the word "mechanical" is in that first paragraph of

21 column 2?

22 **A "Mechanical valves" about --**

23 Q Yes.

24 **A -- line 8?**

25 Q If we look at column 2, line 8 of Exhibit 2229,

Page 139

1 your patent, it says, "Mechanical valves have been used

2 for many years and encompass a wide variety of designs

3 that accommodate the blood flow requirements of the

4 particular location where they will be implanted.

5 Although the materials and design features of these

6 valves are continuously being improved, they do increase

7 the risk of clotting in the blood stream, which can lead

8 to a heart attack or stroke. Thus, mechanical valve

9 recipients must take anti-coagulant drugs for life to

10 prevent the formation of thrombosis." I read that

11 correctly?

12 **A You did.**

13 Q And so a person receiving a mechanical valve is

14 forced to take drugs to stop clots from forming, correct?

15 **A Downstream from the valve, yes.**

16 Q And in designing your device, is avoiding clots

17 something that you consider?

18 MR. BARUFKA: Objection, relevance.

19 A Avoiding downstream clots, yeah.

20 Q Well, if you had a clot at the surgical site,

21 that clot can travel downstream, correct?

22 **A It could, yes.**

23 Q And that can lead to a stroke, correct?

24 **A Depending on where it goes, yes.**

25 Q And so the absolute last thing you would want

Page 140

1 to do is encourage the formation of additional clots,

2 correct?

3 **A Yes.**

4 Q With respect to this Wolfe patent, the

5 structure you referred to as a ring, that was -- I

6 believe it was number -- I think it was --

7 **A It's 56.**

8 Q Well, there was two of them. There was 56, and

9 then the other one was, I believe, 14 if I'm using the

10 right reference. Yeah. That device or that ring is in

11 fact a perfect circle, a rigid circle, is it not?

12 MR. BARUFKA: Objection as to form.

13 Q Yeah. Let me --

14 **A I would have to look back to find that.**

15 Q And I'll help you out. If you look at column 3

16 of the Wolfe patent -- this is on page 5. It says in the

17 last paragraph, referring to Figure 2A, "a preferred

18 valve seat assembly 14 includes a soft seating ring 16, a

19 hard, rigid, cast supporting ring 18 and a fixation cover

20 20." Did I read that correctly?

21 **A You did.**

22 Q And that hard, rigid, cast supporting ring 18,

23 that is fashioned as a perfect circle as it's depicted in

24 this patent?

25 MR. BARUFKA: Objection as to form.

Page 141		Page 143	
1	A Most of the diagrams are isometric or from the	1	Q You know for sure that the aorta moves,
2	side. What is --	2	correct?
3	Q If you take a look at Figure 1, Figure 3, those	3	A It expands and contracts.
4	are the two figures I've referred to. Figure 1 appears	4	Q And contracts?
5	to be a circle, does it not?	5	A Yes.
6	A It could be a circle.	6	Q And does -- when it expands and contracts, does
7	Q Figure 3 appears to be a circle, does it not?	7	it do so with equal force about its circumference?
8	A Could be a circle.	8	A Depends on the condition of the aorta.
9	Q The aorta itself is not a perfect circle?	9	Q Explain that.
10	A The --	10	A So if it's a normal, healthy aorta, yes. And
11	MR. BARUFKA: Objection as to form.	11	the blood pressure as it's distributed would cause it to
12	A The aorta where?	12	expand and contract radially, so outward from the center
13	Q Is there anywhere in the aorta where you can	13	equidimensionally.
14	look down at it, and it's an absolute perfect circle?	14	Q What if it's not a healthy aorta?
15	A Define perfect circle.	15	A Then the potential is therefore to not equally
16	Q Yeah, a circle.	16	and circumferentially expand.
17	A Within what bounds? You can measure locations	17	Q In the case of a patient suffering from aortic
18	in the aorta where it's -- let's say we have two	18	stenosis, does that patient have a healthy aorta?
19	diameters, and one would be 28.1, and one would be 28.05.	19	A It depends on the particular patient. Some
20	Q So that's not a perfect circle, right?	20	patients could; some patients may not.
21	A But that's what I'm asking is that -- that's	21	Q What does it depend upon?
22	pretty close to a perfect circle.	22	A The degree of aortic stenosis.
23	Q When I say a perfect circle, I mean a perfect	23	Q Aortic stenosis causes calcification at the
24	circle where --	24	native valve site?
25	A Okay.	25	A At the leaflets typically.
Page 142		Page 144	
1	Q -- it's got from --	1	Q And it can also cause calcification about the
2	A Exact --	2	aortic wall?
3	Q -- equidistant from the center point.	3	A It can.
4	A I imagine that there are. I don't know that --	4	Q And that calcification can cause that structure
5	I don't know for sure if --	5	to become more rigid?
6	Q As you sit here today -- I'm sorry. Go ahead.	6	A The calcification is rigid, yes.
7	A I don't know for sure if they would exist.	7	Q Yeah. And so if we were to look at a healthy
8	Q As you sit here today, you know that the aorta	8	aorta, a healthy aorta is pliable?
9	is typified by an irregular oblong shape if we looked at	9	A Typically, yes.
10	a cross-section of it?	10	Q An aorta where stenosis is present loses some
11	A The aorta?	11	of its pliability?
12	Q Uh-huh.	12	A I would say that's fair, yes.
13	A I would say it's most likely circular in most	13	Q If we're trying to implant a circular device
14	cases.	14	into a passageway that's not circular, is it true that in
15	Q But not a perfect circle, correct?	15	order for that device to seat, the passageway must
16	A I don't know for sure. I haven't measured	16	conform to the shape of the device?
17	enough of them to know or looked at enough data to say	17	MR. BARUFKA: Objection as to form.
18	that, yes, it is typically a perfect circle or not a	18	A Can you say it one more time?
19	perfect circle.	19	Q Yeah. If you are trying to implant a circular
20	Q So you can't answer sitting here today what	20	device within a non-circular passageway, the only way for
21	shape exactly the inside of the aorta is?	21	that circular device to properly seat would be either for
22	A I would say the aorta is close to a circle.	22	the device to conform to the shape of the passageway or
23	It's more circular than not.	23	for the passageway to conform to the shape of the device?
24	Q Okay. Not a perfect circle, though?	24	MR. BARUFKA: Object as to form.
25	A I can't say for sure if it is a perfect circle.	25	A I think the -- so I guess what do you mean by

Page 145	Page 147
<p>1 properly seat? What --</p> <p>2 Q So that the entire circumference of the device</p> <p>3 is touching the wall of the structure you're putting it</p> <p>4 into.</p> <p>5 A Then I would agree with that.</p> <p>6 Q Okay. And so in the case of the Wolfe device,</p> <p>7 that is a rigid circle, correct?</p> <p>8 A Part of it is rigid.</p> <p>9 Q The hard, rigid, cast supporting ring 18,</p> <p>10 that's a circular -- that's a circular shape?</p> <p>11 MR. BARUFKA: Asked and answered, form.</p> <p>12 A Let's see. (Perusing document.) I don't see</p> <p>13 18 depicted in the figures as circular.</p> <p>14 Q Well, if we look at Figure 1, there's a</p> <p>15 Figure 14 depicted, correct?</p> <p>16 A Yes.</p> <p>17 Q And what Figure 14 is is the valve seat</p> <p>18 assembly, correct?</p> <p>19 A Yes.</p> <p>20 Q And the valve seat assembly is comprised of</p> <p>21 seating ring 16 and supporting ring 18, correct?</p> <p>22 A Yes.</p> <p>23 Q And valve seat assembly 14 is depicted as a</p> <p>24 circular structure in --</p> <p>25 MR. BARUFKA: Objection --</p>	<p>1 give a number for how rigid it is or is not.</p> <p>2 Q Well, they say hard, rigid, cast supporting</p> <p>3 ring. That sounds like something that's pretty rigid,</p> <p>4 doesn't it?</p> <p>5 MR. BARUFKA: Objection, asked and answered.</p> <p>6 A I mean, it could be. It does sound like it's</p> <p>7 hard. It says hard, rigid, but it doesn't say exactly</p> <p>8 how hard.</p> <p>9 Q Okay. Now, if that device were placed within a</p> <p>10 patient suffering from aortic stenosis, that could</p> <p>11 prevent that device from seating properly against the</p> <p>12 aortic wall?</p> <p>13 A Again, it's a relative -- it's a relative</p> <p>14 rigidity, pliability question.</p> <p>15 Q Well, in order for that valve to seat properly</p> <p>16 against the aortic wall, the aortic wall would have to be</p> <p>17 pliable enough for it to conform to the shape of the</p> <p>18 structure, correct?</p> <p>19 A Sure.</p> <p>20 Q And if that patient was suffering from aortic</p> <p>21 stenosis, it could be true that that aortic wall could</p> <p>22 not conform to the shape of the structure, correct?</p> <p>23 MR. BARUFKA: Objection as to form.</p> <p>24 A It's possible. But the calcification could be</p> <p>25 more rigid.</p>
<p>1 Q -- Figure 1?</p> <p>2 MR. BARUFKA: -- asked and answered.</p> <p>3 A It's off axis. It's hard to say if it's</p> <p>4 circular or not.</p> <p>5 Q If you assume that valve seat assembly 14 is a</p> <p>6 circular structure, and that structure is implanted</p> <p>7 within a non-circular passageway, that passageway would</p> <p>8 have to conform to the shape of that structure in order</p> <p>9 for that device to properly seat?</p> <p>10 MR. BARUFKA: Objection to form.</p> <p>11 A If I assume that it is circular and it is put</p> <p>12 into a non-circular orifice for it to properly seat, and</p> <p>13 by properly seat you mean touch the aorta all the way</p> <p>14 around, I would expect that the aorta would conform to</p> <p>15 the more rigid object.</p> <p>16 Q And in order for that to occur, the aorta must</p> <p>17 be pliable?</p> <p>18 A Pliable is a relative term. So it has to be</p> <p>19 more pliable than what it is being in contact with.</p> <p>20 Q Would the -- in a healthy aorta, that would be</p> <p>21 true, right? The aorta would be more pliable than this</p> <p>22 valve seat assembly?</p> <p>23 MR. BARUFKA: Objection to form.</p> <p>24 A I don't know. It's hard to say what the --</p> <p>25 they don't give a -- they say it's rigid, but they don't</p>	<p>1 Q Because the calcification creates rigidity</p> <p>2 around the area where this valve would be placed,</p> <p>3 correct?</p> <p>4 A Well, it may or may not. It depends on where</p> <p>5 the valve is placed, and it depends on where the</p> <p>6 calcification is located.</p> <p>7 Q Take a look at Exhibit 1009, if you would.</p> <p>8 A Okay.</p> <p>9 Q Exhibit 1009 is a device or patent issued to</p> <p>10 Schreck, correct?</p> <p>11 A Yes.</p> <p>12 Q And the way this device is designed, it's got</p> <p>13 a -- it looks like a structure called a "tissue-engaging</p> <p>14 base."</p> <p>15 A Can you point out to where that terminology is</p> <p>16 at?</p> <p>17 Q Yeah. If you look at -- well, it appears</p> <p>18 throughout the patent. But if you look at -- you could</p> <p>19 look at column 3, for example.</p> <p>20 A Okay.</p> <p>21 Q If you look at the first full paragraph of</p> <p>22 column 3, it says, "In a still further aspect, the</p> <p>23 present invention provides a two-part expandable</p> <p>24 prosthetic heart valve for placement in a host heart</p> <p>25 valve annulus, comprising: a leaflet subassembly having a</p>

Page 149	Page 151
<p>1 wireform defining a plurality of upstanding commissures 2 and a plurality of arcuate cusps extending between 3 adjacent commissures, a midpoint of each cusp being 4 located approximately equidistant from the adjacent 5 commissures; a generally annular tissue-engaging base 6 defining an axis; and a system for connecting the leaflet 7 subassembly and the tissue-engaging base, including a 8 plurality of mating connectors on the leaflet subassembly 9 and on the tissue-engaging base, wherein one connector 10 each is provided at each commissure, and one at each cusp 11 midpoint." Do you see all that language?</p>	<p>1 posts are intended to act as commissures for a valve 2 that's situated in between them? 3 MR. BARUFKA: Objection as to form. 4 A By the terminology, I would expect that, but I 5 would have to review the patent. 6 Q Well, you did review the patent and the -- 7 A Yeah. I mean to find the exact wording. But 8 if it's a commissure post, I would expect that it is 9 to -- without finding the exact wording here, that it is 10 to support a commissure.</p>
<p>12 A I do. 13 Q And so if we look at these diagrams -- there 14 are several diagrams within this patent. But each of the 15 diagrams features on the ventricular side of the device 16 this structure called a "tissue-engaging base"? 17 MR. BARUFKA: Objection as to form. 18 A It says it's generally an annular engaging 19 base. 20 Q Okay. And I'm fine with that terminology as 21 well. I guess the point I'm trying to address is, with 22 each structure defined in the Schreck patent, you have a 23 device on the bottom half of the device that engages with 24 surrounding tissue when the device is deployed, correct? 25 A One more time. Sorry.</p>	<p>11 Q And if we look at Figure 7, that's one 12 embodiment of this invention. Do you see Figure 7? 13 A I do. 14 Q And Figure 7 shows on the bottom half of this 15 structure this base that we've been talking about, 16 correct? 17 A It does not show the base. 18 Q You don't believe that figure depicted at the 19 bottom is a base? 20 A That's not the base that is described in this 21 patent as I read it. 22 Q Point out where the base as described in this 23 patent is shown. 24 A I would say it's Figure 6 at the top, this 25 part.</p>
Page 150	Page 152
<p>1 Q With respect to the device described in -- 2 strike that. 3 With respect to the device described in 4 Schreck, it features a structure on the bottom half of 5 the device which is designed to engage with surrounding 6 tissue. 7 A Yes. 8 Q And then extending upward from that structure, 9 there are these posts? 10 MR. BARUFKA: Objection, form. 11 A Well, there's two sets of posts. One of the 12 posts is the commissure post, and one of the posts is the 13 midpoint, and -- 14 Q Both -- 15 A -- they extend along the ceiling -- 16 Q Both -- 17 A -- area. 18 Q Okay. Both sets of posts extend upwards from 19 this annular engaging base? 20 A It appears that way. It looks like they expand 21 it and then extend beyond it in one of the cases. 22 Q Directionally, though, they're expanding -- or 23 they're extending upward from the base, correct? 24 A Yes. 25 Q And in the case of the commissure posts, those</p>	<p>1 Q Okay. Well, Figure 6, the top -- I'm sorry. 2 You gestured to the top part of that? 3 A This part, yes. 4 Q Now, that is actually -- if we look at how 5 that's defined, look at column -- hold on one second. 6 Okay. Yeah, look at column 8. Let's look at column 8. 7 And we can see how these structures were defined. 8 A Okay. 9 Q The bottom of column 8 states, "Figure 6-15 10 illustrate an expandable prosthetic heart valve 100." Do 11 you see that sentence? 12 A I do. 13 Q And if we look at Figure 6, you can see where 14 Figure 100 is shown, correct? 15 A Yeah. 16 Q That would define the entire structure shown as 17 Figure 6? 18 A Figure 100 is encompassing the entirety of the 19 structure. It appears that way. 20 Q Okay. And then it says, "including, as best 21 seen in Figure 6, a leaflet subassembly 102." And if you 22 flip back to Figure 6, you can see where the leaflet 23 subassembly 102 is shown, correct? 24 A Uh-huh. 25 Q That's a yes?</p>

Page 153

1 **A** **Yes.**

2 Q "Adapted to connect to a tissue-engaging base

3 104." Do you see that language?

4 **A** **Yes.**

5 Q And if we flip back to Figure 6, can you see

6 where 104 is pointing towards?

7 **A** **It's hard to say exactly what it's pointing**

8 **towards, but it's pointing in the general direction of**

9 **the bottom of the image.**

10 Q And then it says, "The two components are both

11 shown in Figure 6 in their radially expanded

12 configurations, though both are designed to be radially

13 compressed and delivered through a catheter or cannula,

14 for example. In contrast with the first embodiment,

15 however, the two components are stored separately, and

16 connected just prior to delivery into the body of the

17 patient. In general, the two components provide a

18 tissue-engagement ring and a relatively more flexible

19 valve member having fluid occluding surfaces. It should

20 be understood that configurations of these two

21 connectible components other than those specifically

22 shown may be encompassed by the appended claims. As seen

23 in Figure 6, the leaflet subassembly 102 comprises an

24 elastic wireform 106 supporting a plurality of prosthetic

25 leaflets 108 and a fabric skirt 110." Now look at where

Page 154

1 those numbers are called out on Figure 6. Do you see

2 that?

3 **A** **I see 106 and 110, yes.**

4 Q And so when we look at 110, what that is

5 defined as is a fabric skirt, correct?

6 **A** **That's what it says, yes.**

7 Q And when this device is fully assembled, that

8 fabric skirt drops down over the tissue-engaging base,

9 does it not?

10 **A** **I believe so.**

11 Q And it is that tissue-engaging base which

12 expands to cause the skirt to contact the annulus?

13 MR. BARUFKA: Objection as to form.

14 A Yes. "The fabric skirt 119 is sized to drape

15 outside of and surround the tissue-engaging base 104."

16 Q And if we look over at Figure 7 then, what

17 Figure 7 does is it depicts this device fully assembled

18 but without the skirt. Do you see that?

19 A Yes.

20 Q And so you can see there the way this device

21 works is you've got this base -- this tissue-engaging or

22 annulus-engaging base at the bottom and then above it

23 this trileaflet valve design?

24 MR. BARUFKA: Objection as to form.

25 A That's what's depicted here. But I think the

Page 155

1 part that's actually contacting the annulus is the skirt.

2 Q Certainly, but my point being, if we look at

3 the structure which lies beneath the skirt, the structure

4 we see is this tissue-engaging base and then above that

5 base this trileaflet valve?

6 **A** **Yes.**

7 Q And then if we drop the skirt over as is shown

8 in Figure 6, this tissue-engaging base would expand to

9 cause the skirt to contact the wall of the annulus?

10 MR. BARUFKA: Objection as to form.

11 A That is my understanding.

12 Q And this device is designed so that the

13 tissue-engaging base is placed within the annulus?

14 **A** **It says generally annular.**

15 Q Yeah. If we look at column 4, this actually

16 refers to the base as an "annular tissue-engaging base."

17 Do you see that? This is the --

18 **A** **Uh-huh.**

19 Q -- second paragraph.

20 **A** **Yes.**

21 Q And then when it describes the method of

22 implantation, it refers to "delivering the heart valve

23 with the connected base in its collapsed state and

24 wireform subassembly in its reduced size to an annulus of

25 the patient's heart valve being replaced." Do you see

Page 156

1 that language?

2 **A** **I'm sorry. What line was that on? Is it just**

3 **below it?**

4 Q It's line, it looks like, 38 -- or rather 34.

5 Begins on 34 --

6 **A** **Okay.**

7 Q -- and goes to 39. Do you see that?

8 **A** **I do.**

9 Q And so this device is designed to be placed

10 with the tissue-engaging base and surrounding skirt

11 within the annulus of the heart?

12 **A** **It says, "to an annulus."**

13 Q And if this is going to be an aortic valve,

14 **then this would be placed within the aortic annulus?**

15 **A** **Yes.**

16 Q And then above it -- above the tissue-engaging

17 base would be this trileaflet valve design that we see

18 depicted here?

19 **A** **Yes.**

20 Q This design with the tissue-engaging base

21 cannot be placed in the ascending aorta. Is that

22 correct?

23 MR. BARUFKA: Objection as to form.

24 A Well, part of it would likely be in the

25 ascending aorta.

<p style="text-align: right;">Page 157</p> <p>1 Q The ascending aorta begins in the -- or begins 2 just above the sinotubular junction?</p> <p>3 A In one interpretation.</p> <p>4 Q And the tissue-engaging base, you cannot place 5 the tissue-engaging base above the native annulus, can 6 you?</p> <p>7 A Well, which annulus are we referring to? 8 There's --</p> <p>9 Q The one where this one -- well, hold on a 10 second. When I use the term "annulus," I'm referring to 11 that term as used in the book that you edited. Do you 12 recall how that term was used in the book you edited?</p> <p>13 A The virtual annulus as opposed to the true 14 annulus, the attachment of the leaflets annulus?</p> <p>15 Q Well, the annulus as described in the book that 16 you edited. Let me see if I can get that exhibit number 17 for us.</p> <p>18 A I think I referred to it as the virtual 19 annulus.</p> <p>20 Q Yeah. If we look at Exhibit 2225, there is a 21 reference to "virtual annulus" that's on page 32.</p> <p>22 A Yes.</p> <p>23 Q The tissue-engaging base of the Schreck device 24 is designed to be placed there, is it not?</p> <p>25 A I don't know. It doesn't specifically say. At</p>	<p style="text-align: right;">Page 159</p> <p>1 that one of the two coronary arteries shown?</p> <p>2 A Without it being labeled, I would imagine that 3 it is, yes.</p> <p>4 Q And if you place the tissue-engaging base above 5 the annulus as shown in this design, the tissue-engaging 6 base when it expands could interfere with the coronary 7 arteries?</p> <p>8 A Again --</p> <p>9 MR. BARUFKA: Objection, asked and answered.</p> <p>10 A -- it depends on the height of the base, the 11 location of the coronary, and the exact positioning.</p> <p>12 Q Well, the only way it wouldn't interfere if you 13 placed it above the annulus is for it to be short enough 14 so that you could place it just above the annulus and 15 just below the coronary arteries, correct?</p> <p>16 A Yes.</p> <p>17 Q And if it was that narrow, would it effectively 18 hold this device in place?</p> <p>19 A It could. That height is 10 millimeters to 20 15 millimeters.</p> <p>21 Q Is there anywhere where that sort of placement 22 is shown in the Schreck patent?</p> <p>23 A That's a good question. (Perusing document.)</p> <p>24 Q If we look at -- in fact, if we look at 25 column 4, line 34, this refers to "delivering the heart</p>
<p style="text-align: right;">Page 158</p> <p>1 least I don't -- it says "annular," so that could be one 2 interpretation of the placement.</p> <p>3 Q If you were to place it above that location 4 such that it was where the anatomical ventriculo-arterial 5 junction is -- this is on page 32 of Exhibit 2225. If 6 you place it above the --</p> <p>7 A Sorry. Which page?</p> <p>8 Q Page 32 of your book. It's actually page 8 of 9 the exhibit, Exhibit 2225.</p> <p>10 MR. BARUFKA: Objection as to relevance.</p> <p>11 Q If you place the tissue-engaging base above the 12 aortic annulus, then that base could interfere with the 13 coronary arteries?</p> <p>14 A It depends on the height of the valve, and it 15 depends on the orientation of the valve.</p> <p>16 Q Okay. Explain that to me, because, as I 17 understand the structure -- and in fact, we've got a 18 better picture of it. Let's take a look at 19 Exhibit 2224 -- page 2 of Exhibit 2224. This was the 20 article attached to your declaration?</p> <p>21 A Yes.</p> <p>22 Q You see there the aortic root described.</p> <p>23 A Yes.</p> <p>24 Q And if we look at that picture, to the right 25 there appears to be an offshoot or a structure there. Is</p>	<p style="text-align: right;">Page 160</p> <p>1 valve with the connected base in its collapsed state and 2 wireform subassembly in its reduced size to an annulus of 3 the patient's heart valve being replaced; and expanding 4 the base into its expanded state in contact with the 5 annulus." Do you see that?</p> <p>6 A I do see that.</p> <p>7 Q What annulus is this referring to if it's not 8 the aortic annulus shown --</p> <p>9 A Well --</p> <p>10 Q -- on page 2 of Exhibit 2 -- or excuse me -- 11 Exhibit 2224?</p> <p>12 A That very well could be one of -- that is one 13 annulus here. The other annulus is the attachment of the 14 semilunar valves. It doesn't specifically say -- or the 15 semilunar leaflets. It doesn't specifically say which 16 annulus it's referring to. I would -- I mean, I would 17 assume that it's the green one, but it doesn't 18 specifically say in the patent.</p> <p>19 Q Well, where else -- if it's not the green one 20 with reference to page 2 of 2224, what other annulus 21 could it be referring to?</p> <p>22 A Well, the annulus -- the other term for annulus 23 that's used by anatomists is the attachment of the 24 leaflets themselves as we discussed earlier.</p> <p>25 Q If you're -- okay. So show us on this picture</p>

Page 161	Page 163
<p>1 where that location would be.</p> <p>2 A Well, for it to engage the annulus, it could be</p> <p>3 anywhere along the red line.</p> <p>4 Q Anywhere along that semilunar shape?</p> <p>5 A (Indicating.)</p> <p>6 Q Okay. Is there anywhere in the Schreck patent</p> <p>7 that it says that's what it's referring to?</p> <p>8 A Not that I'm aware of.</p> <p>9 Q We've looked at some reference materials here</p> <p>10 today, including that book, that 2225. Can you show us</p> <p>11 anywhere where that is defined as the annulus?</p> <p>12 A Not in the references that we have.</p> <p>13 Q Okay. And if you placed the tissue-engaging</p> <p>14 base higher, that would result in the trileaflet valve</p> <p>15 structure being higher as well, correct?</p> <p>16 A Yes.</p> <p>17 Q If that trileaflet valve structure is higher</p> <p>18 than the coronary arteries, when it closes, it could</p> <p>19 occlude the coronary arteries?</p> <p>20 MR. BARUFKA: Objection as to form.</p> <p>21 A When it closes, it wouldn't occlude the</p> <p>22 arteries.</p> <p>23 Q If it closes above the coronary arteries, it</p> <p>24 would, would it not?</p> <p>25 A When it closes, it's coming inward, so the</p>	<p>1 Q Yeah. Instead of placing the valve itself</p> <p>2 within the aortic root, if you were to move the</p> <p>3 tissue-engaging base up, it would also move up the valve</p> <p>4 itself, correct?</p> <p>5 A The valve -- yeah. If the engaging base is up,</p> <p>6 the valve is above it, so yes.</p> <p>7 Q And if you moved up high enough, you could</p> <p>8 create a situation where when that valve closes, it does</p> <p>9 not allow blood to flow back to the coronary arteries?</p> <p>10 A If it was high enough.</p> <p>11 Q And if you -- and so let's look at -- do you</p> <p>12 have 2224 in front of you still?</p> <p>13 A Yes.</p> <p>14 Q If you placed that tissue-engaging base within</p> <p>15 the ascending aorta such that the valve was above it,</p> <p>16 when that valve closed, would it occlude the coronary</p> <p>17 arteries?</p> <p>18 MR. BARUFKA: Objection, asked and answered.</p> <p>19 A Can you point to where you're envisioning?</p> <p>20 Q Yeah. You see on the right-hand side of that</p> <p>21 diagram, there's a label "ascending aorta"?</p> <p>22 A Okay.</p> <p>23 Q And it shows where it is defining the location</p> <p>24 of the ascending aorta, correct?</p> <p>25 A Uh-huh.</p>
<p>1 arteries would be open. It's when it -- when the valve</p> <p>2 closes?</p> <p>3 Q Here. We're going to show you this.</p> <p>4 A Maybe I'm confused.</p> <p>5 Q Yeah, I think so. Let me pull out this patent.</p> <p>6 Okay. In the native valve, the way it works is that the</p> <p>7 valve closes, but when it closes, the coronary arteries</p> <p>8 remain unobstructed because they're located within the</p> <p>9 sinuses of two to three valve leaflets, correct?</p> <p>10 MR. BARUFKA: Objection as to form.</p> <p>11 A When the aortic valve closes, the leaflets come</p> <p>12 to the middle, and the sinuses are outside of that, and</p> <p>13 the coronary arteries are at the edges of the sinuses.</p> <p>14 Q And so if you -- so in the native valve, when</p> <p>15 that -- the native valve comes together, it does not</p> <p>16 obstruct the coronary arteries. And in fact --</p> <p>17 A When it's closed.</p> <p>18 Q Yeah. And in fact, when it's closed, that's</p> <p>19 when the coronary arteries are perfused with blood, which</p> <p>20 then works its way into the heart, correct?</p> <p>21 A Yes.</p> <p>22 Q Now, if you place that structure, instead of</p> <p>23 placing it in the -- whatever that thing is called.</p> <p>24 Instead of placing it within the aortic root --</p> <p>25 A The virtual annulus?</p>	<p>1 Q That's a yes?</p> <p>2 A Yes.</p> <p>3 Q And if you move the tissue-engaging base up so</p> <p>4 that it was in that location, what's defined on this</p> <p>5 diagram as the ascending aorta, it would have above it</p> <p>6 the trileaflet valve structure?</p> <p>7 A Sure.</p> <p>8 Q And if the trileaflet valve structure was in</p> <p>9 that location, when it closed, it could occlude the</p> <p>10 coronary arteries?</p> <p>11 MR. BARUFKA: Objection, asked and answered as</p> <p>12 to -- form.</p> <p>13 A If it's in that location, yes, but that would</p> <p>14 not be contacting the annulus -- either of the annuluses.</p> <p>15 Q All right. So -- all right. Let me back up</p> <p>16 then. So your interpretation of the Schreck device is it</p> <p>17 would be placed somewhere below the sinotubular junction?</p> <p>18 A In order --</p> <p>19 MR. BARUFKA: Objection, asked and answered --</p> <p>20 form.</p> <p>21 A In order for it to contact one of the</p> <p>22 annuluses, yes.</p> <p>23 Q Okay.</p> <p>24 A The base would be there.</p> <p>25 Q All right. So I think I understand what you're</p>

Page 165	Page 167
<p>1 saying. So as I understand your testimony, the Schreck 2 device would either be placed at the aortic annulus as 3 shown in Figure 1 of Exhibit 2224 or somewhere above that 4 annulus and below the sinotubular junction? 5 A I think it's possible. 6 Q But it would not be your testimony that that 7 tissue-engaging base would be placed in the ascending 8 aorta? 9 A Again, it depends on your description of 10 ascending aorta. In this particular article, the 11 ascending aorta is from the sinotubular junction and up. 12 But in other descriptions, the ascending aorta includes 13 the entirety of the aortic root. 14 Q Well, if we look at the -- again, I'll just 15 pull it out here. In the article that you co-authored in 16 the book that you edited, Exhibit 2225, you defined the 17 ascending aorta as "beginning at the sinotubular junction 18 and extending upward." 19 A In this article, yes. 20 Q Have you heard of the European Society of 21 Cardiology? 22 A Uh-huh. 23 Q What is the -- 24 A Sorry. Yes. 25 Q What is the European Society of Cardiology?</p>	<p>1 entitled "2014 ESC Guidelines on the diagnosis and 2 treatment of aortic diseases" put out by the European 3 Society of Cardiology. Do you see that? 4 MR. BARUFKA: Objection, relevance. 5 A I do see that. 6 Q And if we flip over to page 7 of this 7 Exhibit 2234 -- 8 A Uh-huh. 9 Q -- you'll see a figure shown. 10 A Yeah. 11 Q And this shows the aorta, does it not? 12 MR. BARUFKA: Objection, relevance. 13 A It does. 14 Q And it defines an area as the "Aortic root"? 15 MR. BARUFKA: Objection, relevance. 16 A It does. 17 Q And then it defines the "Sinotubular junction"? 18 MR. BARUFKA: Objection, relevance. 19 A It does. 20 Q And in this design, it shows the ascending 21 aorta extending from the sinotubular junction upward to 22 the aortic arch? 23 MR. BARUFKA: Objection, relevance. 24 A It does. 25 Q And this would be consistent with the</p>
<p data-bbox="716 1052 841 1077">Page 166</p> <p>1 MR. BARUFKA: Objection, relevance. 2 A It's a society of cardiologists in Europe. 3 Q Does it put out authoritative publications of 4 any kind? 5 MR. BARUFKA: Objection, relevance. 6 A I believe so, but I'm not exactly sure. 7 Q You recognize it as a -- well, what kind of 8 body is it? Do you know? Is it a professional 9 organization, professional association, regulatory body? 10 What is it? 11 MR. BARUFKA: Objection, relevance. 12 A I believe it's a professional physician 13 organization. I'm not a part of it, though, so I don't 14 know. 15 Q How do you know what it is? I mean, what's 16 your -- in what context did you become familiar with it? 17 A They sponsor meetings, conferences. 18 Q And Medtronic will from time to time present at 19 those conferences? 20 MR. BARUFKA: Objection, relevance. 21 A I would assume potentially they could, yes. 22 Q Take a look at Exhibit 2234, if you would. 23 (Deposition Exhibit Number 2234 24 was marked for identification.) 25 A I've handed you an excerpt from a document</p>	<p data-bbox="1403 1052 1528 1077">Page 168</p> <p>1 description in the article you referenced, Exhibit 2225? 2 A Yes. 3 Q We talked about those posts on the Schreck 4 device. Those posts -- at least part of those posts 5 serve as commissures for the leaflets? 6 MR. BARUFKA: Objection, form. 7 A Part of the posts attach -- 8 Q That was a bad question. Let -- there are two 9 sets of posts described in the Schreck device, correct? 10 A Yes. 11 Q One set of posts are the commissure posts? 12 A One set go to the commissures, yes. 13 Q And so they serve as commissures for the valve 14 leaflets described in this device? 15 MR. BARUFKA: Objection, form. 16 A I don't know if they would serve as the 17 commissure. It's a post located at the commissure. 18 Q Well, the valve leaflets hang on those posts, 19 correct? 20 A I think the -- 21 MR. BARUFKA: Objection, form. 22 A -- valve leaflets hang on the wireform. 23 Q The valve leaflets is attached to the wireform. 24 The wireform is attached to the post, correct? 25 A I believe so.</p>

Page 169		Page 171	
1	Q So the posts support the valve leaflets?	1	form.
2	A They support the wireform.	2	A Well, it's also supported elsewhere by the
3	Q If those posts are not sufficiently rigid to	3	other set of posts.
4	withstand the compressive forces applied during normal	4	Q Take a look at Exhibit [sic] 7.
5	movement of the heart, it could result in varied forces	5	A Okay.
6	being opposed on the valve leaflets?	6	Q Let me know when you've got Exhibit [sic] 7 in
7	MR. BARUFKA: Objection, form.	7	front of you.
8	A Could you rephrase that?	8	A Figure 7 --
9	Q Yeah. There are forces that are exerted on the	9	Q Yeah, Figure 7. I'm sorry.
10	valve during normal function of the heart, correct?	10	A -- from Schreck?
11	A Correct.	11	Q It's Exhibit 1009, and it's Figure 7, which is
12	Q And if you put a prosthetic valve in, those	12	on page 7. Do you see that Figure 7?
13	same forces would be exerted on the prosthetic valve,	13	A I do.
14	correct?	14	Q And that depicts these leaflets attached to
15	A Correct.	15	these posts, correct?
16	Q And so if you've got a prosthetic valve like	16	MR. BARUFKA: Objection, asked and answered --
17	Schreck where you've got these posts, those posts need to	17	form.
18	be sufficiently rigid such that they can withstand the	18	A Again, it's hard to say. It looks like the
19	forces exerted upon them during more normal function of	19	posts are attached to the wireform, which is what the
20	the heart, correct?	20	leaflets are attached to.
21	MR. BARUFKA: Objection to form.	21	Q Okay. There is an attachment between the posts
22	A I think with the rest of the valve wireform and	22	and the leaflets?
23	assembly in concert with that, yes.	23	MR. BARUFKA: Objection, form.
24	Q If those posts bend in unevenly, I mean, if the	24	A Okay. I would have to look back to find it.
25	forces are exerted upon that device and then those posts	25	Can you show me the attachment?
Page 170		Page 172	
1	bend in unevenly, in other words, they don't all bend in	1	Q Yeah. I'm not trying to make this complicated,
2	the same amount, that could cause the valve itself to	2	but you can see here -- and maybe I'm missing it --
3	fail to coapt?	3	there's -- look at Figure 7.
4	MR. BARUFKA: Objection as to form.	4	A Yeah.
5	A It would be a matter of how unevenly and how	5	Q And look at the post on the far right. Do you
6	much they bent in and how much thought was put into the	6	see that?
7	leaflet design in concert with those posts.	7	A Yeah.
8	Q Yeah. Let's talk about that for a second. The	8	Q Okay. Now, that appears to show -- and tell me
9	patent itself acknowledges that the commissure and cusp	9	if I'm seeing this incorrectly. It appears to show a
10	posts could cantilever inward during the movement of the	10	wireform extending out above two leaflets that have come
11	heart, correct?	11	together. Do you see that there at the top right-hand
12	A I believe so.	12	corner of that image?
13	Q And when they cantilever inward, that's going	13	A Right here?
14	to impact the valve leaflets.	14	Q Yeah. Do you see that?
15	A By reducing stresses on them, yes.	15	A Yeah.
16	Q Well, no. What I mean -- and I understand what	16	Q And then that structure is resting on that
17	you're saying. But when I say impact, when those posts	17	post.
18	move, those leaflets are going to move, correct?	18	A Okay. I see that.
19	A It depends. If the leaflets are attached to	19	Q And you agree with that? That's what -- I've
20	the wireform, not the posts.	20	described it correctly?
21	Q But the wireform is attached directly to the	21	MR. BARUFKA: Objection, form.
22	posts, correct?	22	A Okay.
23	A At one spot, yes, so --	23	Q If that post bends in, is that structure not
24	Q It's hanging on the post, right?	24	going to move with it?
25	MR. BARUFKA: Objection, asked and answered and	25	A The wireform?

Page 173	Page 175
1 Q Yes.	1 bend inward when force is exerted upon them but not bend
2 A At the top, it could move in with it.	2 inward so much that they cause the valve leaflets to
3 Q Okay. And if that post moves in with it as it 4 bends in, that could affect the function of the valve?	3 misalign.
5 A It could affect the function of the valve. But 6 I would imagine if you were designing the post to be 7 flexible that you would design the valve in concert with 8 that flexion.	4 A It would be determining what the right 5 rigidity, stiffness, flexibility, whatever term you want 6 to use, of those posts are, characterizing that, and then 7 optimizing the leaflet coaptation so that when they flex, 8 the leaflets are allowed to still coapt appropriately.
9 Q Well, when you say design the post to be 10 flexible, explain that to me. If you make it more 11 flexible, is that not going to cause the post to bend in 12 more?	9 Q Do you see anywhere in the Schreck patent where 10 that is described?
13 A If they're more flexible, then they would 14 potentially bend in more.	11 A I would have to read it again to say that -- 12 MR. BARUFKA: Objection, form.
15 Q And if they bend in more, is that not going to 16 create a greater risk that these leaflets will misalign?	13 A -- but --
17 A It would be, but they say in the patent that 18 there is some flexing in the posts, correct?	14 Q If those posts -- let me ask you this. If 15 those posts are rigid as opposed to flexible, then if 16 they bend, that could affect the manner in which the 17 tissue-engaging base seats against the native annulus?
19 Q They acknowledge that -- well, the patent says 20 that those posts are going to cantilever, correct?	18 MR. BARUFKA: Objection, form.
21 A Cantilever. (Nods head.)	19 A If they bend in, I would imagine that the skirt 20 would move out and engage more.
22 Q And if those posts are so flexible -- I mean, 23 you mentioned making them more flexible. The more 24 flexible they are, the more likely they are to cantilever 25 when first force is exerted upon them, correct?	21 Q And when that skirt moves, that could result in 22 perivalvular leaking?
	23 A It would reduce it.
	24 Q Well, if it's moving in and out -- because, 25 again, as we know, the heart doesn't just contract in. I
Page 174	Page 176
1 A I don't think I mentioned making them more 2 flexible. I said if they were designed to be flexible, 3 so if they were designed to cantilever is what I meant.	1 mean, you have an outward contraction as well, correct?
4 Q And if they were designed to cantilever, then 5 you're going to have these posts that bend in when force 6 is exerted upon them during the normal function of the 7 heart, correct?	2 A Uh-huh.
8 A Yes.	3 Q So if these posts bend back and forth, as that 4 movement occurs, is that not likely to cause perivalvular 5 leaks through the tissue-engaging base as it moves in 6 concert with the posts?
9 Q And if that happens, that's going to impact the 10 movement of the valve leaflets?	7 MR. BARUFKA: Objection, form.
11 A It could impact the movement of the valve 12 leaflets, but I would imagine that the valve leaflets 13 would be designed with that cantilevering effect in mind.	8 A I would imagine that this would be expanded out 9 so that at the minimal state, it has contact, and when it 10 bends in, it has more contact and then goes to the normal 11 contact, more contact, normal contact, so it wouldn't 12 leak.
14 Q You're saying you would imagine. But you don't 15 see any evidence of that in the Schreck patent itself, do 16 you?	13 Q The movement alone could cause leakage, 14 couldn't it? I --
17 A Well, I would think one of ordinary skill in 18 the art would design the leaflets appropriately to work 19 in concert.	15 A Not --
20 Q And describe how you would do that. And let -- 21 go ahead. Describe how you would do that.	16 Q -- mean, if it's moving in and out, in and out, 17 in and out, and in and out, that movement could cause 18 leakage between the -- for example, between the 19 tissue-engaging base and the fabric skirt?
22 MR. BARUFKA: Objection to form.	20 MR. BARUFKA: Objection, form.
23 A How --	21 A Between the base and the skirt? So in between 22 those two?
24 Q Yeah. How you make this device a device that 25 incorporates posts that are flexible enough so they can	23 Q Sure.
	24 A I would -- I don't know how that would -- I 25 don't know how that would occur based on this design. I

Page 177	Page 179
<p>1 can't envision it.</p> <p>2 Q Take a look at Exhibit 2129 if you would. Have</p> <p>3 you seen this document prior to today?</p> <p>4 A I believe this was part of Dr. Catchings'</p> <p>5 deposition.</p> <p>6 Q Okay. And you commented -- is this one of the</p> <p>7 drawings that you commented on in your declaration?</p> <p>8 A I believe so.</p> <p>9 Q And you say that -- and this is paragraph 70.</p> <p>10 "Dr. Catchings' deposition testimony further presents</p> <p>11 various hypothetical drawings of the Schreck valve, and</p> <p>12 also presents testimony of what 'could happen' with</p> <p>13 various manners of implantation." Did I read that</p> <p>14 correctly?</p> <p>15 A Yes.</p> <p>16 Q Is that language you came up with or your</p> <p>17 attorneys came up with?</p> <p>18 MR. BARUFKA: Objection, privileged. Instruct</p> <p>19 the witness not to answer.</p> <p>20 Q When you received the first draft of your</p> <p>21 declaration, was this terminology or this language as</p> <p>22 appears in paragraph 70 already there?</p> <p>23 MR. BARUFKA: Objection, privileged. Instruct</p> <p>24 the witness not to answer.</p> <p>25 Q You say, "None of this testimony or drawings</p>	<p>1 refers to as the cantilevering of the posts.</p> <p>2 Q Have you ever seen one of these Schreck devices</p> <p>3 live?</p> <p>4 A I have not.</p> <p>5 Q Like a physical structure of it or a model of</p> <p>6 it of any kind?</p> <p>7 A I have not.</p> <p>8 Q Did you in preparing your declaration talk to</p> <p>9 the inventor of the Schreck device?</p> <p>10 MR. BARUFKA: Objection as to relevance.</p> <p>11 A I did not.</p> <p>12 Q And you acknowledge that the Schreck device</p> <p>13 refers to the possibility of these posts cantilevering?</p> <p>14 A It does.</p> <p>15 Q Now, these posts here, they are shown</p> <p>16 cantilevering to a significant degree?</p> <p>17 MR. BARUFKA: Objection as to relevance.</p> <p>18 A Agree.</p> <p>19 Q And it is possible, is it not, that depending</p> <p>20 upon the pressure being exerted upon them and how</p> <p>21 flexible they are, they could cantilever to this degree?</p> <p>22 MR. BARUFKA: Objection, relevance.</p> <p>23 A Depending on the flexibility and the pressure.</p> <p>24 Q And if they do cantilever to this degree, that</p> <p>25 could affect the alignment of the valve leaflets?</p>
<p>Page 178</p> <p>1 find a basis or foundation in Schreck." If we look at</p> <p>2 2129, the drawing that's shown there, do you not believe</p> <p>3 that's a reasonable schematic of the Schreck device?</p> <p>4 A It's missing in one set of the posts. But in</p> <p>5 general, it appears to be the same valve.</p> <p>6 Q Okay. And do you recognize the structure in</p> <p>7 which it's placed as the aortic root with the coronary</p> <p>8 arteries shown to the sides?</p> <p>9 MR. BARUFKA: Objection as to relevance.</p> <p>10 A I would imagine without it being labeled that</p> <p>11 this could be construed as an aortic root in a ventricle,</p> <p>12 yes.</p> <p>13 Q And where this device is shown as being placed,</p> <p>14 that's one location where it could be placed?</p> <p>15 A It's hard to say if that is the virtual annulus</p> <p>16 that we're talking about. It's unlabeled. If that is</p> <p>17 indeed the case, that could be a position that it was</p> <p>18 placed.</p> <p>19 Q Sure. Take a look at 2130, if you would. Did</p> <p>20 you look at 2130 in coming up with your declaration?</p> <p>21 A Yes.</p> <p>22 Q What's shown in 2130, is that something that</p> <p>23 could happen to this device?</p> <p>24 MR. BARUFKA: Objection as to relevance.</p> <p>25 A That's not what I would imagine the patent</p>	<p>Page 180</p> <p>1 MR. BARUFKA: Objection as to relevance.</p> <p>2 A It could affect the alignment of the valve</p> <p>3 leaflets.</p> <p>4 Q Take a look at Exhibit 2131, if you would.</p> <p>5 You've seen Exhibit 2131 prior to your deposition here</p> <p>6 today?</p> <p>7 A I have seen that.</p> <p>8 Q And this is a top-down depiction of the Schreck</p> <p>9 device with the post cantilever inward. I'll just</p> <p>10 represent that to you.</p> <p>11 MR. BARUFKA: Objection as to relevance.</p> <p>12 A Okay.</p> <p>13 Q If the valve is misaligned as depicted in</p> <p>14 Exhibit 2131, that could result in aortic regurgitation?</p> <p>15 MR. BARUFKA: Objection as to relevance.</p> <p>16 A If this happened, it could result in aortic</p> <p>17 regurgitation.</p> <p>18 Q Because that would create a gap between the</p> <p>19 leaflets, which would allow blood to pass from the aorta</p> <p>20 back into the left ventricle?</p> <p>21 A It's possible if this were to occur.</p> <p>22 Q And that could overload the left ventricle and</p> <p>23 cause significant health consequences to the patient?</p> <p>24 A Depends on the amount of leakage.</p> <p>25 Q I'll show you 2235.</p>

Page 181		Page 183	
1	(Deposition Exhibit Number 2235	1	Q This is the DiMatteo device, correct?
2	was marked for identification.)	2	A Yes.
3	Q I'll show you 2235. You said in your	3	Q This device involves valve leafs formed from a
4	declaration that one of the things you could look at in	4	covered valve leaf frame, correct?
5	determining how to construe claim terms was other patents	5	A Yes.
6	in the field. Do you recall that?	6	Q So the leaflets used in this valve are formed
7	A Yes. Prior art.	7	by an actual frame that surrounds them?
8	Q You don't actually say in your declaration	8	A I would think that the leafs around the frame
9	prior art, do you? Let's look at that. You say --	9	would be my interpretation, but --
10	you've got your declaration in front of you?	10	Q Well, let's look at the drawings. You see
11	A I do.	11	Figure 6 there?
12	Q If we look at this, it says -- yeah. It's	12	A 6, yes.
13	paragraph 3. And it's maybe the midpoint. It says,	13	Q Figure 6 shows the valve leaf frame, does it
14	"Finally." Do you see that language?	14	not?
15	A Yes.	15	A I believe so.
16	Q "Finally, I also understand that claim	16	Q And then that frame attaches to a -- or is
17	interpretation may be aided by reference to other sources	17	combined with a scaffold. Yeah. I can -- if this
18	of information, such as dictionaries, textbooks, and	18	helps --
19	literature or other patents in related fields, in order	19	A Yeah, if you can point it to me.
20	to determine the ordinary meanings of terms used in the	20	Q -- if you look at the summary of the invention,
21	claims." Did I read that correctly?	21	it says, "The present invention is directed to providing
22	A Yes.	22	a fully prosthetic valve having valve leafs formed from a
23	Q Would you agree that what I've handed you as	23	covered valve leaf frame and which may be implanted using
24	Exhibit 2225 [sic] is a patent in the related field at	24	a minimally-invasive, endoscopic technique. The present
25	least?	25	invention provides a prosthetic valve for implantation
Page 182		Page 184	
1	A Yes.	1	within a body lumen." And then it says, "The prosthetic
2	MR. BARUFKA: Objection as to relevance.	2	valve of the present invention provides a device for
3	Q And I want to direct your attention to one	3	regulating and maintaining the direction of a pulsating
4	passage in this, if I could. Yeah. Look at column 2.	4	fluid flow through the body lumen. The valve includes a
5	And this is line 35. It's column 2, page 12. I'm sorry.	5	radially-collapsible scaffold portion and a
6	It's page 12 of the exhibit. And it says, line 35,	6	radially-collapsible leaf valve portion. The scaffold
7	"While the valve prosthesis of Bessler and Andersen may	7	portion includes a tubular open body scaffold defining a
8	be readily collapsed for delivery, those designs are	8	fluid passageway therethrough. The leaf valve portion is
9	susceptible to problems once deployed. For example, the	9	deflectable between a closed configuration in which fluid
10	longitudinal projections of such prostheses may not	10	flow through the valve passageway is restricted and an
11	provide sufficient rigidity to withstand compressive	11	open configuration in which fluid flow through the valve
12	forces applied during normal movements of the heart.	12	passageway is permitted." Did I read that correctly?
13	Deformation of the commissural anchors may result in	13	A Yes.
14	varied forces being imposed on the commissures and	14	Q And so would you understand then that the valve
15	leaflets, in turn adversely impact functioning of the	15	leaf frame is attached to this scaffold structure?
16	leaflets." Did I read that correctly?	16	A Yes.
17	MR. BARUFKA: Objection as to relevance.	17	Q And is that shown there in, for example,
18	A Yes.	18	Figure 1?
19	Q And that is a problem that also could affect	19	A Figure 1. Figure 1 would be the closed
20	the device described in Schreck, is it not?	20	configuration, I think.
21	MR. BARUFKA: Objection as to relevance.	21	Q And what allows these leaflets to open and
22	A As we've been discussing, yes.	22	close is that they are separated by a hinge line?
23	Q Take a look, if you would, at Exhibit 2198.	23	A I believe so.
24	You've got 2198 in front of you?	24	Q And so within each valve leaf frame, there is a
25	A Yes.	25	hinge that allows the leaflet to open and close in

Page 185	Page 187
1 response to pressure changes within the aorta and 2 ventricle?	1 Q And if the structure in which the hinge lines 2 incorporate, if that structure moves, that hinge line is 3 going to move.
3 A That would be my understanding.	4 MR. BARUFKA: Objection as to form; objection 5 as to relevance.
4 Q And this invention, as we see it illustrated -- 5 and there are several illustrations. But we look, for 6 example, at Figure 2, we see one, two, three, four, 7 five -- six leaflets abutting one another in a closed 8 configuration?	6 A It could move. 7 Q And if it does move, that could impact the 8 ability of these leaflets to abut one another?
9 A Yes.	9 A It could.
10 Q And the way that these leaflets coapt, or come 11 together, is that they do abut one another, correct?	10 Q And if it does that, these leaflets could 11 misalign?
12 A As in this drawing, it appears that way, yes.	12 MR. BARUFKA: Objection as to form; objection 13 as to relevance.
13 Q And that's specifically spelled out in the 14 patent, that these leaflets are designed to come together 15 in an abutment?	14 A It's possible that they could.
16 A Okay.	15 Q And if they misalign, that could allow aortic 16 regurgitation to occur?
17 Q And every depiction of this device shown in 18 this patent that is a top-down depiction -- a bottom-up 19 depiction depicts it as a perfectly circular design?	17 MR. BARUFKA: Objection as to form; objection 18 as to relevance.
20 MR. BARUFKA: Objection as to form.	19 A If they misalign and there's a gap.
21 Q Take a look, for example, at Figures 2, 4, 13C. 22 You can also look at 24B or 25B if you would like.	20 Q And you've said a couple times "if." What 21 factors would determine whether or not these hinges move 22 when this valve device changes shape from a circle to 23 more of an oblong shape?
23 A Yeah. They look circular. It's hard to say if 24 they are perfectly a circle as we discussed earlier.	24 MR. BARUFKA: Objection as to form; objection 25 as to relevance.
25 Q Okay. Now, if this device, instead of being a	
Page 186	Page 188
1 perfect circle, if it is placed in a passageway where it 2 is forced to change shape from what's depicted here to 3 more of an oval shape, that movement would cause the 4 leaflets to move?	1 A The amount of change in shape is what would 2 affect that.
5 MR. BARUFKA: Objection as to form.	3 Q I see. Is it true that if there is a slight 4 change in shape, that could cause slight change in the 5 movement of the leaflets?
6 A It could cause the leaflets to move.	6 A Yes, or no change.
7 Q Because the device is designed such that the 8 leaflets are attached to the scaffold?	7 Q Depending on how slight the change was, 8 correct?
9 A Yes.	9 A Uh-huh.
10 Q And so if the scaffold is contorted upon 11 placement, that will cause at least some contortion to 12 the leaflets attached to the scaffold?	10 Q That's a yes?
13 MR. BARUFKA: Objection as to form; objection 14 as to relevance.	11 A Yes. Sorry.
15 A It could.	12 Q So if we look at Exhibit 2133 --
16 Q And it could cause the hinges that are 17 incorporated within these leaflets to move?	13 A Okay. 14 Q Is Exhibit 2133 one of the drawings that you 15 examined?
18 A What would cause the hinges to move? Sorry.	16 A Yes.
19 Q Yeah. The hinges, as I understand this 20 device -- but tell me if you've got a different 21 interpretation -- is a device where these framed leaflets 22 are able to move closed and open because they have hinges 23 or a hinge line incorporated within them, and so they 24 move open and closed about this hinge line, correct?	17 Q In the bottom drawing, that depicts a 18 top-down -- or that shows a top-down view of an aorta 19 that has an oblong shape. Do you see that?
25 A Sure. Uh-huh.	20 MR. BARUFKA: Objection as to form; objection 21 as to relevance.
	22 A Yeah. It's an oblong structure, may or may not 23 be in the aorta, but yes.
	24 Q Is what -- let me ask it this way. Well, in 25 preparing your declaration, one of the things you for

Page 189	Page 191
<p>1 sure looked at was Dr. Catchings' deposition, correct?</p> <p>2 MR. BARUFKA: Objection as to form.</p> <p>3 A I scanned his deposition and his declaration,</p> <p>4 yes.</p> <p>5 Q And he specifically identified what structures</p> <p>6 were being shown by these drawings we've looked at,</p> <p>7 correct?</p> <p>8 A Yes.</p> <p>9 Q And he specifically said this was intended to</p> <p>10 be a top-down view of the aorta, did he not?</p> <p>11 A Sure. It's just not labeled on here. That's</p> <p>12 all. Yes.</p> <p>13 Q Okay. And what he said -- and tell me if you</p> <p>14 don't recall this, but the top -- if you look at the top</p> <p>15 drawing on this Exhibit 2133, that would be an aorta if</p> <p>16 the aorta was a perfect circle, correct?</p> <p>17 MR. BARUFKA: Objection as to form; objection</p> <p>18 as to relevance.</p> <p>19 A I don't recall exactly if that's what he said,</p> <p>20 but if these are aortas, that would be a circular aorta.</p> <p>21 Q Okay. If the aorta was instead the shape of</p> <p>22 the bottom illustration, so more of an oval shape, is</p> <p>23 what we see here something that could occur to the</p> <p>24 DiMatteo device?</p> <p>25 MR. BARUFKA: Objection as to form; objection</p>	<p>1 more deformation when it's implanted?</p> <p>2 A Yes.</p> <p>3 Q And that greater degree of deformation could</p> <p>4 cause misalignment of the leaflets?</p> <p>5 A It could, yes. But I would imagine you would</p> <p>6 take that into account when building this device.</p> <p>7 Q The leaflets are designed to, as we talked</p> <p>8 about earlier, to touch one another, to abut one another,</p> <p>9 right?</p> <p>10 A Uh-huh. Yes.</p> <p>11 Q That's a yes?</p> <p>12 A Yes.</p> <p>13 Q They're not designed to overlap. They're</p> <p>14 supposed to abut.</p> <p>15 MR. BARUFKA: Objection as to form.</p> <p>16 A As described in the patent.</p> <p>17 Q Correct?</p> <p>18 A Yes.</p> <p>19 Q So how would you take into account possible</p> <p>20 deformation of the device upon placement if you wanted to</p> <p>21 have the device retain its functionality upon</p> <p>22 implantation?</p> <p>23 A I think you would seek to understand the shapes</p> <p>24 that you might see in the implantation location and the</p> <p>25 rigidity of or the pliability of the two structures.</p>
<p>1 as to relevance.</p> <p>2 Q In other words, if there was this amount of</p> <p>3 contortion of the device where it went from the top shape</p> <p>4 to the bottom shape, so you go from the circular shape</p> <p>5 that's shown at the top to this more oval shape at the</p> <p>6 bottom, could that cause these leaflets to misalign in</p> <p>7 the manner shown in Exhibit 2133 at --</p> <p>8 MR. BARUFKA: Objection as to form.</p> <p>9 Q -- the bottom picture?</p> <p>10 MR. BARUFKA: Objection as to relevance.</p> <p>11 A It's possible that that could happen. It</p> <p>12 depends on the specifics of the device.</p> <p>13 Q And when you say that, what do you mean?</p> <p>14 A The material properties of what is -- I mean,</p> <p>15 the degree of deformation is going to be dependent on the</p> <p>16 interaction between the device material properties and</p> <p>17 the aorta material properties.</p> <p>18 Q The device, if the device is a rigid structure</p> <p>19 such that it resists deformation, that could cause it to</p> <p>20 retain more of a circular shape?</p> <p>21 A If it's rigid or less pliable than the aorta or</p> <p>22 less flexible than the aorta. I'm sorry. More -- less</p> <p>23 flexible, yeah. I had that right.</p> <p>24 Q In contrast, if it is more flexible, so you've</p> <p>25 got a real flexible or pliable device, that could cause</p>	<p>1 Q Would you try to make the DiMatteo structure</p> <p>2 more rigid so that it resisted deformation?</p> <p>3 A That's one avenue, to make the scaffold resist</p> <p>4 or less flexible than the aorta. The other would be to</p> <p>5 change the cusp design such that they would function and</p> <p>6 abut in a structure like this or in a shape like this.</p> <p>7 Q So you would change it so it's designed to be</p> <p>8 more of an oblong or oval structure if that was the site</p> <p>9 that you were implanting?</p> <p>10 A You could. You could envision that happening.</p> <p>11 Q But that's not shown anywhere in the patent,</p> <p>12 correct?</p> <p>13 A The drawings don't show that, no.</p> <p>14 Q Take a look at Exhibit 2199, if you would.</p> <p>15 Exhibit 2199 is Leonhardt. This is one of the patents</p> <p>16 you considered in coming up with your declaration?</p> <p>17 A Yes.</p> <p>18 MR. BARUFKA: Objection to the relevance.</p> <p>19 He --</p> <p>20 Q If we look at the abstract, it says -- and I'm</p> <p>21 trying to find the location. Yeah. Towards the bottom</p> <p>22 half of this abstract, it says, "The artificial valve may</p> <p>23 be completely sealed to the living tissue by light</p> <p>24 activated biocompatible tissue adhesive between the</p> <p>25 outside of the tubular graft and the living tissue." Did</p>

Page 193

1 I read that correctly?

2 MR. BARUFKA: Objection as to relevance.

3 A You did.

4 MR. BARUFKA: Can we go off the record for just

5 one second?

6 MR. MARCUS: Yeah.

7 (Discussion was held off the record.)

8 MR. MARCUS: My understanding is that Medtronic

9 intends to object to all questions about the

10 Exhibit 2199. So I will ask the questions, and

11 Medtronic will have a standing objection to all

12 questions concerning 2199. Is that accurate?

13 MR. BARUFKA: Yes.

14 Q So if we look at 2199, there's a reference to

15 this light activated adhesive.

16 A Uh-huh.

17 Q Do you see that?

18 A In the abstract, yes.

19 Q Are you aware of any light activated adhesive

20 that works in the environment where this is designed to

21 be installed?

22 A I have no particular awareness of light

23 activated adhesives that have been used for this. I know

24 there are light activated adhesives that would

25 potentially perform this function.

Page 194

1 Q Do you know whether they existed in November of

2 2000?

3 A I don't know.

4 Q Is that something you looked at in preparing

5 your declaration?

6 A Whether the adhesives -- I did not.

7 Q And from the time you began working with

8 prosthetic valves until today, are you aware of any light

9 activated adhesive that's been used successfully in

10 connection with a prosthetic aortic valve?

11 A Nothing that's released on the market that I'm

12 aware of. I'm trying to think back if we've done any

13 research on it. But no, I don't seem to recall anything.

14 Q This particular device, do you agree that it is

15 designed to be placed within the aortic annulus?

16 A I would have to read more into the patent to be

17 sure exactly where it's designed to be placed. Would you

18 like me to do that?

19 Q I'm trying to find that. Yeah. I mean, I

20 guess help me with this one. If we look at this patent,

21 and I'm looking at these figures, it looks like Figure 2

22 depicts this valve -- or this prosthetic valve placed

23 within the mitral position. Is that right?

24 A Without labels, that would be my

25 interpretation, yes.

Page 195

1 Q And then Figure 3, is that showing this valve

2 placed within the aorta?

3 A That's -- it could be. It's tough to say

4 without it being labeled.

5 Q Did you form an understanding when you

6 considered this patent as to where it was to be placed?

7 A As I'm reading it now, again, it said cardiac

8 valves, all valves.

9 Q But in terms of the precise positioning of this

10 device within the aorta, did you form a belief as to

11 whether it ought to be placed in the annulus or

12 elsewhere?

13 A I didn't. I didn't review this patent in-depth

14 with respect to my declaration.

15 Q For what purpose did you review this patent in

16 preparing your declaration?

17 A As another piece of patent art -- relevant art

18 at the time.

19 Q Let me show you this. Take a look at 2139. In

20 preparing your declaration, did you consider

21 Exhibit 2139?

22 A This one doesn't look as familiar to me as the

23 others. If it was part of the deposition and

24 declaration, then yes, I would have reviewed it. The

25 other ones were familiar. This one doesn't look as

Page 196

1 familiar.

2 Q Let me just see if I can figure this out. Take

3 a look at 2140. Did you consider 2140 in preparing your

4 declaration?

5 A Neither of these look as familiar as the

6 others. If they were part of the documents, then yes, I

7 would have looked at them, but they don't look as

8 familiar.

9 Q I guess just to complete the thought then,

10 2141, did you look at 2141 in preparing your declaration?

11 A Same answer.

12 Q Are you prepared to provide any testimony

13 whatsoever as to the Leonhardt device and its similarity

14 or differences with the device described in the '228

15 patent?

16 A No.

17 MR. MARCUS: Let's go off the record just for

18 one second. Let's take a break.

19 (Break, 3:22 p.m. until 3:29 p.m.)

20 Q When we were talking about the DiMatteo and

21 Schreck devices a few moments ago, you made a comment

22 that you would interpret those structures and those

23 leaflets in a manner where they would function, where

24 they would work. Do you recall that testimony?

25 A That one -- if the device was deformed, that

Page 197

1 they could work?

2 Q No. Let me back up. I had asked about the

3 design of those structures, and you said that a person

4 designing those structures would do that in a way where

5 they could function, where they would not misalign in the

6 manner that I had described to you. Do you recall that?

7 A If the base was deformed. I think that was

8 what we were discussing.

9 Q Would you apply that same standard in

10 construing the claims of the '228 patent? Would you

11 construe those claims in a manner where that structure --

12 where those embodiments described in that patent would

13 work?

14 MR. BARUFKA: Objection, relevance.

15 A I would apply the same logic, yes.

16 MR. MARCUS: No more questions.

17 MR. BARUFKA: Okay.

18 (Break, 3:31 p.m. until 3:44 p.m.)

19 MR. BARUFKA: We have no more questions. So --

20 THE COURT REPORTER: I need to put on the

21 record the reading and signing and a statement about

22 who is supposed to pay for the transcript.

23 MR. BARUFKA: The Petitioner pays for your

24 services.

25 MR. MARCUS: And on the record, what do we do

Page 198

1 for -- she needs stipulations on the record as to

2 reading and signing. What do you typically do here?

3 MR. EDMAN: We'll read and sign.

4 MR. MARCUS: I like e-Tran and then PDF

5 exhibits, but then we need the original, too, the

6 original which we get, but then an e-transcript and

7 then PDF exhibits if you can do it. The transcript

8 in PTX.

9 THE COURT REPORTER: Mr. Barufka, what format

10 would you like your transcript in?

11 MR. BARUFKA: We'd like it expedited

12 electronic.

13 THE COURT REPORTER: PDF or ASCII format? Do

14 you know?

15 MR. BARUFKA: PDF.

16 THE COURT REPORTER: Would you like the

17 exhibits in PDF also?

18 MR. BARUFKA: Yes, please.

19 THE COURT REPORTER: Okay. Thank you.

20 (Deposition concluded at 3:45 p.m.)

21 *****

22

23

24

25

Page 199

1 REPORTER'S CERTIFICATE

2

3 STATE OF MINNESOTA)

4 COUNTY OF HENNEPIN) ss.

5 I hereby certify that I reported the

6 deposition of ALEXANDER J. HILL, on the 5th day of

7 December, 2014, in Minneapolis, Minnesota, and that

8 the witness was by me first duly sworn to tell the

9 whole truth;

10 That the testimony was transcribed by me and

11 is a true record of the testimony of the witness;

12 That the cost of the original has been

13 charged to the party who noticed the deposition, and

14 that all parties who ordered copies have been

15 charged at the same rate for such copies;

16 That I am not a relative or employee or

17 attorney or counsel of any of the parties, or a

18 relative or employee of such attorney or counsel;

19 That I am not financially interested in the

20 action and have no contract with the parties,

21 attorneys, or persons with an interest in the action

22 that affects or has a substantial tendency to affect


23 my impartiality;

24 That the right to read and sign the

25 deposition by the witness was reserved.

WITNESS MY HAND AND SEAL, this 8th day of

December, 2014.



Lori L. Morrow, RMR, CRR, CCP, CLR
Notary Public, Hennepin County, Minnesota
My commission expires: January 31, 2015