## Entire Transcript of Deposition of Dr. Hansen A. Yuan, dated August 22, 2014

This transcript is being filed in IPR2013-00506 pursuant to a request by Patent Owner and the Board's concurrence. *See* Paper 31.

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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
MEDTRONIC, INC.,
                   Petitioner,
          -vs-
NUVASIVE, INC.,
                    Patent Owner.
Patent Number 8,361,156 B2
Issue Date: January 29, 2013
Case IPR2013-00506
MEDTRONIC, INC.,
     Petitioner,
          -vs-
NUVASIVE, INC.,
                   Patent Owner.
Patent Number 8,187,334 B2
Issue Date: May 29, 2012
Case IPR2013-00507
MEDTRONIC, INC.,
     Petitioner,
          -vs-
NUVASIVE, INC.,
                    Patent Owner.
Patent Number 8,187,334 B2
Issue Date: May 29, 2012
Case IPR2013-00508
      Examination Under Oath of HANSEN A. YUAN, M.D.,
    held at 211 West Jefferson Street, Suite 21,
    Syracuse, New York, on August 22, 2014, before
    MARITA PETRERA, Registered Professional Reporter,
    and Notary Public in and for the State of New York.
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2
    APPEARANCES
2
    For the Petitioner:
3
          FOX ROTHSCHILD, LLP
         Attorneys at Law
5
          The Executive Building
6
          1030 15th Street, N.W.
7
          Suite 380 East
         Washington, DC 20005
         BY: JEFF E. SCHWARTZ, ESQ.
10
               jeschwartz@foxrothschild.com
11
               202-236-0459
12
13
         MARTIN & FERRARO, LLP
14
          Attorneys at Law
15
          5151 Headquarters drive
16
          Suite 170
17
          Plano, Texas 75024
18
          BY: BRENT D. MARTIN, ESQ.
19
               bmartin@martinferraro.com
20
               972-668-3129
21
22
```

		3
1	For the Patent Owner:	
2	FISH & RICHARDSON	
3	Attorneys at Law	
4	12390 El Camino Real	
5	San Diego, CA 92130	
6	BY: MICHAEL A. AMON, ESQ.	
7	amon@fr.com	
8	858-678-4708	
9		
10	FISH & RICHARDSON	
11	Attorneys at Law	
12	3200 RBC Plaza	
13	60 South Sixth Street	
14	Minneapolis, MN 55402	
15	BY: STUART NELSON, ESQ.	
16	snelson@fr.com	
17	612-337-2538	
18		
19	* *	*
20		
21		
22		

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18		replacement device (unidentified)	
19			
20	*	* *	
21			
22			

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	7
1	HANSEN A. YUAN, M.D., having been
2	called as a witness, being duly sworn, testified as
3	follows:
4	MR. AMON: I'll make appearances
5	first on the record.
6	MR. SCHWARTZ: Jeff Schwartz for
7	Medtronic and Brent Martin for
8	Medtronic.
9	MR. AMON: Michael Amon, of Fish
10	& Richardson on behalf of NuVasive and
11	of Dr. Yuan. With me is Stewart
12	Nelson, also of Fish & Richardson, and
13	we'll put on the record that Dr. Yuan
14	is waiving review and signature of his
15	deposition.
16	
17	EXAMINATION BY MR. SCHWARTZ:
18	Q. Dr. Yuan, could you state your full name
19	for the record?
20	A. Hansen A. Yuan.
21	Q. And your address, sir?
22	A. Right now is address 3692 Nelson's Walk,

8 Naples, Florida, 34102. 2 Sir, have you ever been deposed before? Ο. 3 I've been deposed before. Α. How many times have you been deposed? Q. 5 Α. The deposition most of the time when I was 6 actively practicing, so the last time probably is 7 about eight or nine years ago, and totally, maybe a 8 dozen times. 9 Q. Okay. Have you ever been deposed in a 10 Patent Office proceeding before? 11 Α. No. 12 Okay. So I'm not going to belabor some of Ο. 13 the typical stuff. You know how this works. 14 ask questions and then the Court Reporter will take down my question and your answer, you understand 15 16 that, right, sir? 17 Yes, sir. Α. 18 And you're under oath, so you understand 19 that there's an obligation to tell the truth, 20 correct? 21 Α. Yes, sir. 22 And if you don't, there's a potential Ο.

Yuan, M.D., Hansen A.

- penalty of perjury, you understand that, right, sir?
- 2 Α. That's correct.
- 3 And the Court Reporter will need you to
- 4 answer out loud, so shaking your head or something
- 5 like that, I might understand, but the Court
- 6 Reporter won't know how to transcribe that.
- 7 we'll need your answers to be verbal, if that's
- 8 okay?
- 9 Yes, sir. Α.
- 10 The other thing is that the Court Reporter
- 11 will need for us to not talk over each other, so
- 12 when I'm asking a question, just wait until I'm
- 13 finished and I'll try to not interrupt you while
- 14 you're making an answer. Is that okay?
- 15 Yes, sir. Α.
- 16 Okay. And if you need a break for any Ο.
- 17 reason, stretch your legs or whatever, just let me
- 18 know, and I'll be glad to go off the record so long
- 19 as there's not a question pending, okay?
- 20 Α. Yes.
- 21 And one of the nuances which you may not Ο.
- 22 be used to, since this is a Patent Office

- proceeding, is that now that the -- this is
- 2 considered Cross-Examination, and once the
- 3 Cross-Examination has begun, you're not to consult
- with counsel until the Cross-Examination is
- 5 complete.
- 6 You understand that, sir?
- 7 Α. Yes.
- 8 Ο. So if we take a break, of course you're
- 9 free to talk about the weather or what you want to
- 10 have for lunch or something like that, but you
- 11 shouldn't be talking about the questions or answers
- 12 or what may be coming up or something like that.
- 13 You understand that, sir?
- 14 Α. Yes.
- 15 Have you taken any medication that might
- 16 affect your ability to answer my questions today,
- 17 sir?
- 18 No, sir. Α.
- 19 Okay. And have you taken any medication
- 20 that might affect your ability to understand my
- 21 questions?
- 22 No, sir. Α.

- Q. Okay. What did you do to prepare for this
- deposition, sir? And as a prerequisite, I'm not
- intending to elicit any conversations you may have
- 4 had with counsel as to the specifics of what you
- 5 said or what they said to you. But I just want to
- 6 know in general what you did to prepare for this
- 7 deposition?
- A. I review a series of documents, I review
- 9 actually four patents that is my Declaration along
- with certainly the two patents that we are discussing
- 11 for NuVasive which is a patent '334 and patent '156.
- 12 And I have reviewed Dr. Hynes's deposition with you,
- along with reviewing the Medtronic's and also
- NuVasive's position; certainly the Declarations.
- Q. And when you say the Medtronic and
- NuVasive positions, was that in a document?
- A. Excuse my word, I'm not an attorney, so I
- merely saying that I have reviewed what is, what
- 19 today's issue is going to be. That's the two points
- concerning the, I'm not saying the right word, but I
- 21 guess is a declaration or your, maybe not the word is
- position, but just what Medtronic's and the

- 1 NuVasive's declaration is as good a word as I can
- <sup>2</sup> say.
- O. Sure.
- 4 A. If I look at the document, I will know what
- 5 I actually say. I didn't memorize.
- Q. Yep. And sir, again, my questions are
- <sup>7</sup> also not intended to be a memorization test. I'll
- 8 certainly be asking you questions that may be from
- 9 your memory, but I'm not trying to trip you up or
- something like that. I'm just trying to get
- whatever your recollection is, if that's okay.
- 12 A. Yes.
- Q. Do you recall how much time you spent
- preparing for today's deposition, sir?
- 15 A. A general estimate, I read through these
- documents probably somewhere around about seven,
- eight hours, and then I spent time with my attorneys,
- 18 Mr. Amon and also Mr. Nelson, sometimes one of them,
- sometimes both of them, over the last two days.
- Q. Did you talk about your deposition
- 21 preparation with anyone other than the two attorneys
- that are here in the room?

- 1 A. No, sir.
- Q. Okay. During your review of the documents
- in preparation for this deposition, did that review
- 4 suggest to you that you should change or alter
- 5 anything that was in your declaration?
- 6 A. Can you ask me that one more time?
- Q. Sure. When you were, you just discussed
- 8 what you did to prepare for your deposition, you
- 9 reviewed a number of documents, depositions, things
- 10 like that. As part of that thought process, in your
- preparation, did that bring to mind to you that you
- wanted to change or alter something that you said in
- your declaration in these matters?
- 14 A. We obviously discussed more specifically
- verbally some of the topics and some of the points.
- 16 There was some going back and forth. So mainly for
- me to be educated on the terminology, the legal
- terminology side which I'm not an attorney so it was
- a learning experience, but we didn't change anything.
- Q. Okay. So as far as the conclusions that
- you reached in your reports, right now you're fine
- with those conclusions, is that right?

	14
1	A. It stands, correct.
2	Q. Sir, I'm going to hand you what's
3	previously been identified as NuVasive Exhibit 2021.
4	(Handed.)
5	MR. AMON: Thank you.
6	Q. Sir, do you recognize that document?
7	MR. AMON: Dr. Yuan, take your
8	time to review, if necessary.
9	THE WITNESS: Thank you. I'll
10	take a look at this.
11	MR. SCHWARTZ: For the record, I
12	would ask Counsel not to converse with
13	the witness while I'm asking
14	questions.
15	Q. The question pending, sir, is just whether
16	you recognize that document.
17	A. This is my CV. I'm just looking through.
18	Yes. This is my CV, and it may not be exactly up to
19	date today, but generally it is correct.
20	Q. It's not up to date today?
21	A. I don't know, because every month something
22	changes, still going forward.

15 Q. Okay. 2 But nothing, nothing of significance. 3 Nothing of issue. Things continue to evolve even though I'm no longer academically active at the 5 university being professor emeritus, there are other things I'm continuing to do. 7 Do you have a more up to date CV, sir? 8 That I have to ask my assistant because she 9 constantly update. Same thing I got to ask my wife 10 what I can do. 11 But what I'm quite honestly trying to 12 avoid, sir, going through your life's history to the 13 extent it's accurately represented in your CV so I 14 don't have to ask you questions where you worked and 15 when and all that type of stuff. 16 So is it fair that we can rely on the 17 information in this CV as being accurate as to what it reflects? 18 19 Yes, sir. 20 Okay. So other than the possibility that Q.

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appointment since this was created, the information

there may be some new paper or presentation or

21

```
16
    in this document's accurate?
2
         Α.
               Exactly.
3
         Q.
               Okay.
4
         Α.
               I'd just like to be exactly up to date.
5
               Okay. And sir, avoiding getting into your
         Ο.
6
    life's history, I'd like to get into a little bit of
7
    your connection with NuVasive. So starting out, you
8
    served on their board of directors, correct?
9
               That's correct.
         Α.
10
         O.
               And you're no longer in that capacity?
11
         Α.
               It's been many years since I resigned.
12
               Do you recall about when you resigned?
         Ο.
13
               I don't know exactly. I can look it up.
         Α.
14
    Do you know exactly which page it is, if you do you
15
    will help.
16
               I honestly don't but I will look through
          Ο.
17
    it as you do. I apologize if it says on your
18
    resume.
19
               It lists, on page, what appears to be
20
    Page 114 which is about the second to last page,
21
    that you were on the board of directors for
22
    NuVasive, it doesn't give any dates for that which
```

- is why I was asking the question.
- A. I apologize for that. I will say it's
- 3 approximately six or seven years ago.
- Q. Okay.
- 5 A. That's as far as I can approximate.
- Q. And do you recall around when you started
- <sup>7</sup> on the board?
- 8 A. I was totally on the board about three and
- 9 a half years. Three and a half to four years.
- 10 Q. So you started about 10 years ago, about?
- 11 A. That's correct.
- Q. Can you tell me generally what your
- responsibilities were as a member of the board for
- 14 NuVasive?
- 15 A. Yes, sir. When I was asked to join the
- board, there was no technical person on the board,
- technical meaning somebody who is either an engineer
- or somebody who is a physician. And there was one
- 19 just before me who served, who was one of the
- founders, and then after him there was another spine
- $^{21}$  surgeon who served on the board for several years,
- and I was merely asked to join to really offer more

- clinical and more technical position on the board;
- 2 nothing financial, nothing business, which is not
- 3 anything of my forte.
- 4 And were you paid for that responsibility, Q.
- 5 sir?
- 6 Α. There was stock options, and I guess they
- 7 assigned some number of restricted stocks for the
- 8 year you were on the board, and then there's a
- 9 vesting period.
- 10 Any other payment of any type besides O.
- 11 stock options, sir?
- 12 They paid for expenses. Α.
- 13 Ο. Anything else, sir?
- 14 Trying to think, so I'm not missing Α.
- 15 something.
- 16 Ο. Was there a salary of any type?
- 17 Because I'm not employees, I'm not on Α. No.
- 18 salary. I think there was a fee that they paid if
- 19 you attend a board meeting.
- 20 Q. Okay.
- 21 I don't even, I don't even recall the
- 22 amount, but I was -- this will be a guess -- maybe

```
19
    like $2,000 per board meeting.
2
               Okay.
         0.
3
               As a guess.
4
              And do you still have any of those stock
5
    options?
6
         Α.
               My stock options vested, I still have those
7
    stocks, correct.
8
               Okay. So you have some amount of stock in
9
    NuVasive at this point?
10
         Α.
               Yes, sir.
11
               Do you have a general feel for how much
12
    that is worth?
13
               I don't follow the stock market so I don't
         Α.
14
    look at it so to answer your question, do I have a
    general feel, I could, I wouldn't even be able to
15
16
    tell you what the value is. The number of stock
17
    probably is in the ballpark like 20,000 shares.
18
    there are options still.
19
               And so 20,000 shares that are vested, is
20
    that --
21
               They are vested but in order for me to
         Α.
22
    exercise obviously you have to pay the value of what
```

- it is at the time that was vested, or what was --
- 2 when was given. So it could be, like, \$39 a share,
- 3 or today I wouldn't want to sell it, and I guess
- understanding with the stock prices, you know, my
- 5 wife does this so I don't look at it, and she doesn't
- manage my stock but she always tell me it's going up,
- 7 going down, so I only know that some stocks are at
- 8 about 39, some stocks are at about \$20. So there's a
- 9 wide variation over those years.
- 10 So in broad terms are we looking at about
- 11 a couple hundred thousand dollars worth of stock?
- 12 MR. AMON: Objection;
- 13 speculation.
- 14 I'm just asking for your best guess. 0.
- 15 We can do the math. I didn't figure it
- 16 out.
- 17 Right. 0.
- 18 So I would say it's approximately that. Α.
- 19 Okay. Thank you, sir. Ο.
- 20 Thank you. Α.
- 21 Sir, when you were on the board in this Q.
- 22 technical role, did you -- maybe I should just ask

21 it open-endedly, what if anything did you do as part 2 of that? 3 In those technical -- let me answer that 4 directly first. If they going to be designing a new 5 pedicle screw, they will ask me would it be something I would use, would it be something that is better 7 than what I'm using at the time. I'm not involved 8 with the so-called, the development of it. It's just 9 merely a general question of whether as a physician I 10 will use it or not or if it was an improvement over 11 what I have. 12 And they will be showing new technology 13 that they are considering acquiring such as a bone 14 graft material, what bone graft material I'm using 15 currently, is this new one with this different 16 properties be something that is of more value to me. 17 More in that capacity, and also I, you have to serve 18 on a committee so as a board member I serve on the 19 compensation committee. 20 And what did the compensation committee 21 do?

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I'm just a member and basically the

Α.

- 1 chairman of the committee would gather all the
- information and then there will be three of us that
- 3 would review the information for each one of the
- 4 senior managers and executives, and then to see what
- 5 the market compensation should be and then there's an
- open discussion of how well one person performed or
- <sup>7</sup> how poorly one person performed.
- Q. Okay. Did you ever get involved in
- <sup>9</sup> discussions about the safety or efficacy of
- products, either existing products or new products?
- 11 A. No.
- 12 Q. Okay.
- 13 A. Those things are already -- merely is a
- 14 functionality of a product, how it would improve in
- usage. But safety efficacy, those things are
- something handled by the regulatory and generally
- it's products, either they are too early in the
- development phase and they haven't gone through
- 19 regulatory, or at the end after the FDA approval. So
- the safety efficacy, those things are documented and
- they will present to see, just the question of does
- it help me in my practice.

So for example, when you mentioned that 2 they might show you something new and ask you about 3 your possible use of that in your practice, would you be asked or offer any opinion about the safety of that new thing that they were showing you? 5 6 MR. AMON: Objection; compound. There never was a time we talked about Α. 8 safety. 9 Okay, fair enough. Did you have any sense 10 in your role on the NuVasive board as to whether or 11 not NuVasive was promoting anything that was unsafe? 12 Not at all. I would have to say that my 13 experience on the board there, I been on a few other 14 boards, so that was an experience where I was very, 15 very impressed by the very careful and detail 16 assessment of products. As far as safety issues 17 concerned, that is not an issue that there is 18 anything that, that would be risky at all to 19 patients. Those things are absolutely something that 20 they will not be involved with.

were to put out marketing material, you felt

Is it fair to say, sir, that if NuVasive

Ο.

21

24 confident that the information they were 2 disseminating was not promoting something unsafe? 3 That's correct. I will say that their 4 marketing is managed very, very carefully, very 5 strictly, and I didn't look at marketing brochures or 6 topics as such but I do know that one aspect of their 7 maybe quote, unquote, marketing, is really 8 concentration in making sure surgeons are 9 well-trained to use their products. They made a 10 point of making sure that the launching, 11 introduction, and continued education both on a 12 directly, I would say lecture and also on a hands-on 13 cadaver session is very well done. So as I said, my 14 experience with them on the safety side is that they 15 are very, very careful and I don't know of any, I 16 didn't see or perceive any unsafe path that they 17 would pursue. 18 Is the same true with regard to 19 information they describe in their patents and 20 patent applications? 21 MR. AMON: Objection; vague, 22 outside the scope.

	25
1	A. On the patents side. The only patents I
2	have looked at is a patent '334 and '156. So those
3	are the only two patents that I'm familiar with of
4	theirs, because I did that for this Declaration. So
5	I'm trying to understand your question, Counselor.
6	Q. Well, sir, you talked about the way that
7	NuVasive approaches safety as it pertains to their
8	marketing material. And I'm asking you now, sir, if
9	you think that NuVasive approached the descriptions
10	in their patents the same way?
11	MR. AMON: Same objection;
12	including lacks foundation.
13	A. Your first statement is that can you
14	repeat your first statement again? I apologize. I
15	don't want to say something that I didn't understand.
16	(Whereupon, the pending question
17	was then partially read.)
18	THE WITNESS: Hold on. I didn't
19	look at the marketing material, so I
20	can't correlate your statement of
21	safety to their products, okay. I
22	only know that what's presented and

	26
1	what I as a surgeon would be, would
2	understand, and there was never an
3	issue of safety that was raised, so
4	that statement that you asked is why I
5	didn't understand it, is I didn't make
6	any correlation between the marketing
7	material and safety.
8	EXAMINATION BY MR. SCHWARTZ:
9	Q. Okay. Do you have any reason to think
10	that information that NuVasive puts in its patent
11	applications would promote something unsafe?
12	A. I have no reason to believe that.
13	Q. Okay. Thank you, sir.
14	A. Thank you.
15	Q. Sir, I'd like to talk a little bit about
16	your background and experience, specifically as it
17	pertains to intervertebral fusion, and in
18	particular, with the use of artificial implants,
19	okay.
20	Can you explain in general how many
21	surgeries that are fusion procedures using
22	intervertebral implants you've done?

- 1 A. To give you a number would be totally a
- guess. I did a lot of fusions because of
- degenerative and traumatic spinal condition is a bulk
- of our practice. I don't do any so-called idiopathic
- 5 scoliosis, so no adolescents. Basically degenerative
- 6 and trauma and infections.
- <sup>7</sup> So I would say that between cervical spine,
- 8 thoracic spine and lumbar spine, for fusion
- 9 procedures would be over 60 percent of my total
- number of cases done. So if I did anywhere between
- 11 eight or nine thousand cases totally in my career, I
- would say 60 percent of that.
- Q. Okay. And of that, how many would you say
- were lumbar cases, sir?
- 15 A. So lumbar, outside of cervical and thoracic
- would be the biggest number. The cervical now has
- become bigger number in the hands of a surgeon
- because several of the diseases have more ability to
- so call take care of it, but in the older days, the
- cervical ones are really managed much more on a
- 21 non-operative basis. In my days, I would say the
- lumbar, the lumbar were easily be over, again,

- 1 probably over 60 percent of total fusions, 60 to
- <sup>2</sup> 70 percent.
- 3 Q. So 60 percent to 70 percent of the
- 4 60 percent of your total cases?
- 5 A. Right.
- MR. AMON: Dr. Yuan, please let
- 7 Mr. Schwartz finish his question.
- 8 THE WITNESS: Sorry.
- 9 Q. Okay. Sir, and then of those lumbar
- cases, could you break out anterior procedures
- versus posterior procedures?
- 12 A. There were period of time that we did
- anterior surgery and the anterior surgery that we did
- 14 are actually relatively few. We did a
- laparoscopically, we did open, so the majority of the
- lumbar cases, I would say over 80, 85 percent, either
- going to be posterior, posterolateral. And these all
- happen over a period, so in the early, early days, we
- would have done a lot more anterior -- posterior
- 20 because we didn't have any other, and then for a
- 21 short period of time we went ahead and did a lot of
- anterior, and then towards the end with the

- improvement of the modern interbody spacers, cages,
- we shifted again to posterior and posterolateral and
- 3 then of course the lateral approaches.
- Q. When did you first start doing lateral
- 5 approaches, sir?
- MR. AMON: Objection; vague.
- A. Lateral approaches, for what condition?
- Q. Well, any lateral approach using an
- 9 intervertebral implant for any condition.
- 10 A. I did lateral approaches as early as 1980s.
- 11 Q. 19?
- 12 A. 80s.
- 13 O. 1980s.
- 14 A. And that included using cages, but those
- 15 are mostly for fractures, and most of those cases are
- in the thoracic, and in the thoracolumbar junction.
- Q. Could you explain what the thoracal lumbar
- 18 junction is?
- 19 A. Between the thoracic which is the ones with
- the ribs and fairly stable and so between the
- thoracic transiting to the lumbar which is more
- flexible, so most of the injuries that's going to

```
30
    occur most commonly is between the thoracic and the
2
              So it's pretty much like T11, T12, L1, L2.
    lumbar.
3
               Okay.
          Ο.
          Α.
               And maybe L3.
5
               Did you do any vertebral body
          Q.
6
    replacements?
7
          Α.
               Yes.
8
               Did you do any of the vertebral body
9
    replacements laterally?
10
          Α.
               Oh, yes.
11
               The way you said that, "oh, yes," does
12
    that suggest that that was routine for you to do
13
    vertebral body replacements laterally?
14
               It isn't routine, because most of the cases
          Α.
15
    for a period of time that we did vertebral
16
    replacement, for example, like in the TB, infections,
17
    and certainly in certain fractures, but most of the
18
    fractures we still treat posteriorly.
19
               You did do some vertebral body
20
    replacements laterally?
21
          Α.
               Yes.
22
               Did you do any anteriorly, from an
```

- 1 anterior approach?
- 2 A. Vertebral body replacement, is that what
- you're referring to?
- 0. Um-hmm.
- 5 A. I'm trying to, I'm trying to think the
- 6 term. When you make an exposure, if you are going to
- <sup>7</sup> go to replace a whole vertebral body, you can say
- 8 that you're using a lateral incision because in those
- 9 days not so-called minimally invasive, we use a long
- incision. So when you use a long incision, you are
- 11 literally able to approach the spine direct
- anteriorly, so this is why to be specific to answer
- you, I, when I say we are using a lateral approach,
- we are using a lateral incision because it is an open
- procedure and we could replace a vertebral body
- depending on the anatomy of where the major blood
- vessels are, either putting the implant lateral or
- putting an implant in anteriorly.
- Q. Okay. What about an oblique approach,
- sir, did you do any vertebral body replacements
- through what's referred to as an oblique approach?
- A. You tell me what you mean by an oblique.

32 Maybe I should switch that around. Do you Ο. 2 have an understanding of what an oblique approach 3 is, sir? 4 Α. Standing by itself, an oblique just means 5 you're going at an angle. I don't understand the 6 question. 7 Ο. Sure. Sir, we talked about vertebral body 8 replacements going in laterally, and we talked about 9 vertebral body replacements going in anteriorly, 10 correct. So now I'm asking about variations from 11 the lateral and anterior, and what I'm asking is, is 12 there something that is angularly different than 13 lateral and anterior where you might go in between 14 those two? Perhaps I'll rephrase. Strike the question. And unfortunately we don't have a video, 15 16 so I can't capture the precision of this. 17 But anteriorly, generally we are talking 18 about coming in through the belly, right, sir, 19 coming in from the surgeon's perspective and, well, 20 what I'm pointing to towards the belly, towards, 21 towards the spine, correct, sir?

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Α.

(Nodding.)

33 And then laterally, generally we are Q. 2 talking about from the side of the patient going in 3 at an angle towards the side directly into the vertebra, or generally, correct, sir? 5 Α. (Nodding.) 6 So for an oblique, I apologize again for 7 not having this down. 8 Α. Go ahead. 9 Ο. Would be somewhere in between where my 10 hand and my pen are, so at an angle something like 11 this? 12 You are still referring, so let me qualify. 13 You are still referring to in the thoracolumbar 14 junction? 15 Correct, sir. 16 Okay. And the thoracolumbar junction, when 17 you are saying going in obliquely, we don't use a 18 term because of the, once you open with a long 19 incision, you can put the implant in lateral,

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you can do all of those.

Okay.

O.

anterior, slightly off anterior, and in adjusting it,

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20

21

- A. So I was a little puzzled why you would ask
- me to describe that, in those levels, an oblique.
- Because I'm, I have the whole area open.
- 0. Okay.
- 5 A. So the implant can go in slightly at an
- 6 angle, direct lateral or anterior.
- 7 O. So something that would be off an angle
- 8 from the lateral or anterior, you would just
- <sup>9</sup> generally categorize as one of those two, lateral or
- anterior as opposed to calling it an oblique?
- MR. AMON: Objection;
- mischaracterizes Dr. Yuan's testimony.
- 13 A. We have not used the word oblique, so
- that's, excuse me, so we will say you are making a
- lateral approach and then you have the ability to see
- both lateral and anterior, depending on the visceral
- structures, and how the peritoneum falls away,
- whether it is L2 near where the kidney is, you
- definitely cannot go anterior laterally. So consider
- the kidney is, you are going to go laterally. And
- then when you get below the kidney, you going to go
- 22 anterior. So in that area, there is visceral

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structures, particularly the thoracolumbar junction,

- so we have never used the term oblique approach.
- Q. Okay.
- <sup>4</sup> A. But you are looking at the whole thing.
- <sup>5</sup> Q. Maybe I can do this by diagrams just so we
- 6 can actually have a record. Well, we'll get to
- <sup>7</sup> that. There will come a document that will perhaps
- 8 help us.
- Getting back to your CV, sir,
- Exhibit 2021, there's a couple of entries that I'd
- 11 like to talk about. If you could turn to Page 27 of
- that document, I'll wait -- okay. Do you see, sir,
- the entry for Thai Orthopedic Association.
- 14 A. Yes.
- Q. And within that is the One Year Follow Up
- on Experiences With BAK in Posterior Interbody and
- 17 Anterior Interbody Fusion For Degenerative Disc and
- 18 Low Grade Degenerative Spondylolisthesis of the
- 19 Lumbar Spine. Do you see that entry, sir?
- 20 A. Yes.
- Q. Can you explain to me, if you recall, what
- that one year follow-up was describing? I realize

- it's 20 years ago, sir, so if you don't recall I
- <sup>2</sup> appreciate that.
- A. That's okay. Very simple. I can cover
- 4 that topic.
- 5 As I was testifying before during your
- 6 questioning of what cases, when we did them -- this
- <sup>7</sup> is back in 1994 -- so in 1994 there was a period of
- 8 time as I mentioned we did some anterior approaches.
- 9 So in this case here, we are using the
- either posterior which is the very popular described
- 11 mostly by my neurosurgical colleagues who are
- comfortable doing posterior interbodies, and we are
- kind of developing and pioneering an approach of
- doing laparoscopic anterior.
- So what the caption here reads is a
- minimally invasive, so is no longer an open
- procedure. We are making stab wounds in different
- 18 location and once we make the stab wounds, we
- 19 actually -- we are filling the abdominal cavity with
- air or carbon dioxide. So we insufflating the
- 21 abdominal cavity and then what that does is allow the
- 22 structures to be able to be moved aside. And then we

37 are then going directly in midline to implant the 2 So when we said insufflated anterior lateral 3 approach, the insufflation portal is not put directly to the midline, because the midline is where we want 5 to be cutting the cages, through the scope. So the 6 insufflation channels, you are making them just off 7 midline so you can put in a unit you can seal and 8 fill with air. 9 Ο. Okay. Sir, and the anterior lateral 10 approach, what, can you describe that approach in 11 more detail? 12 MR. AMON: Objection; asked and 13 answered. Go ahead. 14 The direction, vis-a-vis the body? 0. 15 The abdomen as you just now showed very 16 nicely, this is anterior, is correct, and this is 17 lateral. 18 Ο. Okay. 19 So you put little portals, mean little 20 holes, you make little stabs, and you make little

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stabs through the skin, through the subcutaneous fat,

through the peritoneum, and you want to make a little

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21

- 1 stab there, so that is anterior lateral direction
- where we put the air insufflation channels in, into
- 3 the abdominal cavity, then you insufflate the
- 4 abdominal cavity with air, you distend it. Then once
- you distend it you go in from the front with a little
- 6 incision either at the umbilicus or a little bit
- below, depending on the level of the spine that you
- 8 are going to put in the BAK.
- 9 The BAK for generally degenerative
- condition here, most commonly the best level to do is
- 11 L5-S1 because that's at the bifurcation of the
- vessels. So below the bifurcation you got space. So
- we know when you do this laparoscopically at the L4-5
- level, that that's the hardest level, that's at the
- bifurcation junction, many variations of the vessels.
- 16 So you cannot retract those vessels very much. You
- can retract the artery, but the vein, to retract the
- vein, you have to be very cautious because the vein
- 19 can flatten out and float underneath your retractor.
- 20 So generally we are doing L4-5, L5-S1. The better
- 21 surgeons will do it at L4-5 also.
- 22 So generally when we teach, we like to let

- them do 5-S1, do many, many of those and get
- 2 experience. And then once they get to be very good
- and understand the anatomy well, then we teach them
- 4 how to do the L4-5. So this is just a time where we
- 5 are teaching them how to do the anterior lateral
- insufflation, filling the belly with air, and the
- <sup>7</sup> anterior approach. So that's why it says here
- 8 minimally invasive, mean small incision, and retro
- 9 peritoneal insufflated anterior lateral approach.
- 10 Your filling air, okay, into either the abdomen or
- the retro peritoneum, we did both, depending on
- 12 cases, and anterior laparoscopic approach to the
- lumbar spine. So the anterior approach is for
- 14 putting in the cages and the fusion.
- Q. Okay. And sir, the reference to posterior
- interbody, is that a description of the BAK device?
- 17 A. No.
- 18 O. Okay.
- 19 A. The BAK is only a device.
- Q. Right.
- 21 A. The BAK is a device as I mentioned clearly,
- I apologize, that some surgeons are much more

- 1 comfortable with a posterior approach and they will
- use the BAK cage from a posterior approach.
- 9 O. Okay.
- A. That means going in from the back, removing
- a lot of bone, and so the posterior approach, the
- for risk is removing too much bone in order to get these
- big cages in. But neurosurgeons, I train both, so
- 8 the neurosurgeon are more comfortable with that
- 9 approach because that's a standard approach. At that
- particular time, the innovative young surgeons which
- 11 majority are orthopedic, some are neurosurgeons also,
- because that's when they train a little later, a
- little younger, and at that time they will do the
- 14 anterior approach which is a lot safer once you get
- there. But the approach is you got to handle the big
- vessels. So the BAK merely says it's a cage that
- here we did either anterior approach or we did
- posterior approach, the two comparison.
- 19 Q. So that that same device, the BAK device,
- could be put in from a posterior approach or an
- 21 anterior approach?
- 22 A. That is correct. The BAK was never labeled

- for one or the other.
- 2 Okay, sir. If you would, I'd like to move O.
- 3 to another entry. This is on Page 33 of your CV.
- It's the North American Spine Society entry. And
- 5 specifically, sir, do you see that entry?
- 6 Α. Yes.
- 7 Specifically, sir, I'm interested in the
- 8 Posterior Lumbar Interbody Fusion With Single
- 9 Posterolateral Threaded Cage Insertion.
- 10 Did I read that correctly?
- 11 Α. Yes.
- 12 Can you describe what that was about? Ο.
- 13 I'm sorry it's taking time. Α.
- 14 Sure, no problem. Q.
- 15 I'm reading. I haven't looked at this in Α.
- 16 long time. So I'm thinking back, as you say 1997.
- 17 Northern American Spine we have several papers.
- 18 Ο. Okay.
- 19 And so I train a lot of fellows, so each
- 20 fellow in the laboratory will be doing different
- 21 studies. So one of the studies, so this here is
- 22 speaking of a cadaver study. It's a cadaver study.

- 1 Why I say it's a cadaver study is because we are
- trying to evaluate how a single posterolateral cage
- 3 as far as allowing us to know the stability of the
- 4 segment after it's implanted. So by going in here we
- 5 are testing how instead of using two cages routinely,
- 6 we are using only one cage. And we are also
- evaluating how this one cage will distract and how
- 8 the dynamics and the stability will be on different
- 9 testings.
- Q. Now, when you say posterior lateral cage,
- 11 I think was the word you used, what do you mean by
- 12 that?
- 13 A. It's the same cage that we are talking
- about, is like the -- again, this is in the same
- period that we are doing the BAK, and so we are using
- a single BAK cage.
- Q. Do you recall if it was longer than the
- anterior or posterior cage?
- 19 A. The BAK cage has a series of sizes. The
- 20 BAK cage sizes generally and here, I don't have the
- document in front of me to let me know exactly, I'm
- just doing this all by recall, so it's an estimate.

43 I would say the longest cage probably is 2 28 millimeters, okay. That's what I can recall, was 3 28 millimeters. So if it was 28-millimeter cage we are using here, we are putting one cage from 5 posterolateral angle to study the mechanical stability and ability to distract a segment. 7 When you have like spondylolisthesis, 8 meaning the spine is slightly slipped because the 9 disc material has settled and the facet joints are 10 worn a little bit to allow the slip, so if you go to 11 the front and, then the spine is so-called little bit 12 kyphotic, tilted to the front, if you distract it and 13 actually open the space up and you also somewhat 14 reduce the slippage, this is we are talking about is 15 really as we say here is a degenerative 16 spondylolisthesis, not isthmic, isthmic meaning, 17 meaning a crack in the bone along a slip, but 18 degenerative meaning just a wear and therefore 19 settling. 20 Now, you mentioned the posterior lateral 21 angle. What is that referring to? 22 You're going through a transforaminal Α.

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- 1 approach.
- Q. So you're coming in from the posterior but
- you're going in diagonally across the space?
- 4 A. Correct.
- <sup>5</sup> Q. And you refer to that as posterior
- 6 lateral?
- 7 A. That's correct.
- 8 Q. Okay. Sir, you mentioned that you
- 9 distract and open the space up. About how much
- would you open the space up?
- 11 A. That's a very important comment, because
- once a disc is degenerated particularly from the
- posterior approach or posterolateral approach, you
- 14 can only distract it whatever the ligaments or the
- annular ligaments will allow. You don't have the
- ability of putting in a spreader and jacking it up
- 17 like a jack.
- 18 So what, how we do this is by putting in a
- debrider so you prepare the disc space by cleaning it
- out, and then you use a smaller size bore of a drill
- to drill the space and when you drill the space you
- 22 actually remove bone from both inferior end plate of

45 the level above to the superior end plate of the 2 level below, so there's a smaller bore drill, and 3 then you put in your cage. 4 The front of the cage slightly tapered, so 5 the slightly tapered cage will allow you to purchase 6 and as it purchase it will slowly raise the level as 7 it's implanted. So that's how you distract. 8 don't distract very much. You distract probably a 9 couple millimeters at the most. 10 O. Okay. Would that be a couple millimeters 11 on both sides or a couple millimeters in total? 12 Pretty much in total. Α. 13 Okay. Sir, if you would turn to Page 34 0. 14 in your CV. You see the entry there for January 24th to the 27th of 1998, that begins Spinal 15 16 Surgery dot dot dot? 17 Α. Yes. 18 Specifically my question is with regard to 19 the portion dealing with Posterior Lateral Interbody 20 Approach With BAK Cage and Facet Fixation. Do you see that, sir? 21

Α.

Yes.

- Q. Perhaps as a shortcut, is that basically
- the same procedure you were just talking about with
- regard to NASS or is there something different?
- <sup>4</sup> A. It is something different.
- <sup>5</sup> Q. Okay. I'm trying to avoid duplication,
- but what were the differences?
- 7 A. The NASS was a presentation of anatomical
- 8 cadaver study. This thing here is the, this
- 9 paragraph really speak about current and innovative
- 10 theories and technique. So it is not, it's not the
- standard of care, it's not what is generally used.
- 12 It is really speaking about either, either anatomical
- 13 studies or small clinical studies, small means small
- 14 number.
- So the idea here is, for example, if you
- look at the whole paragraph to make sense, we're
- using anterior thoracolumbar plates for trauma.
- 18 O. Okay.
- 19 A. This is a 1998. There's a major question
- whether that is stable after you put in a vertebral
- 21 body replacement, and because the biomechanics of
- this is not as stable as using pedicle screws. So we

- 1 are using anterior thoracolumbar plates and again
- here is a current and innovative theory and
- 3 techniques that we are talking about.
- 4 So with that the posterolateral in the body
- 5 approach using the BAK cage, a single cage, and then
- once you put the cage in, I shared a little bit with
- you before to say once you distract a segment, that
- 8 segment is a little bit unstable because it has a
- 9 little bit of a slippage or listhesis, and once you
- distract you like to hold that position, so then you
- 11 are using the facet joints to fix the facet joints.
- 12 So it's an addition of adding fixation to that
- segment to give it more stability.
- 14 Q. Okay.
- 15 A. So important thing here is really, again
- the topic goes on to talk about anterior load
- sharing. And you know, it's understanding the
- 18 biomechanics. So this is again a biomechanical study
- and describing these techniques and the testing
- 20 results.
- Q. And the posterolateral interbody approach
- with the BAK cage that's being studied here, is that

- 1 same single BAK put in at a diagonal?
- <sup>2</sup> A. Yes.
- Q. Okay. Sir, and then further on down that
- 4 same page, you see the Ray TFC Symposium?
- 5 A. Yes, sir.
- Q. And the entry that says "My experience
- with BAK open anterior/posterior laparoscopic and
- 8 transforaminal approach with adjunctive fixation and
- 9 lateral approach using minimally incisional
- 10 approach."
- 11 A. Yes.
- 12 Q. I read that correctly?
- 13 A. That's correct.
- Q. Can you describe what that is and if it's
- the same as something you've already said, you can
- just tell me that.
- A. We've been doing BAKs at that time in the
- beginning all posterior. And then we begin to
- develop the anterior approach, either open or
- laparoscopic. And it's an extension of what we talk
- 21 about using the single cage lateral --
- transforaminally and then begin to start putting in a

49 few of these cages laterally. All of this is done 2 pretty much in the upper lumbar spine, thoracolumbar 3 junction, upper lumbar spine. The reason for us doing these studies is to assess can we go to a 5 minimal incisional approach. 6 At this particular time, actually Dr. Paul 7 McAfee was my fellow -- actually was my resident --8 and so we were doing cases in the laboratory looking 9 at the biomechanical and then the, we begin to do a 10 few cases clinically. But none of this went on to 11 marketing. The reason why is the specifics of that 12 cage design, because it has to drill out the end 13 plates and then putting in a small cage, even though 14 with adjunctive fixation these things collapsed. So 15 none of it was developed, none of it went to market. 16 Both the mechanical testing results tells us the

- adjunctive fixation might make it work, but
- 18 clinically Paul and I have done a couple lateral
- 19 approach; didn't work. And neither did the
- 20 transforaminal approach.
- Q. Are you done, sir? I don't want to
- <sup>22</sup> interrupt.

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50 1 The couple lateral that you did with Paul, 2 were those in human patients? 3 Α. Yes. So living people? 5 Α. Yes. 6 Q. And when you say it didn't work, what do 7 you mean by that? They didn't die, did they? 8 Α. No. Patient didn't die. But spine 9 actually we tried to correct it into lordotic posture 10 and then as I said, the, the properties are not 11 correct because of the end plates being removed to 12 use those cages even though they were big cages, and 13 the length of them we only had 28s, so those cages 14 actually subsided and then the spine basically 15 resumed the deformity, which is kyphosis. 16 kyphotic spine is not a good end result. 17 patients didn't die. But these are done under 18 individual hospital IRB approval. 19 So the IRB communicated to you that it was 20 okay to go ahead with the procedure? 21 It's all approved and documented. Α. 22 patients' permission and signature and all of this is

51 notified to the FDA. 2 So at least you and Dr. McAfee thought it 3 would be safe to do it with a patient? 4 No. We've done mechanical testing, the 5 mechanical testing results indicated to us that mechanically we're able to achieve the stability, but 7 on the clinical usage of it over time, it didn't 8 prove out. So many, many, many things that as we say 9 innovative and technical, you go through testing, it 10 is safe to use on a patient, but when you do it on a 11 patient the outcome is not 100 percent. 12 So the outcome in our mind listing here is 13 something we should not propagate. 14 But before you put it in the patient you thought it was safe to do what you ultimately did, 15 16 correct, sir? 17 It is safe. Α. 18 Okay. It is safe? 19 But it's not efficacious. 20 And when you -- before you did the Q. 21 procedure, you thought it was reasonable to proceed

with the procedure, correct?

We have documentation that as far as we can 2 ascertain from a mechanical, biomechanical point of 3 view and understanding all the variables, we feel that this could be something that can be done using a 5 much smaller incision, less trauma to the patient, so you're balancing benefit versus risk. So there is no 7 risk but the benefit wasn't as much as we 8 anticipated. 9 So you thought it was reasonable to 10 proceed as you ultimately did, correct? 11 MR. AMON: Objection; asked and 12 answered, argumentative. 13 As I said, we have done all the studies, we 14 have all the mechanical and the technical and the 15 clinical understanding that this is not dangerous to 16 the patient or safe. We are merely here to try to 17 improve a technology from one that took patient weeks 18 to recover from the incision in those days, to one 19 that we're doing minimally invasively. Maybe I will 20 extend it, try to clarify what I'm trying to say. 21 Actually, sir, I'd like you to answer my 22 question.

	53
1	MR. AMON: Mr. Schwartz, he's
2	answering your question.
3	MR. SCHWARTZ: Please don't make
4	interruptive speaking objections.
5	MR. AMON: I'm not.
6	MR. SCHWARTZ: You are.
7	MR. AMON: No.
8	Q. I'm asking you, yes or no, was it
9	reasonable for you to proceed strike that.
10	Before you did the surgery, when you were
11	planning to insert this implant in this patient, did
12	you think it was unreasonable to do so?
13	MR. AMON: Objection; asked and
14	answered.
15	MR. SCHWARTZ: It hasn't been
16	answered.
17	MR. AMON: For the third time.
18	MR. SCHWARTZ: And you're
19	interrupting me improperly.
20	Q. You can answer the question, sir.
21	MR. AMON: Same objection.
22	A. I explained to your question that I have

54 not I -- we as a team have evaluated the parameters 2 that is a standard of care for mechanical testing, 3 for stabilization, added stabilization, understanding that this is going to be an initially one column 5 stability, we've added to make it a two-column 6 stability. 7 So to the best of our knowledge we expected 8 this to be something that will improve the outcome of 9 what we're doing. We did -- is not unsafe to the 10 patient. It's totally safe. It just that our 11 outcome even though the patient -- it didn't achieve 12 our standard outcome result. 13 Most, most of the patients, these two 14 patients that we did the procedure on, they went on 15 and was able to function, but not to our standard, 16 because we like the spine to have been corrected. 17 But the deformity basically allowed to settle into 18 more of a kyphos that we do not feel that this 19 technology should be further carried out, because we 20 feel that that's not going the right direction and is 21 something that we need to stop.

22

MR. AMON: Mr. Schwartz, we've

	55
1	been going for over an hour actually.
2	MR. SCHWARTZ: Let me finish the
3	line of questions and then we will
4	take a break.
5	MR. AMON: Doctor, do you need a
6	break or can you go on?
7	THE WITNESS: I'm okay right now.
8	EXAMINATION BY MR. SCHWARTZ:
9	Q. Okay. Sir, you understand what I mean
10	when I ask you if you think you are acting
11	unreasonably. Do you understand what that means?
12	A. I don't.
13	Q. Do you have an understanding of what the
14	word unreasonable means?
15	A. I understand unreasonable, the word itself,
16	yes.
17	Q. Because you used it in your Declaration.
18	A. Where, tell me.
19	MR. SCHWARTZ: He's asking me a
20	question, so this will take a little
21	longer.
22	Q. I'm going to hand you, sir, what's been

	56
1	marked previously as NuVasive Exhibit 2020.
2	MR. AMON: Thank you.
3	MR. SCHWARTZ: Why don't we go
4	ahead and take a break so I can find
5	where the word unreasonable is used.
6	How much time do you need, sir?
7	MR. AMON: 10 minutes.
8	THE WITNESS: I'm fine. I have
9	to go to the bathroom. I'm all set.
10	MR. SCHWARTZ: 10 minutes or
11	less. We'll come back on the record.
12	(10:07 a.m.)
13	(Discussion off the record.)
14	(10:17 a.m.)
15	EXAMINATION BY MR. SCHWARTZ:
16	Q. Ready to go, sir?
17	A. I'm ready.
18	Q. Okay. We are back on the record, sir.
19	You understand you are still under oath?
20	A. Yes, sir.
21	Q. Okay. Let's back up and try to approach
22	this discussion a little differently.

57 1 And actually, since I handed you a 2 document, just so the record's clear I handed you a document that was identified as NuVasive Exhibit 3 2020 for case IPR 2013-00506. I read the case number into the record because NuVasive used the 5 6 same exhibit number for each of your Declarations, 7 so it's clear which one I've handed you. And for 8 the record, sir, can you identify that document? 9 Α. This is my Declaration concerning the 10 United States Patent and Trademark Office before the 11 Patent Trial and Appeal Board. 12 Okay. On the last page, Page 62, that's 13 your signature, sir? 14 Yes, sir. Α. Okay. Sir, perhaps I don't need to get 15 16 into that document for these questions, but if so I 17 will. 18 Getting back to the two lateral surgeries 19 that we were talking about using the BAK device, 20 when you were about to perform that procedure but 21 before you had, did you believe that it was rational 22 for you to do so?

- 1 A. Can you qualify for me what you mean by
- rational, sir? I'd like to understand.
- Q. Do you have an understanding of what the
- word rational means, sir?
- 5 A. I know what rational mean.
- 6 Q. Okay.
- 7 A. I'm just trying to understand what you mean
- by rational in relationship to your question,
- 9 Counsel.
- Q. What's your understanding of the word
- 11 rational?
- 12 A. We want to open a dictionary?
- Q. No, sir, I'm just asking you your
- understanding of the word rational.
- 15 A. I'm trying to ask you your question of the
- word, you are, you told me before that if I have any
- question or don't understand, I'm only asking you to
- qualify for me. I'm not challenging you, just a
- 19 qualification of what you want the word rational to
- mean.
- Q. I just want you to apply it as you
- 22 normally do, sir.

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- A. Again, I go back to say I like to answer
- your question but I like to understand what you are
- 3 asking.
- Q. Okay. If you would turn in your
- 5 Declaration to Page 54, paragraph 102.
- 6 A. What page is that?
- 7 Q. Well, it's a little bit confusing because
- 8 there appears to be two different page numbers, but
- 9 it's paragraph 102, the continuation of that
- paragraph on to what appears to be Page 54 of the
- document.
- 12 If you see, sir, eight lines down from the
- top, you use the word "rational." Do you see that?
- 14 A. Yes.
- Q. Okay. Using your use of the word
- rational, was it rational for you to proceed with
- those two lateral surgeries using a BAK?
- 18 A. I'm having difficulty, not because I don't
- 19 want to answer. The word rational is in the
- dictionary. The word rational is in this sentence,
- 21 but the word rational here is meaning and what I
- don't understand from your question is it rational is

60 that's not a word I have used in deciding for a 2 patient whether I will use a certain procedure or do 3 a certain procedure or implant. 4 So I'm just trying to be very accurate 5 because I'm supposed to testify under oath to be very 6 accurate and totally clear and honest. So not at all 7 challenging you, Counselor, I'm just trying to 8 understand so that I will use, so I can respond. 9 Ο. So you're unable to answer my question, 10 sir? 11 In your form of asking me whether is 12 rational, in that sense, I don't understand. 13 Ο. Okay. Was it reasonable for you to 14 proceed at the point in time before you did the surgery, was it reasonable for you to proceed with 15 16 those two lateral surgeries using the BAK device? 17 MR. AMON: Objection; asked and 18 answered for the fourth time now. 19 As I said, Counselor, we have tested it, we 20 have the approval from the IRB, we have data and we 21 are, we are doing what we think is best to advance a

technology and having done all the prerequisite, not

- only on the FDA standard but on our own standard
- also, we feel that it was the correct thing to do.
- Q. You felt it was the correct thing to do.
- 4 Thank you, sir.
- Now, you use the term transforaminal in
- 6 describing the procedure that we were talking about
- <sup>7</sup> from the Ray TFC symposium, correct, sir?
- 8 A. Yes.
- 9 Q. What do you mean by the term
- 10 transforaminal?
- 11 A. Transforaminal is, there is a space
- underneath the pedicle on the upper boundary. The
- disc in the front with the facet joint in the back
- and that the exiting nerve root on the caudal side.
- 15 There is a space. So transforaminal meaning that we
- can use that space, we can enlarge the space by
- removing some bone from underneath the facet joint.
- We can remove a little bit of the end plate both on
- the upper and lower end to make the space big enough
- so that we can safely implant.
- Q. Okay. Sir, would you categorize
- transforaminal as a posterior approach?

- 1 A. Transforaminal is posterolateral approach.
- 2 O. You would describe that then as a subset
- of a posterior lateral approach, or a type of
- 4 posterior lateral approach? Strike that.
- 5 Would you describe the transforaminal as a
- 6 type of posterior lateral approach?
- 7 A. The transforaminal is a posterolateral
- 8 approach.
- 9 Q. Okay.
- 10 A. As you probably try to broaden it to say
- 11 there are other approaches that we call
- posterolateral that could involve more bone removal
- but this is certainly a form of it.
- Q. So is it fair to say, sir, that you were
- involved in surgeries with the BAK device using it
- in a posterior approach, an anterior approach, a
- transforaminal approach, a posterior lateral
- approach, and a lateral approach, is that correct?
- 19 A. Yes.
- Q. Okay. Sir, rounding out this question, if
- you would turn to Page 35 in your CV, do you see the
- entry for the ISSLS annual meeting?

- Α. In the middle of the page?
- 2 Yes. And the title of that paper O.
- 3 presentation is "posterior lumbar interbody fusion
- 4 with single posterior lateral threaded cage
- insertion, a biomechanical evaluation." 5
- 6 Α. Yes, sir.
- Ο. I read that correctly, sir?
- 8 Correct. Α.
- 9 Q. Can you describe what that is and again,
- 10 if that is the same thing as what you've already
- 11 told me about you can just refer back to whatever it
- 12 is you told me about.
- 13 Α. It is what we talked about, and sentence
- 14 here is a biomechanical, so is a cadaver study.
- 15 O. Okay. This may be the last question on
- 16 your CV. If you would turn to Page 29, the fourth
- 17 entry down -- I'll wait until you get there -- the
- 18 fourth entry down for North American Spine Society
- 19 Annual Meeting?
- 20 Yes, sir. Α.
- 21 About halfway through that paragraph, it Ο.
- 22 talks about a video assisted thoracic corpectomy and

64 spinal reconstruction, do you see that reference, sir? 2 3 Α. Yes. 4 Can you describe what that thoracic Q. 5 corpectomy was? 6 At that time as I mentioned, there was a 7 period of time that we are trying to take big 8 incisions to smaller, and the -- everything we tried 9 to do with video assisted is really to make it 10 minimally invasive, so only needing little stab 11 wounds so you get vision and then we are able to do 12 the procedure through a small incision. 13 So here is a video assisted thoracic 14 corpectomy, meaning we will go in, here again is a 15 biomechanical study, so was cadaver study that we 16 will actually use special tools to remove the 17 vertebral body of a segment, and these are in the 18 thoracic spine. So a thoracic corpectomy and spinal 19 reconstruction, the spinal reconstruction would be 20 putting in the cage to stabilize the segment, so the 21 anterior column is built back. Then to see the 22 stability of that versus doing this open or using

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65 this as an endoscopic approach. 2 And what direction was the approach, sir? Ο. 3 The approach here in the thoracic spine 4 will be a lateral approach. 5 O. A lateral approach. 6 Do you know what the implant was that you 7 were putting in? 8 We were using implant at that time, we 9 start off in the beginning using only a bone 10 construct called fibular graft and then we shortly 11 moved on to testing using a Harms cage. 12 O. Harms cage? 13 Harms, H-A-R-M-S, Professor Harms, cage. 14 You think that procedure you were talking Q. 15 about discussed the Harms cage? 16 Α. I don't know, I don't have the whole paper 17 in front. 18 Sir, I'm asking the question in part 0. 19 because we don't have it either, fair enough. 20 know I'm testing your memory and I appreciate that. 21 Α. Okay.

Would you describe that implant as a

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```
66
    vertebral body replacement?
2
                          MR. AMON: Objection; vaque.
3
               Can you ask that one more time.
4
               Sure. Sir, we were talking about
          Ο.
    vertebral body replacements before.
5
6
          Α.
               Yes.
7
               In this context, for the thoracic
8
    corpectomy, would that implant be a vertebral body
9
    replacement?
10
          Α.
               Yes.
11
                          (Exhibit MSD 1015, Posterior
12
                    Lumbar Interbody Fusion Using
13
                    Posterior Lateral Placement of a
14
                    Single Cylindrical Threaded Cage,
15
                    marked for identification, this date.)
16
    EXAMINATION BY MR. SCHWARTZ:
17
               Sir, you've been handed what was
          Ο.
     identified as MSD 1015.
18
19
          Α.
               Thank you.
20
          Q.
               Do you see your name there, the last named
21
    author?
22
          Α.
               Yes.
```

August 22, 2014

```
67
         O.
               So that's you?
2
         Α.
               That's correct.
3
               So you're a co-author of this article?
         Q.
 4
         Α.
               Yes.
5
         Ο.
               Okay. Sir, I know we've been talking some
6
    about posterior lateral placements of the BAK cage
7
    and take as much time as you want to look at that
8
    article.
9
               Thank you.
         Α.
10
         Ο.
               My question is, is this generally
11
    describing that posterolateral placement of a single
12
    BAK cage?
13
               Sorry taking me so long.
         Α.
14
              Had a chance to read it, sir?
         Q.
15
               I read through it, I haven't analyzed in
16
    detail, but in general I have some information.
17
               So this is describing that posterior
          Ο.
18
    lateral placement of the single cylindrical threaded
19
    cage we were talking about before?
20
               Single cylindrical longer cage, yes.
         Α.
21
               Longer in this instance was 36 millimeters
         O.
22
    long, correct?
```

68 That's correct. 2 So this was a little longer than the Ο. 3 anterior or posterior cages we were talking about before, right, sir? 5 Α. Just the PLIF or the anterior posterior cages are shorter. 7 So this one was longer than that? 8 That's correct. 9 Ο. And why did you use a longer cage for this 10 posterior lateral placement? 11 We wanted to gain more surface area, the 12 paper actually made a statement that they didn't test 13 a longer diagonal cage versus a shorter one, they 14 didn't do that. They just tested one longer one with 15 a goal of getting more surface area to proximate 16 closer to two cages, as far as the surface area. 17 Okay. And this was work that you did Ο. 18 sometime in 1998, is that right, or before then? 19 Α. Around that time. 20 Q. Okay. 21 Yes, sir. Α. 22 And this article actually published some Ο.

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- time in 2000?
- 2 2000. Α.
- 3 Okay. If you would, sir, turn to
- 4 Page 430, the paragraph just above the Conclusions.
- 5 There's a sentence, this is the last page, sir.
- 6 paragraph just above the Conclusions, about halfway
- 7 through that paragraph that starts Despite. There's
- 8 a sentence there: "Clinically, a single long
- 9 threaded cage in comparison with a single regular
- 10 length cage has a largest purchase area, (load
- 11 bearing surface) and a larger region for potential
- 12 bony ingrowth."
- 13 Did I read that correctly?
- 14 Α. That's correct.
- Do you agree with that statement, sir? 15
- 16 Α. The theory, the theory is correct. I say
- 17 the theory is correct because a longer cage certainly
- 18 would have more, as we said, more surface area, more
- 19 weight bearing area.
- 20 Q. Okay, sir.
- 21 When they say clinically, this is, this is
- 22 what we discuss, and so in a clinical case, this is

- an assumption, that's correct.
- Q. Okay. And that, the first sentence of
- that paragraph where it says, "Despite these
- 4 limitations, this study shows some biomechanical
- 5 advantages of posterior lateral insertion of a long
- threaded cage over two posteriorly placed cages."
- 7 Did I read that correctly, sir?
- 8 A. Yes, sir, in this study.
- 9 Q. Do you agree with that sentence?
- 10 A. For this, for this cadaver, for this study,
- using the bovine spine, that's what they referring
- 12 to. So the answer is that is true for this study,
- because that they are, they are specifics of a bovine
- spine that is not true in that of a human.
- Q. Sir, do you recall if that 36-millimeter
- long BAK device was commercially available at that
- 17 time?
- MR. AMON: Objection;
- speculation.
- A. I don't know for sure. I think the most,
- the most routine length that we use, the longest cage
- I've used, is generally a 28, 26-28. So I'm not sure

```
71
    what a 36 -- I'm not positive.
2
               Okay. You are aware that at some point in
         O.
3
    time BAKs were offered in longer lengths, correct,
    longer than 28 millimeters?
5
                         MR. AMON: Objection; assumes
6
                    facts not in evidence.
7
               I don't know that.
         Α.
8
         Q.
               Okay.
9
               I'm not sure.
         Α.
10
               Looking back to your CV again, sir.
         O.
11
    Page 56 in workshop and training sessions, there's a
12
    reference to Sulzer Spine-Tech -- it's about the
13
    fourth entry down -- it says Sulzer Spine-Tech -
14
    BAK-L and Proximity Training. Do you see that, sir?
15
               Yes, sir.
         Α.
16
               What is the BAK-L?
         O.
17
               The BAK-L mean the BAK lumbar.
         Α.
18
               Lumbar, okay, sir. Just to round out this
         Ο.
19
    piece of your CV, on the last page, Page 116, under
20
    Medical Advisory Board, it indicates that you were
21
    on the Medical Advisory Board for CenterPulse,
22
    Spine-Tech, Inc, is that correct?
```

	72
1	A. Yes.
2	Q. Do you remember when you were on that
3	advisory board?
4	A. I don't remember the date. I can tell you
5	the circumstances.
6	Q. Sure.
7	A. It's after Spine-Tech was sold.
8	Q. After Spine-Tech was sold?
9	A. Was sold.
10	Q. To CenterPulse.
11	A. To CenterPulse, so it was just an extension
12	of my participation with the company.
13	Q. Okay. So you were, were you in some way
14	advising Spine-Tech before it was purchased by
15	CenterPulse?
16	A. Yes.
17	Q. Okay. And I apologize, I'm not sure that
18	I saw that on your bio, so could you tell me what
19	was your role with Spine-Tech before the acquisition
20	by CenterPulse?
21	A. I worked with Dr. Bagby (phon) and also
22	with Spine-Tech for several years, and worked with

```
73
    meaning both on the advisory board and also work on
2
    the development of the proximity cage. I don't
3
    remember exactly which years, but it's several.
4
              Do you remember -- strike that.
         Q.
5
               How many years before the CenterPulse
6
    acquisition were you working with Spine-Tech?
7
               Several years.
         Α.
8
         Ο.
               So less than ten?
9
              Less than ten.
         Α.
10
         Q.
              Okay. More than five?
11
                         MR. AMON: Objection;
12
                    speculation.
13
               More than five? You're allowed to
         Ο.
14
    speculate, by the way, sir.
15
               I know. My attorney doesn't want me to.
16
    So I don't really know. I will say several, because
17
    I don't recall how many years exactly.
18
              Okay. But you don't know if it was more
         Ο.
    than five?
19
20
         Α.
               I cannot recall.
21
               Okay. Do you recall if you were doing
         Ο.
22
    anything with Spine-Tech in 1997 or 1998?
```

74 I don't know when they were sold to Α. 2 CenterPulse, so that would be the date that I would 3 be able to answer. 4 Q. Okay. 5 (Exhibit MSD 1016, Document re: 6 Premarket approval extension for BAK 7 interbody fusion system, marked for 8 identification, this date.) 9 EXAMINATION BY MR. SCHWARTZ: 10 Ο. Sir, I'm handing you what's been 11 identified as Exhibit MSD 1016. I'll represent for 12 the record that this is a document pulled off of the 13 internet at the website on the top of the page and 14 reflects a premarket approval extension for the BAK 15 interbody fusion system. 16 Sir, what I'm going to ask you to do is 17 just look at the bottom part of that document, where 18 it says Approval Order Statement and has a number of 19 sizes for the BAK implants. 20 Do you see that portion of the document, 21 sir? 22 Α. Yes.

75 So it appears that in 1997 the decision O. 2 date of this document being May 9th, 1997, BAK or 3 Spine-Tech, Inc, had approval to market BAK products with those dimensions in a diameter and length, 5 correct, sir? 6 Α. I'm just reading. O. Sure. 8 Approval ... Α. 9 MR. AMON: I'm going to object. 10 It's calling for a legal conclusion. 11 Α. As far as I can comment, I'm reading here 12 they do have the sizes, but --13 Okay so -- I'm sorry, go ahead. Ο. 14 I'm not, I'm not a lawyer so I'm not able 15 to say what this means, but I do read it here saying 16 approval order. 17 As a person of skill in the art who had 18 some relationship with Spine-Tech and obviously had 19 some experience using BAK devices, you're here 20 testifying in that capacity, correct, sir? 21 Α. That's correct.

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Okay. And as that person, is it fair to

Ο.

76 say that Spine-Tech had approval in 1997 to market, 2 for example, BAK devices that were 36 millimeters 3 long like the one that you used in your study? 4 MR. AMON: Objection; calls for a 5 legal conclusion. You can go ahead 6 and answer. 7 We have used it in the laboratory. I don't 8 remember what size, but the length is 36. 9 Q. Okay. And so it's fair to say that 10 Spine-Tech, at least, had FDA approval to sell those 11 at that time? 12 MR. AMON: Objection; calls for a 13 legal conclusion. 14 I don't -- I've not used one of that 15 length, but in the laboratory we have certainly 16 tested it. 17 When you say you haven't used one, do you 18 exclude from your word use the word Test? 19 Α. No. Used, mean use it clinically in a 20 patient. 21 So you did use it in the context of Ο. 22 testing, correct?

```
77
               We did the testing.
2
               And you did that sometime generally around
          Ο.
3
    '97 or '98, right, sir?
4
               Around that time.
         Α.
5
          Q.
               Okay. And as far as you can tell, the FDA
    had approved Spine-Tech selling them at that time,
7
    correct?
8
                         MR. AMON: Objection.
9
         Q. As far as you can tell?
10
                         MR. AMON: Objection.
11
               From reading this document here that you
         Α.
12
    showed me, I'm reading that, so now I know.
13
               You have no reason to doubt that, do you,
          Ο.
14
    sir?
15
         Α.
               No, I don't doubt that. It's on the
16
    document.
17
               Okay. Do you recall at any time
          Ο.
    Spine-Tech selling long BAK devices, long meaning
18
19
    longer than 28 millimeters?
20
               I have not used any longer than that
21
    length, so I would be only making a wild guess, but I
22
    don't know the answer.
```

```
78
               So you don't recall one way or the other?
         O.
2
         Α.
               I don't recall them selling it that I know
3
    of.
4
               Okay. Let's turn back to your Declaration
         Q.
    that I handed you before, which was Exhibit 2020 for
5
6
    the 506 case.
7
               Actually, before we do that I'm going to
8
    start with the patent. I'm going to need to mark
    this, it's MSD 1115.
10
                          (Exhibit MSD 1115, 8,361,156
11
                    Patent, marked for identification,
12
                    this date.)
13
14
    EXAMINATION BY MR. SCHWARTZ:
15
               I'm handing you what's been marked as
16
    MSD 1115 and ask if you've seen that document
17
    before.
18
              Yes, I have.
         Α.
19
               You've seen that document before, sir?
         Q.
20
    And, sir, I know you're not a patent attorney.
21
         Α.
               Thank you.
22
               Of course you are testifying here in a
         Ο.
```

79 patent proceeding, so I'm curious, do you understand 2 the difference between device claims and method 3 claims in a patent? 4 I've heard about it, but I don't know that, 5 the difference. 6 Okay. Sir, looking at claim 1 of the '156 7 patent which starts at column 12 around line 32, and 8 then ex -- well, it ends at the bottom of column 12. 9 Do you see claim 1? 10 Α. Yes, sir. 11 I'm sorry, sir, I'm not quite sure what 12 document that is you have in front of you. Is that 13 something I handed you? 14 These are two that I brought, these are Α. 15 merely so-called the, my own Declaration, these are 16 merely the -- describe from a patent, from a 17 document, from a Declaration, this is a '156 patent 18 that we are looking at here, and this is the '156 19 merely -- this rerepresented the pages of the 20 information that's in my Declaration. 21 Do you mind if I look at it, sir? Q.

Please.

Α.

	80
1	Q. So it's sort of a table of contents
2	although there's not one in your Declaration, is
3	that right, sir?
4	A. That's a table of contents.
5	Q. Do you mind if I make a copy of these at a
6	lunch break?
7	A. Oh, no.
8	MR. AMON: We can actually give
9	you a copy now, Mr. Schwartz.
10	THE WITNESS: This way I won't
11	waste your time.
12	MR. SCHWARTZ: I appreciate that,
13	sir. I am trying to make this move as
14	quickly as possible although I
15	appreciate it may not seem that way to
16	you.
17	THE WITNESS: I'm here at your
18	service.
19	(Handed.)
20	MR. SCHWARTZ: Why don't we do
21	this, mark it just so I have a record
22	of it. We'll mark it as MSD 1049.

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81 1 And I'll make a copy of it at the lunch break. (Exhibit MSD 1049, Declaration 3 re: Case IPR2013-00506, marked for 5 identification, this date.) 6 EXAMINATION BY MR. SCHWARTZ: 7 Looking at claim 1 of the '156 patent, do 8 you know if that's a device claim or a method claim? 9 Α. I'm not, like I said, I've heard the note 10 device and the method. I don't know. 11 Okay. Fair enough. Sir, is there 12 anything in claim 1 that requires the implant to be 13 capable of use for a trans-psoas lateral approach? 14 I understand your question, but can you 15 qualify for me just a little bit that the, whether 16 claim 1 requires it to be, that's your words. 17 Um-hmm. Ο. 18 Okay. To the best of my ability as I'm 19 reading this claim 1, because it requires that the, 20 there is a first and second marker in the two 21 sidewalls, and in the central region, this was really 22 designed to allow this cage to use those two markers,

- 1 and those two markers are designed to identify a
- 2 midline and for it to be lined up with the spinous
- process, therefore, to me this one here, the claim 1
- 4 is the beginning or is a main -- I should say the
- 5 main element of qualifying that it is, can be used as
- a lateral approach to be able to identify midline.
- O. Okay. Sir, but let me ask it a different
- 8 way. If an implant meeting these structural
- 9 elements can be used in a different approach, say a
- 10 posterior lateral approach, is it also covered by
- 11 these claims?
- MR. AMON: Objection; incomplete
- hypothetical. Go ahead.
- 14 A. If you using this, the claim 1 from a
- posterolateral approach, the two markers in the
- midline has no meaning.
- Q. Do the markers preclude the implant from
- being used in a posterior lateral approach?
- A. As I said, it doesn't add any information
- and it could be confusing.
- Q. Let me approach this a different way, sir.
- In your Declaration, beginning at Page 33

```
83
    -- strike that -- Page 34, you talk about the
2
    Medtronic Clydesdale. Do you recall that, sir?
3
    Actually it does begin at paragraph 64, Page 33.
4
         Α.
               Your question again one more time,
5
    Counselor, please?
6
         Ο.
              Do you recall discussing Medtronic's
7
    Clydesdale in your opinion?
8
         Α.
              Yes, sir.
9
         Q.
              Okay.
10
                         MR. SCHWARTZ: I'm going to mark
11
                    this as MSD 1020.
12
                         (Exhibit MSD 1020, Medtronic
13
                    OLIF25 Procedure document, marked for
14
                    identification, this date.)
15
    EXAMINATION BY MR. SCHWARTZ:
16
               Sir, I'm going to hand you what's been
         Ο.
    marked as MSD 1020 which for the record is the
17
18
    Medtronic OLIF 25 Procedure, an oblique lateral
19
    interbody fusion for L2 to L3 surgical technique.
20
               Sir, I'll represent to you that Medtronic
21
    markets that Clydesdale implant for use in that OLIF
22
    or oblique lateral interbody fusion, so with that as
```

	84
1	the background, sir, my question is since the
2	Clydesdale can be used in an oblique lateral
3	interbody fusion as opposed to a trans-psoas lateral
4	interbody fusion, does it mean that that implant is
5	not covered by those claims?
6	MR. AMON: Objection; outside the
7	scope. Take all the time you need to
8	review the documents, Doctor.
9	MR. SCHWARTZ: It can't possibly
10	be outside the scope because he's
11	opining on the scope of the claims.
12	You can answer, sir.
13	THE WITNESS: Let me take a quick
14	look at this.
15	MR. SCHWARTZ: Sure.
16	THE WITNESS: I'm almost there.
17	MR. SCHWARTZ: Sure, sir.
18	THE WITNESS: Please ask your
19	question one more time.
20	(Whereupon, the pending question
21	was then read.)
22	A. I'm looking at the Clydesdale and the

- 1 Clydesdale has a midline marker. And if we look at
- the AP, true AP picture photograph on Page 18, we're
- 3 looking at an implant that is requiring the middle
- 4 markers to be focused on the spinous process.
- <sup>5</sup> Q. Which figure, sir?
- $^6$  A. Figure 44.
- 7 Q. Okay.
- 8 A. So the authors here, Dr. Hynes,
- 9 Dr. McMillain and Dr. Kwan, use the approach from an
- anterior lateral oblique approach, but at the time of
- introduction of the cage, literally move this into
- 12 true lateral position.
- 13 O. Okay.
- 14 A. So the skin incision as we talk about is
- anterior lateral, but the implantation of the cage
- itself is a true lateral, and as shown in the
- drawings here, we are -- put a patient in the true
- 18 lateral position and then we are taking X-rays
- 19 coaxial with true AP, with the spinous process in
- <sup>20</sup> midline.
- Q. That's the position of the patient,
- 22 correct, sir?

- A. Correct. And also the final picture here
- of the documentation shows the cage to be truly AP,
- because the X-rays, so it's not in position of
- 4 patient, it's done for a reason. So now you shoot a
- 5 true AP and now you have the spinous process equal
- 6 distance to the two pedicles along with the lateral
- <sup>7</sup> that we are looking at, the final picture here, to
- 8 show that the -- you really need to line up to make
- 9 sure that the implant in the lateral plane also is
- not an oblique angle to the implant as put in, the
- 11 final position of implant is truly lateral from edge
- 12 to edge.
- so because of the two middle markers lined
- up with the spinous process with this quote, unquote,
- oblique anterior lateral -- anterior lateral
- approach, the cage is really put in truly lateral.
- 17 O. Okay.
- 18 A. So your question is can it not be put in in
- an oblique angle. This is not put in oblique angle,
- 20 not in the vertebral body.
- Q. Not my question, sir, but I appreciate
- your point. My question, sir, is since this implant

```
87
    is not put in in a trans-psoas lateral approach,
2
    does that mean that it is not covered by claim 1 of
3
    the '156 patent?
4
               You're asking me this implant because is
          Α.
5
    not put in trans-psoas.
6
          O.
               Um-hmm.
7
               And then the next portion?
8
          Ο.
               Let's take it one at a time. It's not put
9
    in trans-psoas, correct, sir, because it comes in
10
    anteriorly?
11
                         MR. AMON: Objection; assumes
12
                    facts not in evidence; incomplete
13
                    hypothetical.
14
               I know these surgeons and I know what they
          Α.
15
    teach.
             I've been there.
16
          Q.
               Okay.
17
               And I've used the Clydesdale.
          Α.
18
               I understand.
          Ο.
19
               And so when you are doing in the upper
20
    lumbar, you can go in anterior to the psoas.
21
          Q.
               Okay.
22
               But when you get down to L3-4 some of the
```

- time and then at the L4-5, you cannot go in anterior
- oblique. You have to go trans-psoas, the psoas
- muscle is there and there's no way to retract it.
- Q. In the circumstance where you can go in
- 5 anteriorly and not go through the psoas as you just
- 6 described, does that implant meet the terms of the
- 7 claim?
- 8 A. Then this is only limited to the upper
- 9 lumbar spine.
- 10 Q. In any instance where you put it in
- anteriorly without going through the psoas muscle.
- 12 A. This implant that you're using is still put
- in whether it be anterior to the psoas or exactly
- trans-psoas, but it lies true lateral so you're still
- lining this up on the patent '156 of the two medial
- markers being lined up. When they are lined up, it
- means it is true lateral.
- 0. Okay. Sir, that's not my question.
- My question is, for an implant that is not
- put in in a trans-psoas approach, is it covered by
- claim 1 of the '156 patent?
- MR. AMON: Objection; asked and

		89
1	answered.	
2	A. Claim 1 doesn't say trans-psoas.	
3	Q. Okay.	
4	A. Claim 1 really just says two medial market	rs
5	are lined up, mean it's a lateral approach.	
6	Q. So you would agree that claim 1 does not	
7	require an implant to be put in trans-psoas,	
8	correct?	
9	A. I didn't say that.	
10	Q. Okay.	
11	A. I just said claim 1 shows a two medial	
12	markers lined up on an on the AP view, so it	
13	really stands lateral to lateral of the vertebral	
14	body.	
15	Q. Does claim 1 require that you put the	
16	implant in through the psoas muscle?	
17	A. It did not.	
18	Q. Okay. Where do you see in the claim that	
19	it requires the markers to line up in an AP view?	
20	A. The two medial markers are put there for	
21	the purpose that it is really to exemplify location	
22	so there's no rotation to the implant. That's the	

90 intent. 2 Okay, sir, we'll agree there's two Ο. 3 markers. Do you read the claim as requiring that those markers are lined up in the AP view? 5 Α. As one skilled in the art, when you put in 6 any markers, there is a strategic or there is a --7 invent a reason for the markers, otherwise they are 8 redundant. So as one skilled in the art, myself and 9 others, seeing the two markers at midline, there's a 10 reason that you want to line them up for the safety 11 of the patient and for the stability of the 12 That's the intent of the invention. construct. 13 And if the markers are not lined up when Ο. 14 the implant is inserted, does that implant no longer infringe? 15 16 MR. AMON: Objection; outside the 17 scope. 18 I'm not an attorney. I couldn't even tell 19 you whether it should be a patent should be --20 whether there is a method or whether it's an implant. 21 So I can't answer your question.

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Okay. Fair enough. While we are on the

Ο.

- topic of the two midline markers, sir, is it useful
- to know if the markers are not lined up in the AP
- yiew? Does that tell you something?
- $^4$  A. Yes, it does.
- <sup>5</sup> Q. What does it tell you?
- 6 A. It tells you that the device is oblique or
- 7 rotated.
- 8 Q. So in a hypothetical where a surgeon wants
- 9 to put in an implant in the oblique, do those
- markers give him information to advise him that they
- 11 have been put in in the oblique?
- MR. AMON: Objection; incomplete
- hypothetical, but go ahead.
- 14 A. In the lumbar spine you don't want to put
- in an implant of this length that we are talking
- about that is spanning cortex to cortex. If you want
- to put in a short implant, you can put in an oblique
- 18 as long as totally contained within the annual wall.
- But when you going to use a longer implant,
- if it's long and then is oblique, okay, that is not
- something a surgeon would like to do, somebody who is
- skilled in the art, because on the opposite side

- where, when you're penetrating the cortex, you may
- 2 have one edge of the implant not weight bearing if
- 3 it's oblique because the long implant is supposed to
- span it, and because the corner may be non-weight
- bearing. The second reason is that that corner which
- is protruding could be abutting against vessels. So
- <sup>7</sup> intentionally for the safety of the patient that
- 8 would not be something you would like when you are
- 9 doing this in oblique angle to penetrate and then
- 10 turn an oblique angle. You want to keep it lateral,
- 11 you want to keep it behind the vessels, and you want
- 12 it to be true lateral.
- Q. Okay. Sir, you said that if the implant
- is shorter, you might be motivated to put it in in
- the oblique, correct?
- A. You can put it in oblique, sure.
- Q. And in that circumstance, having middle
- markers, would tell you that it is inserted
- obliquely, correct?
- A. It will tell you that you're not true
- 21 lateral.
- O. So it would tell you that it's in

```
93
    obliquely?
2
               It wouldn't let you know which direction of
3
    oblique, but it would tell you you are not in a true
    lateral position, I mean the true side to side
5
    position, yes, sir.
6
               Okay. So putting it another way, it would
7
    tell you that it's in at an angle relative to the AP
8
    view?
9
          Α.
               Yes.
10
               Okay. Do you need a break, sir?
11
               No, I'm okay.
12
               Sir, in the '156 patent, Exhibit MSD 1115,
          Ο.
13
    I'd like you to turn to column 5, '156 patent, sir.
14
    I'm referring to the '156 patent, sir. It's this
15
    document here.
16
         Α.
               Sorry.
17
               No problem. If you could turn to column
          Ο.
18
     5?
19
               I'm not used to looking --
20
          Q.
               I understand, sir. It's a unique type of
21
    a document.
22
               It will be words.
```

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94
               Do you see column 5, sir?
         Q.
2
         A.
               Yes.
3
               Starting at around line 29, I'll go ahead
          Ο.
    and read the sentence so you don't have to.
            "The implant 10 is particularly suited for
5
    says:
6
    introduction into the disc space via lateral
7
    trans-psoas approach to the spine, but may be
8
    introduced in any of a variety of approaches such as
9
    posterior, anterior, anterolateral and
10
    posterolateral without departing from the scope of
11
    the present invention, (depending upon the sizing of
12
    the implant 10.)"
13
               Did I read that correctly, sir?
14
         Α.
               That's correct.
15
               Do you agree with that sentence, sir?
         Q.
16
         Α.
               I agree.
17
               Okay. So it's fair to say that the
         Ο.
18
    implant being claimed is not limited to a lateral
19
    trans-psoas approach but may be introduced in a
20
    variety of other approaches, correct, sir?
21
         Α.
               Depending upon the size and length of the
22
    implant.
```

	95
1	Q. Right. So if it fits in the
2	intervertebral space and can be put in safely, it
3	would apply, correct?
4	A. Yes.
5	MR. AMON: Objection;
6	mischaracterizes the scope of claim 1.
7	MR. SCHWARTZ: Your expert is
8	testifying about the scope of claim 1
9	and he answered the question. Unless
10	you're going to say he's not competent
11	to testify about the scope of the
12	claim.
13	MR. AMON: If you want to engage
14	in discussion, I'm not saying that.
15	I'm making the objection for the
16	record.
17	MR. SCHWARTZ: Sir, while we're
18	at it, why don't we go ahead and get
19	the other implant or other patent into
20	the record. This is MSD 1013.
21	(Exhibit MSD 1013, 8,187,334
22	patent, marked for identification,

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96
1
                    this date.)
2
    EXAMINATION BY MR. SCHWARTZ:
3
               I'm going to hand you, sir, what's been
         Ο.
4
    marked as MSD 1013 and ask you to identify that
5
    document, sir.
6
         Α.
               Yes, sir.
               Is that the patent that you opined on, the
          Ο.
8
     '334 patent, sir?
9
         Α.
               Yes.
10
               Okay. Now, I'm going to try to cover some
         O.
11
    of the same ground we just did with the '156 just to
12
    see if your answers are the same. I apologize for
13
    the duplication but they are two different patents.
14
               So if you would, sir, turn to, again,
15
    column 5 at about the same place, line 29. You see
16
    there, sir, starting about line 29, the same
17
    sentence that I just read into the record with
18
    regard to the '156 patent, correct, sir?
19
         Α.
               Yes.
20
               So as with your conclusion on the '156
         Q.
21
    patent, is it fair to say that the claims of the
22
     '334 patent do not require that the implant be
```

	97
1	introduced by a lateral trans-psoas approach, but
2	also may be introduced by a variety of other
3	approaches?
4	MR. AMON: Objection;
5	mischaracterizes his testimony and is
6	misleading with respect to the
7	document.
8	Dr. Yuan, take as much time as
9	you want to review the claims in the
10	'334.
11	A. I will say again that this will be
12	dependent on the sizing of the implant or the length
13	and the width.
14	Q. But as to the claim itself, it doesn't
15	require a specific approach, it can be put in by any
16	approach, correct?
17	MR. AMON: Are you talking about
18	a specific claim, Mr. Schwartz?
19	A. Would you qualify for me which level, which
20	indications.
21	Q. Is the claim, is claim 1 of the '334
22	patent limited to a particular level or indication?

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98 Claim 1 on this '334? Α. 2 Um-hmm. Ο. 3 Claim 1, the answer to, the answer is it would limit it, yes. 5 Ο. Where is there a limitation in claim 1 to the level or indication? 7 Claim 1 requires of the longitude and 8 length be greater than 40 millimeters. 9 Q. Okay. 10 As we said before, you can use different 11 approaches, now this one here limits the length to be 12 more than 44 millimeters or more. So this doesn't 13 apply to ability to use this in the other approaches. 14 So the answer to your question specifically claim 1 15 does limit this to be able to be used only in lateral 16 approach. 17 Is it your opinion that you cannot safely put in a 40 millimeter implant in any other approach 18 19 other than lateral? 20 I have never used an implant 44 millimeter 21 or longer.

40 millimeter?

0.

99 40 millimeter or longer in any other 2 approach. 3 But are you saying that a surgeon cannot use a 40 millimeter long implant in any other approach than a direct lateral approach? 5 6 Α. I don't know what another surgeon would, 7 but I would say somebody skilled in the art and 8 understand, and understand the anatomy, would not use 9 an implant 44 millimeters or longer. 10 Q. Again, sir, we're talking about 11 40 millimeters, I think your answer is 44. 12 40 millimeter. Α. 13 So to be clear, it's your opinion that a Ο. person of skill in the art would not ever use a 40 14 15 millimeter long implant for any approach other than 16 a direct lateral approach? 17 MR. AMON: Objection; 18 mischaracterizes Dr. Yuan's testimony. 19 MR. SCHWARTZ: I'm not 20 characterizing his testimony. 21 MR. AMON: You are, Mr. Schwartz, 22 that's all. That's fine. Go ahead.

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100 A 40 millimeter long implant, to be 2 implanted into the spine as interbody spacer using it 3 safely and efficaciously should only be used on a lateral approach. 5 Q. Okay. So, sir, will it fit into an 6 interbody, in an intervertebral space between L4 and 7 L5 if you put it in at an angle? 8 MR. AMON: Objection; incomplete 9 hypothetical. 10 Q. For an average male. 11 40 millimeter in an average man. 12 MR. AMON: I'm sorry, can I have 13 the question read back. 14 (Whereupon, the requested portion 15 of the record was then read.) 16 You can, but it is unsafe. That's the 17 reason why surgeons skilled in the art wouldn't use 18 it of this length. 19 But it can fit? 20 It cannot fit most of them, not even an 21 average, maybe in a big person, but it would not fit

the average man, the average would be cortex to

- cortex, that's the reason why I say won't be safe.
- Q. So cortex to cortex in a big man at L4/L5,
- 3 40 millimeters will fit at a diagonal?
- 4 MR. AMON: Objection; incomplete
- 5 hypothetical, vague.
- A. It depends on the, it's going to depend on
- <sup>7</sup> several variable. One of the main variable is the
- 8 approach and the, the direction.
- 9 So if it was like where Clydesdale that you
- showed me, and you're using the approach of anterior
- 11 but you're truly putting in lateral in all the
- 12 pictures that it showed, okay, and it is really a
- lateral implant. At 40 millimeter using it as an
- oblique would be risky.
- Posteriorly, if you're going anterior
- lateral to posterior, you can potentially injure the
- nerve. If you are going posterior lateral to
- anterior lateral, you can penetrate the cortex, the
- 19 anterior cortex, annulus, so it will be unsafe. So
- as a 40 millimeter cage here, that paragraph that you
- read to me tells me this has to be used laterally.
- Q. Okay. Sir, but that's not my question.

102 1 My question was, for a large man at L4/L5, 2 can you safely put a 40 millimeter cage in without 3 it being direct lateral? 4 MR. AMON: Objection; incomplete 5 hypothetical, asked and answered. 6 I don't think it will be safe to put it in 7 because you, you are potentially risk nerve, 8 depending on which angle you're putting in, or the 9 opposite direction of perforating the anterior or 10 annular wall and then would be in contact with the 11 vessels, because of the length. 12 Sir, so your answer is no, sir? Ο. 13 That's correct. 14 Okay. Sir, I'm going to hand you what's 15 been previously marked as NuVasive Exhibit 2020 in 16 case number IPR 2013-00507. 17 (Handed.) 18 I'm going to ask you to identify that Ο. 19 document, sir. 20 Yes, sir. This is my Declaration, United Α. 21 States Patent and Trademark Office, before the Patent 22 Trial and Appeal Board, concerning patent number

103 1 **'334.** 2 If you would, sir, turn to Page 29 in that 3 document. I think you're looking at Page 30, sir. 29 is to the -- do you see that chart that you have 5 on the top of your report? 6 Α. Yes, sir. 7 Ο. That shows the sizes of NuVasive's 8 Co-Roent XL implants, is that correct? 9 Yes, sir. Α. 10 Do you see there, sir, on the top O. 11 left-hand column of that chart, there are five sizes 12 of implants that are 40 millimeters long, correct? 13 Α. That's correct. 14 And sir, the claim, claim 1 of this patent Q. 15 requires a length of the implant to be greater than 16 40 millimeters, correct? 17 It says 40 millimeters or greater. Α. 18 Actually, sir, if you look at Exhibit MSD Ο. 19 1013, the '334 patent, claim 1, the second element 20 there, I'll read it for you: "Wherein said" --21 strike that. 22 "Wherein said implant has a longitudinal

```
104
     length greater than 40 millimeters."
2
               I read that correctly, right, sir?
3
         Α.
               Yes.
 4
               So the claim requires that the implant be
5
    greater than 40 millimeters, correct, sir?
6
         Α.
               That's what this read, yes.
7
          Ο.
               So the claim requires that, right, sir?
8
                         MR. AMON: Objection; asked and
9
                    answered.
10
         Α.
               That's what it reads.
11
               You seem to be hesitant to agree or
          0.
12
    disagree?
13
               I'm not hesitant. That's what is written.
14
               Okay. So if it's written in the claim, is
          Ο.
15
    it required by the claim, sir?
16
               Here again I'm not an attorney to try to
17
              You asked me does it say length greater than
    answer.
18
    40 millimeter, my answer to you is that's what I
19
    read.
20
               And you're opining about the scope of
21
    these claims, correct, sir?
22
          Α.
               Yes.
```

105 So I'm assuming you have an opinion about O. 2 the scope of these claims, correct, sir? Do you 3 have an opinion about the scope of these claims, sir? 5 Α. Yes. 6 And is your opinion that an implant must 7 be greater than 40 millimeters in length to meet 8 this claim? 9 Α. Yes. 10 Okay. Sir, so going back to the chart in Ο. 11 your Declaration, at least those five sizes of 12 Co-Roent XL standard do not meet the limitation of 13 this claim, correct, sir? 14 That's correct. Α. So they're not covered by the '334 patent? 15 Q. 16 MR. AMON: Objection; asked and 17 answered. 18 Α. That's correct. 19 Okay. But they are apparently capable of Q. 20 trans-psoas lateral implantation, correct, sir? 21 Α. Trans-psoas lateral implant, the average 22 length that we use is usually a 50 is what we

- 1 normally use. So being 40 millimeter we do use it in
- 2 smaller, smaller persons. So it is just a size.
- Q. So the 40 millimeter Co-Roent XL standard
- 4 is capable of being used in a translateral -- strike
- 5 that.
- A 40 millimeter long Co-Roent XL standard
- <sup>7</sup> implant is capable of being used in a trans-psoas
- 8 lateral implantation?
- 9 MR. AMON: Objection; asked and
- answered.
- 11 A. In a smaller individual, it is a size that
- 12 can be used.
- O. Do you know if they are?
- A. As I mentioned, as I stated, the routine
- sizes or the average size that we use are usually the
- 50s. Occasionally the 45s. So the 40 is not a
- common one and I have not used a 40, so that's why my
- answer to you is routinely I use the 50s,
- occasionally the 45s.
- Q. So you don't know one way or the other if
- anybody's ever used a 40 in an XLIF?
- A. I don't know that.

	107
1	Q. Okay. Just so the record's clear, XLIF is
2	a procedure promoted by NuVasive, correct?
3	A. That's correct.
4	Q. And that procedure is a trans-psoas
5	lateral procedure, correct?
6	A. Correct.
7	Q. What's the goal of a spinal fusion
8	procedure, sir?
9	A. That's a big word, goal.
10	Q. Okay.
11	A. Can you tell me little bit of what
12	specifics you would like me to answer? I'd be happy
13	to.
14	Q. Maybe we can make this easier.
15	A. Thank you.
16	Q. In your expert report, Exhibit 2020 from
17	506 matter, paragraph 31.
18	A. Tell me once more, sir?
19	Q. Paragraph 31, Page 15.
20	MR. AMON: Just so the record is
21	clear, the 506 matter relates to the
22	'156 patent.

108 1 THE WITNESS: What page again, 2 please? 3 Page 15. Paragraph 31. Page 15. Q. 4 Α. I'm a little bit hard of hearing, I 5 apologize. 6 O. No problem, sir. I understand. I'm a 7 little hard of hearing myself. Do you see the 8 second sentence in paragraph 31 says: "The goal of 9 interbody fusion, a type of arthrodesis, is to 10 induce bone growth between two vertebrae into a 11 single bony bridge using surgery." 12 Is that correct, sir? 13 Yes, sir. Α. 14 And you also talk right after that about Q. 15 what the procedure is designed to do? 16 Yes, sir. Α. 17 Okay. Does the approach that you put the O. 18 implant in by affect that goal? 19 Can you ask that one more time? 20 Does the approach -- strike that. I won't Q. 21 try to resay it. 22 The approach that you put the implant in,

109 does that affect the goal you've stated? 2 Α. You can use many approaches. Some approach 3 are done open, some approach are done minimally invasively, so you are asking me to just generalize 5 does approach, any one of those approaches -- are you asking me to say do they all try to achieve the same 7 qoal? 8 O. Um-hmm. The answer is yes. 10 Q. Okay, thank you, sir. 11 MR. AMON: Dr. Yuan, we've been 12 going for an hour and a half. Are you 13 okay? 14 THE WITNESS: I'm okay, if he's 15 okay. And we can go a little bit 16 more. 17 MR. AMON: Miss Petrera? 18 THE COURT REPORTER: I'm fine. 19 EXAMINATION BY MR. SCHWARTZ: 20 Sir, are you familiar with when doctors 21 generally started using a trans-psoas approach? 22 I've done trans-psoas approach 30 years Α.

110 ago. 2 0. Okay. 3 But was not, not a common approach because 4 of the risk, the risk, the risk of weakening the 5 psoas muscle but to do the L3-4, L4-5, you have to go 6 trans-psoas because the psoas muscle is so big. You 7 can't go to the front. And the vessels are in the 8 front. 9 So what we generally did in the past is to 10 make an incision in the beginning quite big, you 11 eventually make smaller with better retraction to get 12 there but the nerves are there, so the trans-psoas 13 approach became, is a developmental thing, became, 14 evolved over time, and Dr. Clementa (phon) is the 15 first one to start working with this and then 16 beginning to use neuro monitoring to make it a safer 17 procedure and to become more popular procedure. 18 So when you ask me that, we been using it 19 in the past when we had to go there, but not as a 20 routine. 21 And is one of the circumstances where you Ο. 22 had to go there because there was TB, tuberculosis?

111 Infection. Α. Infection? Ο. 3 Or fracture. 4 Or fracture, okay, sir. Would you say 5 that the use of neuro monitoring made the 6 trans-psoas approach more generally acceptable? 7 I would use the word that made it lot safer 8 and a lot more predictable and also less traumatic 9 and could be done minimally invasively. 10 Q. Do you think the introduction of neuro 11 monitoring motivated more -- strike that --12 motivated more surgeons to do a trans-psoas lateral 13 approach? 14 I wouldn't say motivated. I would say facilitated. 15 16 Going back to that 40 millimeter dimension 17 in the claim, sir, that dimension is largely 18 dictated by the anatomy of the patients we are 19 looking at, right, sir? 20 I'm trying to follow you, Counselor. 21 going back to the 40 millimeter, are we going back to 22 talking about the patent or we are talking about

- 1 clinical?
- Q. Fair question, sir. In the claim 1 of the
- 3 '334 patent, when we were talking about the length
- being greater than 40 millimeters, do you remember
- 5 that conversation?
- 6 A. Yes, sir.
- 7 O. The reason it's 40 millimeters is dictated
- by the patient's anatomy, correct?
- 9 MR. AMON: Objection; vague.
- 10 A. The 40 millimeter length, again, as you're
- 11 referring, going back to the patent of the
- 40 millimeters, I keep saying 44, I apologize.
- O. No problem.
- 14 A. 40 millimeters length, that is the
- beginning of trying to fit a span of anatomical spine
- in the low lumbar region, so 40 is the low extreme
- and going up to 55, okay. Which is again 40 and 55
- 18 are rare to use, more in the middle are going to be
- 19 the majority. So it is designed to fit the
- anatomical structure, mainly the L4-5 and
- occasionally going down to the 3-4. So it fits
- 22 majority of the patients for sizing and also to be

113 able to weight bear and being able to visualize and 2 mark it in the location between the two patents of 3 the claim 1. I'm sorry, I don't mean to go more. I'm just trying to answer your question. 5 Ο. I appreciate it, sir. 6 Α. I'll slow down. 7 Ο. That's just fine for me, sir. 8 Sir, I'm going to turn in your expert 9 report and this again is Exhibit 2020 in the 506 10 matter, I think that's the one you have in front of 11 you, and I'd like to turn to Page 7, talking about 12 the latter part of paragraph 13. In fact the last 13 sentence of paragraph 13. 14 I'll read. "Finally my analysis is based 15 on having personally used both the SVS-PR and 16 Telamon devices in surgery throughout the years." 17 Do you see that, sir? 18 Α. Yes. 19 I read that correctly? Q. 20 Α. Yes. 21 Do you recall when you used the SVS-PR? O.

I don't know the exact date here again.

Α.

- PLIF was the standard procedure that we did before
- the TLIF. So I don't, I don't know the date, I don't
- 3 recall the date.
- Q. Do you recall if it was before 2000?
- 5 A. I cannot tell you. I will be totally
- 6 guessing.
- 7 O. And that's for the SVS-PR?
- 8 A. And the Telamon. They are both about the
- 9 same time. So I don't remember the date. I've used
- numerous PLIF devices, but I have used these two.
- 11 Q. Do you have records that would show that?
- 12 A. I have record in the office.
- Q. Okay. Is that something that maybe you
- could call back to your office during a break and
- 15 find out?
- A. I'm retired almost since '07, '08, so my
- files are probably in my days are still on charts,
- 18 not on computers.
- 19 Q. Okay.
- A. So again, State University of New York
- 21 after so many years, okay, once you have stopped
- 22 practicing, I don't know how long these charts are no

- longer filed. So the answer is not going to be easy,
- 2 but you can, can it be done, with a lot of work you
- 3 probably can.
- When did you stop practicing? Q.
- 5 2007. That's practicing in the US.
- 6 Q. Okay.
- 7 As far as surgery, I'm still doing, still
- doing surgery.
- 9 Ο. But you think you would have personally
- 10 used these products, the SVS-PR and Telamon before
- 11 2007?
- 12 Yes. Α.
- 13 Do you have a feel for how much before
- 14 2007?
- 15 MR. AMON: Objection; asked and
- 16 answered.
- 17 I like to tell you but I don't, I don't Α.
- 18 remember.
- 19 Okay. Do you recall how many times you
- 20 used the SVS-PR?
- 21 I'm hesitating because we have a training
- 22 program, we train a lot of fellows, a lot of

- 1 residents, and what is fortunate for me and the
- <sup>2</sup> university here is that the university allowed us
- fairly free to use devices in those days, not like
- now Obamacare, things are changed.
- 5 So the last few years things have become
- 6 much harder is what I hear from my younger partners.
- 7 So we use any new device that came out that is
- 8 approved, either younger faculty member wants to use
- 9 it, we allow him to acquire it. So I personally
- would review it and probably do the first few. And
- then the rest of the faculty can go ahead and
- continue to use it if that's what they wish.
- I know that the Medtronic is very, very big
- part of a spine practice and I also know that the
- 15 Synthes and J&J, all three major companies. And then
- eventually Stryker became a bigger and bigger force.
- 17 So we use all the products.
- So this is why I cannot remember how many
- 19 times I've used it. When I put that down here is
- with a lot of thought, okay, that I have seen the
- device, I use the device, and as I read through the
- 22 patent I recall having used them. I apologize, not

	117
1	able to give you a number.
2	Q. Fair enough, sir.
3	MR. AMON: Do you want to quit
4	after you finish this section for a
5	while?
6	MR. SCHWARTZ: This is a good
7	time. Do you want to make this a
8	short break or do lunch now? Up to
9	you. We can make this a short break
10	and do lunch in another hour and a
11	half or so. So make this ten minute.
12	(Discussion off the record.)
13	EXAMINATION BY MR. SCHWARTZ:
14	Q. Back on the record. You understand you
15	are still under oath, right, sir?
16	A. I am, sir.
17	Q. Let's go back to your expert, your
18	Declaration, NuVasive Exhibit 2020 for the 506
19	matter which is the '156 patent and turn to, I'd
20	like to address the sentence that is on the bottom
21	of Page 16 and continues to the top of Page 17 in
22	paragraph 35.

118 1 So I'll read the sentence: "The maximum 2 possible length for an implant as is inserted from 3 either the front or the back of the patient is limited to the depth of the vertebra measured from 5 the anterior to the posterior end of the vertebra." 6 Did I read that correctly, sir? 7 Yes, sir. Α. 8 Ο. Okay. Now, sir, we talked for example 9 about your experience with a posterior lateral implantation. Do you remember that? 10 11 Α. Yes. 12 For a posterior lateral implantation, one Ο. 13 that goes in at an angle, the length of that implant 14 is not limited to the depth of the vertebra measured 15 from the anterior to the posterior end of the 16 vertebra, correct? 17 MR. AMON: Objection; incomplete hypothetical. 18 19 May I get a little more clarity in the 20 depth, anterior posterior distance obviously as you 21 well know, Counselor, remains constant. 22 Um-hmm. Ο.

- 1 A. So you are asking me that if you approach
- it from posterolateral, okay, then can you tell me --
- Q. Then the length of that implant is not
- 4 limited by the depth as measured from the anterior
- 5 to the posterior end of the vertebra because it's at
- 6 an angle, right, sir?
- 7 A. That's correct.
- 8 O. So if it's at a diagonal, it can be longer
- <sup>9</sup> than the anterior to posterior end of the vertebra?
- 10 A. That's correct.
- 11 Q. Okay. I'd like to refer you now to your
- paragraph 39 which is just the next page where
- 13 you're talking about the Telamon. Do you see that
- paragraph, sir, it appears in its entirety on
- <sup>15</sup> Page 18.
- 16 You mentioned there that the Telamon was
- designed to be used as a posterior or PLIF implant,
- 18 correct, sir?
- 19 A. Yes.
- Q. Okay, sir. And what do you base your
- opinion that the Telamon was designed to be used as
- a posterior or PLIF implant?

- 1 A. Base that on the patent of Telamon and also
- on the -- because of the sizes of the Telamon there
- was included in the patent and its description that
- 4 it reads intended as a PLIF implant.
- <sup>5</sup> Q. So it can be used as a PLIF, right, sir?
- A. It is designed to be used as a PLIF
- 7 implant.
- 8 O. Okay. Sir, I'm going to hand you what has
- <sup>9</sup> been previously identified as MSD 1107. Is that the
- document that you reviewed for purposes of coming to
- 11 your opinion about the Telamon?
- 12 A. I have --
- 0. Or at least one of them?
- A. Yes, sir.
- Q. Sir, on that document, on the left side of
- the front, do you see in very small letters the
- paragraph on the bottom that starts: The
- 18 Verte-Stack Telamon PEEK, those words?
- 19 A. Yes, I can see it.
- Q. I'll read at least the beginning part of
- that sentence. "The Verte-Stack Telamon PEEK,
- vertebral body spacer is a vertebral body

```
121
    replacement device intended for use in the
2
    thoracolumbar spine, (T1 to L5" -- correction --
3
    "T1-L5), to replace a collapsed, damaged or unstable
4
    vertebral body due to tumor or trauma (i.e.
5
    fracture)."
6
               Did I read that correctly?
7
               That's what you read.
         Α.
               So, and in fact on the right side, in big
8
         Ο.
9
    bold letters, it says: Medtronic Sofamor Danek,
10
    Telamon Verte-Stack PEEK Vertebral Body Spacer,
11
    correct, sir?
12
         Α.
               Yes.
13
               So in addition to being a PLIF, it's also
         Ο.
14
    a vertebral body spacer, right, sir?
15
               That's what that says.
         Α.
               Okay. So at least the document says that
16
          Ο.
17
    this product is a vertebral body spacer?
18
         Α.
               That's correct.
19
               And as a vertebral body spacer, as we
20
    talked about before, it could be put in laterally,
21
    correct?
22
                         MR. AMON: Objection;
```

122 1 mischaracterizes prior testimony. 2 Α. Yes, it can be put in lateral. 3 Q. And it can be put in at an angle? Α. Yes. 5 O. Or anteriorly, correct, sir? 6 Α. It can be put in anteriorly. 7 Ο. Okay. Sir, in paragraph 40, I'm on your 8 report now, sir, I'm not on the Telamon, in 9 paragraph 40 which is on the next page in your 10 report, Page 19, the last sentence, you say: "A 11 small increase in the size of the implant, i.e. a 12 few millimeters difference or a few degrees 13 difference in lordosis can prevent or otherwise 14 hinder the original intended use and can mean the 15 difference between an implant that alleviates pain 16 and one that causes significant additional problems 17 for the patient." 18 I read that correctly, right, sir? 19 That's correct. Α. 20 Q. Now, when we were talking a moment ago 21 about the claim 1 of the '334 patent requiring the 22 implant to be greater than 40 millimeters, it's

- 1 correct, isn't it, that an implant that is
- <sup>2</sup> 40 millimeters can also be used for a translateral
- or -- strike that -- strike that whole question.
- 4 It's correct that an implant that is
- 5 40 millimeters long is also usable as a trans-psoas
- 6 lateral implant, correct?
- 7 MR. AMON: Objection; asked and
- 8 answered.
- 9 A. Yes, it can be used as we qualified before
- that in a smaller upper lumbar vertebral body because
- 11 the size is smaller.
- 12 Q. So at least that small change, the change
- being the claim requires greater than 40 and the
- implant is 40, doesn't affect its ability to be used
- as a translateral -- strike that -- trans-psoas
- 16 lateral implant, correct, sir?
- 17 A. Now your, Counsel, now your comment becomes
- broader because to qualify for use, it has other
- 19 claims, then it becomes depending on the level of the
- vertebral body that you're going to be using it in.
- Q. But in some level that implant with the
- small change of being 40 millimeters as opposed to

124 greater than 40 millimeters is still useful as a 2 trans-psoas lateral implant? 3 The 40 in a smaller vertebral segment can 4 be used as a trans-psoas, correct. 5 O. So that small change at least doesn't 6 hinder its use for a trans-psoas lateral 7 implantation? 8 Α. That's correct. 9 Q. Sir, if you would, turn to the paragraph 10 45 which goes from Page 21 to 22. The sentence that 11 begins at the top of Page 22, I'll read it: 12 complication of using markers as identified by 13 Dr. Hynes is that the implant can have too many of 14 them." I read that correctly, right, sir? 15 16 Α. That's correct. 17 Now, Dr. Hynes did not testify that having Ο. 18 two markers in the center of a long implant is too 19 many, did he? 20 MR. AMON: Objection; assumes 21 facts not in evidence. 22 I don't know whether he did specifically Α.

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125
    that sentence or not. If you want to show me
2
    where -- I don't remember. I read his deposition,
3
    but if you show it to me, I'm happy to --
4
               So you don't recall if he said that or
5
    not.
6
         Α.
               I don't recall.
7
         0.
               Okay. Let's start this way.
8
                         MR. SCHWARTZ: Let's mark this as
9
                    MSD 1050.
10
                         (Exhibit MSD 1050, Excerpt of
11
                    Deposition of Richard Hynes, M.D.,
12
                    marked for identification, this date.)
13
    EXAMINATION BY MR. SCHWARTZ:
14
               Sir, I'm handing you what's been marked as
    MSD 1050 which I'll represent for the record is an
15
16
    extract of Dr. Hynes's deposition transcript. I
17
    tried to save the tree and not present multiple
18
    copies of a large document. But I do want to refer
19
    to the citations that you rely on in your report.
20
    Let's turn first to Page 141, line 7 to 16.
21
               On Page 141, line 7 to 16, the question:
22
    "So then why not, to take it to an extreme, and I
```

126 recognize that my question is an absurd extreme, why 2 not place 50 markers in it?" 3 I read that question correctly, right, 4 sir? 5 Α. Yes. 6 Then I interject an objection; and then 7 the answer: "Well, if you place 50 markers, then 8 you basically have a Michelson and then you can see 9 everything. It's more than you need to know. 10 That's a metal cage. So you can't see the bone 11 graft. That's the whole reason we like the PEEK, is 12 so we can see the graft better." 13 Did I read the answer correctly, sir? 14 That's what he answered. Α. 15 Q. So the question was about 50 markers, 16 right? 17 MR. AMON: Objection; the 18 document speaks for itself. 19 That's what it says. That's what Dr. Hynes Α. 20 declared. 21 That was the question to him, was about 50 Q. 22 markers, correct?

- 1 A. That's correct.
- 2 Q. Not about two in the middle or some number
- $^{3}$  on an end.
- 4 A. That's correct.
- <sup>5</sup> Q. Okay. So he certainly didn't say on this
- 6 page that it would be confusing or complicated or
- <sup>7</sup> too many to have two markers in the middle, did he?
- MR. AMON: Objection. The
- document reads what it reads.
- 10 A. I'm reading here as you read to me, the
- 11 question was an absurd number of 50 markers and
- Dr. Hynes answered in his opinion, only, and then you
- can see everything. That's what he said.
- Q. So he wasn't saying that two markers in
- the middle made it confusing, right?
- 16 A. There is no indication at all and I cannot
- derive anything from him, what he's trying to imply.
- Q. Okay. Well, I'm just asking you, sir,
- because you cited to this for support for your
- 20 statement of what Dr. Hynes said. So I'm just
- 21 asking you about that, okay. I'm trying to
- understand your conclusion based on his testimony.

128 And I want to make it clear that at least for this 2 question and answer, Dr. Hynes is not saying that 3 it's complicated to put two markers in the center, correct? 5 Α. I'm trying to understand what, what you are 6 asking me to answer. 7 Let me try it a different way, sir. I'm 8 sorry, were you answering? I didn't mean to 9 interrupt. 10 I'm trying to understand from this Α. 11 paragraph how you got to where you are. 12 0. Okay. 13 So please, tell me one more time what 14 specifically --15 Is there anything in this question and 16 answer that would tell you that Dr. Hynes believes 17 or thinks that putting two markers in the center of 18 a long implant is complicated? 19 Α. No. 20 Q. Okay. Thank you, sir. 21 Sir, why are there markers in the middle

of the implant claimed in the '156 patent?

```
129
1
                         MR. AMON: I'm sorry, can you
2
                    repeat the question.
3
                         (Whereupon, the pending question
                    was then read.)
5
                         MR. AMON: Thank you.
6
               I read that to tell me that those two
7
    markers that are put in the middle has a strategic
8
    indication and benefit.
9
          Ο.
               What is that strategic indication and
10
    benefit?
11
               It's meant to be used in a lateral cage
12
    that it will allow you to line up to the spinous
13
    process and allow you to know the obliquity or
14
    rotation of the implant so it will be implanted in
15
    the safest and also the proper weight bearing
16
    fashion.
17
               Okay. So if you wanted to put in a long
18
    implant laterally, you would be motivated to put two
19
    markers in the middle?
20
                         MR. AMON: Objection;
21
                    mischaracterizes Dr. Yuan's testimony.
22
               What do you mean you will be motivated?
         Α.
```

130 Sir, do you not understand the word 2 motivated? 3 I'm trying to understand your question, so if you can clarify it I will appreciate it. 5 Do you have an understanding of the word Q. motivated, sir? 7 I don't see the word motivated and the 8 question that you asked as something that, that I 9 understand. 10 Do you have an understanding of the word 11 motivation? I mean you've used it in your report. 12 I can point you to it if you want. 13 It would be a lot easier if you tell me why Α. 14 you're using the word motivated. Maybe use a different word to clarify, I can probably answer. 15 16 Otherwise I wouldn't be able to answer. I'm trying 17 to understand. So you cannot answer a question about the 18 19 motivation to put markers in the center of an 20 implant generally? 21 MR. AMON: Objection. He's 22 asking you for clarification and

```
131
1
                    you're not able to clarify the
2
                    question.
3
               I didn't say I'm not able to answer.
4
    asking you to tell me why you using the word
5
    motivation if you can give me an understanding so I
6
    can understand what you're asking, and there's no
7
    other words you can use or clarify for me?
8
               Okay. Sir, if you're not saying that you
9
    can't answer the question, then I'm going to ask the
10
    Court Reporter to read the question again.
11
                         (Whereupon, the pending question
12
                    was then read.)
13
                         MR. AMON: I'm going to interpose
14
                    an objection as vague as to time.
15
               I don't mean to interrupt you, but I don't
16
    understand the word; why you could not clarify for
17
    me, why you would stick to the one with motivated.
18
    The word motivated in that sentence that you are
19
    asking, I don't understand.
20
               Okay. So you don't -- so your answer is
21
    you can't answer that question?
22
                         MR. AMON: That's not his answer.
```

132 Is that correct? Ο. 2 I did not say I cannot answer the question. 3 I'm asking you to clarify it for me. 4 Okay. If you can answer the question, sir, I'm going to ask you to answer it. So I'll ask 5 6 the Court Reporter to read it again. 7 (Whereupon, the pending question 8 was then read.) 9 MR. AMON: Objection; vague, and 10 vague as to time. 11 I come back to ask you to clarify the word 12 for me so I can understand. 13 Okay. So without clarification, you Ο. 14 cannot answer that question? 15 Α. That's correct. 16 Okay. I'll move on. Q. 17 Sir, on the paragraph or the sentence that 18 runs on the bottom of Page 22 to the beginning of Page 23, I'll read it for the record. 19 20 Α. Which document. 21 Same document we've been reading from. Ο. 22 The Exhibit 2020, Declaration of Hansen I'm sorry.

133 A. Yuan, case IPR 2013-00506. 2 Paragraph 47, the sentence from the bottom 3 of 22 to the top of 24. I'll read it: particular note is that the positioning of the 5 radiopaque markers proximal to the medial plane of the implant represents a novel placement that had 7 not been necessary or even contemplated for PLIF 8 implants such as the SVS-PR and Telamon, and that 9 the claim requirements for longitudinal length, 10 maximum lateral width and the relationship between 11 the length being greater than the maximum width, 12 exclude anterior implants such as Baccelli." 13 Did I read that correctly, sir? 14 Α. Yes. 15 So the part of the sentence where you talk Ο. 16 about the positioning of radiopaque markers proximal 17 to the medial plane of the implant, that was shown 18 in Baccelli, correct, sir? 19 Can you show me Baccelli's? Α. 20 Absolutely. Q. 21 Α. Thank you. 22 Sir, I'm handing you what's been Ο.

```
134
    previously identified as MSD 1004 which I'll
2
    represent for the record is the Baccelli patent
3
    application US 2003/28249.
4
                          (Handed.)
5
                         MR. AMON: Thank you.
6
         Q.
               So, sir, to restate the question.
7
          Α.
               Please.
8
               Baccelli does show the positioning of
9
    radiopaque markers proximal to the medial plane of
10
    the implant, correct?
11
               Can you show me on this drawing which ones?
12
               Sure. Markers 24 here and there, sir.
          Ο.
13
         Α.
               Yes, thank you.
14
          O.
               So Baccelli does show that, correct?
15
               Correct.
16
               Sir, I'm going to turn to paragraph 50,
          Q.
17
    which is the next page, Page 24 in your expert
18
    report.
19
               Which one?
20
               Your expert report, sir. Not Baccelli.
21
    You can put Baccelli to the side.
22
               So paragraph 50, the second sentence says:
```

135 "I'm not, however, aware of Dr. Michelson or any 2 other person using one of these implants to actually 3 perform a direct lateral trans-psoas approach to the lumbar spine for a fusion procedure." 5 Do you see that? 6 Α. Yes, sir. Let me back up a little bit. For direct 8 lateral approach, you could certainly do a direct 9 lateral without going trans-psoas, correct? 10 MR. AMON: Objection; incomplete 11 hypothetical. 12 Let's qualify it just a little bit. Α. 13 Ο. Sure. 14 It can be used in certain aspect of the 15 lumbar spine where the psoas muscle is not big, so in 16 the upper lumbar or the lower thoracic thoracolumbar, 17 the answer is yes.

- Q. You can retract the psoas instead of going
- 19 through it, correct?
- A. Again, we qualify little bit, again in the
- upper lumbar, you can. So like a 2-3, the psoas is
- of course attached to T12, T11, so the psoas at that

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- level is much thinner and has more of a tendonous
- structure, so that can be retract. Most importantly,
- 3 there is no neuro structures in those levels that
- 4 are -- like a plexus, lumbar plexus that you see at
- 5 L3-4, L4-5, L5-S1. So in the upper lumbar, the
- 6 answer is yes, Counselor.
- <sup>7</sup> Q. Okay. And are you aware, you take that
- 8 sentence and take out the word trans-psoas, is that
- 9 still the case, you're not aware of Dr. Michelson or
- any other person using one of these implants to
- 11 actually perform a direct lateral approach to the
- 12 lumbar spine for a fusion procedure?
- 13 A. Well, my Declaration here is specifically
- inclusive of a trans-psoas approach.
- Q. I understand that, sir.
- A. And you were asking me a hypothetical.
- Q. Well, no, sir. I'm not asking you a
- 18 hypothetical. I'm asking you, this sentence as I
- understand it, is providing your awareness of what
- any other person did, correct, and all I'm doing is
- 21 saying if you take out the word trans-psoas, is the
- 22 same true?

137 I'm stating specifically for the Α. 2 trans-psoas. 3 I understand that, sir. What I'm asking 4 you is are you aware of anyone using an implant as 5 described in the Michelson '973 patent to perform a 6 direct lateral approach to the lumbar spine for a 7 fusion procedure? 8 Α. I've done it. Q. You've done it? 10 Α. Correct. 11 Okay. So you are aware of other people Q. 12 doing that? 13 But a trans-psoas approach, the answer is Α. 14 no. 15 Q. Okay. And do you recall when you did it, 16 sir? 17 I don't remember the dates. It's 20 some Α. 18 years ago. 19 Just one time or a number of times? Q. 20 Α. I've done it on two cases. 21 Q. Okay. 22 I've done it on two cases. I don't know Α.

```
138
    somebody else.
2
         Q. Are you aware of others having done it as
3
    well?
4
               I don't know.
5
         O.
               Okay. Have you ever heard of a
    Dr. Bergey, B-E-R-G-E-Y.
7
               B-E-R-G-E-Y, no; no, sir. Where is he?
         Α.
8
         Q.
               I'm sorry, say that again?
9
         Α.
               Where is he?
10
         Q.
              Good question, sir. I'll see if I can
11
    answer your question.
12
         Α.
               Thank you.
13
              Maybe at Cedar Sinai?
         Q.
14
         Α.
              Cedar Sinai in Los Angeles?
15
         Q.
               Yes.
16
               I don't know him. I do know most of the
         Α.
17
    spine surgeons there.
18
               Okay. I'm going to go ahead and mark
         Ο.
19
    this. We'll chat about it. We'll make this MSD
20
    1051.
21
                         (Exhibit MSD 1051, Endoscopic
22
                    Lateral Transpsoas Approach to the
```

139 1 Lumber Spine article, marked for 2 identification, this date.) 3 EXAMINATION BY MR. SCHWARTZ: 4 Sir, I'm going to hand you what's been 5 identified as MSD 1051. 6 Α. Thank you. I appreciate you may not be familiar with it, so I'm not asking you to read the entirety of 9 it. I'm just asking if you are familiar with that 10 at all? 11 I'm not, I've not read this article itself. 12 So when you made this statement in your 13 report that you were not aware of Dr. Michelson or 14 any other person using one of these implants to actually perform a direct lateral trans-psoas 15 16 approach to the lumbar spine for a fusion procedure, 17 you didn't have this article by Dr. Bergey in mind? 18 That's correct. I've not seen this before. Α. 19 Okay. Now, I'll point you to a sentence 20 on the first page where it says Materials and 21 Methods. 22 Yes, sir. Α.

	140
1	Q. It says: "21 patients underwent lumbar
2	spinal fusion via a lateral endoscopic trans-psoas
3	approach between March 1996 and August 2002."
4	Did I read that correctly?
5	A. Yes.
6	Q. So at least assuming this is correct, and
7	I know you don't have personal knowledge of that, if
8	this is correct, then that would be at least an
9	other person that did a direct lateral trans-psoas
10	approach to the lateral spine for a fusion
11	procedure, correct?
12	MR. AMON: Objection;
13	mischaracterizes the document or
14	actually assumes facts not in
15	evidence. Dr. Yuan, take the time you
16	need to review the document so that
17	you can answer Mr. Schwartz's
18	substantive questions.
19	MR. SCHWARTZ: I'm only asking
20	about that sentence, sir. I
21	understand you're not familiar with
22	this document. And I'm asking you the

	141
1	hypothetical of if that sentence is
2	correct.
3	MR. AMON: Your question also
4	assumes facts that he would need to
5	gather from reviewing the article.
6	MR. SCHWARTZ: Please stop
7	coaching the witness.
8	MR. AMON: Not coaching.
9	MR. SCHWARTZ: Please stop
10	coaching the witness.
11	MR. AMON: I'm not coaching.
12	MR. SCHWARTZ: You are coaching
13	and you need to stop.
14	MR. AMON: Mr. Schwartz, please
15	don't raise
16	MR. SCHWARTZ: Mark this record.
17	MR. AMON: Mr. Schwartz, please
18	don't raise your voice, because,
19	honestly, it's concerning to me and
20	it's concerning to the witness. So to
21	the extent you're going to continue to
22	raise your voice, we are going to take

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	142
1	a break.
2	MR. SCHWARTZ: So the record is
3	clear, I did not raise my voice and we
4	need to mark this specific location on
5	the record so that we can bring it to
6	the attention of the Patent Office if
7	it persists.
8	THE WITNESS: Can you ask the
9	question one more time? I apologize,
10	after your
11	(Whereupon, the pending question
12	was then read.)
13	THE WITNESS: Can you ask the
14	question one more time?
15	(Whereupon, the requested portion
16	of the record was then read.)
17	MR. AMON: Objection; assumes
18	facts not in evidence.
19	THE WITNESS: Your question that
20	you asked me to, I read that sentence,
21	and the dates, my answer to you is
22	that's what this paragraph stated.

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August 22, 2014

143 EXAMINATION BY MR. SCHWARTZ: 2 Okay. Going down to paragraph 51, you Ο. 3 talk about Dr. Paul McAfee, and you refer in the third sentence to the fact that -- I'll read the 5 sentence. "Moreover, those procedures were 6 performed using a retracted psoas approach to the 7 spine, not a trans-psoas path." 8 Did I read that sentence correctly? 9 Α. That's correct, sir. 10 So Dr. McAfee performed lateral fusion Ο. 11 procedures by retracting the psoas, correct? 12 Α. Yes. 13 The next sentence you say: "The implants Ο. 14 that we were using were not commercially available." 15 Do you see that? 16 Α. Yes. 17 Why did you use an implant that was not O. 18 commercially available? 19 We didn't have one long, long cage, and we 20 at that particular time stack one cage behind the 21 other to gain the length. So it was approved cages 22 for use in the lumbar spine and thoracolumbar spine,

- and it's IRB approved, it's FDA, it's in compliance
- with FDA ruling. We didn't have any other cage, any
- other implants that we can use for those cases, so we
- use one cage behind the other, so-called stacked.
- <sup>5</sup> Q. But the implant that you were using that
- 6 was not commercially available was not a stacked
- <sup>7</sup> implant, right, it was a longer implant, correct?
- 8 A. Later on we got custom implants.
- 9 Q. Right.
- 10 A. At a later time. And those are the ones
- 11 that Regan's cases came afterwards, so Regan is a
- 12 fellow of McAfee's, so we, the ones I've done are not
- commercially available, the long cage, so we stack
- one behind the other to gain the length. And
- eventually when Regan did it, he used customized
- implants.
- 17 Q. Long BAKs, correct?
- 18 A. Long BAKs, but I was not aware that he
- published this article.
- Q. Okay. Sir, if you would turn to Page 31,
- the same document we've been looking at, 2020. And
- it's the bottom of paragraph 60, the first full

- sentence on the page, top of Page 31, it says:
- 2 "Having two radiopaque markers also allows a surgeon
- 3 to see in an anterior to posterior X-ray view
- 4 whether the implant is askew and the degree to which
- 5 the implant is askew."
- 6 Did I read that correctly?
- 7 Yes, sir. Α.
- 8 Now, sir, referring back to the Baccelli 0.
- 9 implant with the two radiopaque markers in the
- 10 center, would you also be able to tell whether the
- 11 implant is askew and the degree to which the implant
- 12 is askew, using the Baccelli configuration?
- 13 Counsel, what you point to me are the two Α.
- 14 medial markers on the Baccelli, are these two, am I
- 15 correct?
- 16 O. Correct.
- 17 This implant is a cervical implant. Α.
- 18 cervical implant is done with anterior approach to
- 19 the cervical spine.
- 20 O. Okay.
- 21 Α. So these two spikes that are put in there
- 22 will allow you to take an AP X-ray but they are not

- in the quote, unquote, AP plane. They are in the
- <sup>2</sup> middle of this implant because this is an anterior
- implant, so I'm trying to understand what you're
- 4 trying to ask me so that I can answer properly.
- Okay. If you were to take an X-ray view
- from the side, not anterior to posterior, would you
- <sup>7</sup> be able to tell from those markers if the implant is
- 8 askew and the degree to which the implant is askew?
- <sup>9</sup> A. The answer is yes, as long as they were
- 10 true lateral picture.
- 11 Q. Okay. Thank you.
- 12 A. Thank you for the qualification.
- 13 Q. Let's turn to paragraph 76 of your
- Declaration where you're defining what a person of
- the ordinary skill in the art is.
- A. Yes, sir.
- Q. And you generally agreed with Dr. Hynes's
- definition, correct?
- A. Yes, sir.
- Q. But where you deviated was adding the bold
- words, Designing and Testing, correct?
- A. Yes, sir.

- Q. Why does a person of skill in the art need
- to have experience, two to three years of
- 3 experience, designing and testing as opposed to just
- 4 designing?
- 5 A. You can design something because that's
- 6 something that you like to have, and if you don't do
- <sup>7</sup> the testing you don't know how it will really apply
- 8 or don't do enough of what we call accumulation of
- 9 data to be able to make a better judgment.
- Q. So if someone designs, someone has two to
- three years experience designing but not testing, in
- 12 your opinion that's not a person of skill in the art
- relevant to the inquiry we are doing here?
- 14 A. If someone is designing something, we see a
- 15 lot of design that comes through and unless they
- really have information on it, those designs don't go
- anywhere.
- 18 O. Okay. But it's your opinion that someone
- who only designs but doesn't test and only has two
- to three years of experience designing, is not a
- person of skill in the art, correct?
- A. I think this is a very, very unique area,

- and in order to design something, the ability to know
- what you've designed works even if the testing is not
- by yourself, somebody else is doing the testing, but
- $^4$  having the data. That's what's important.
- 5 And so a person of ordinary skill in the
- field, that I will recognize, I say this because not
- <sup>7</sup> to belittle anyone, but we have many, many young
- 8 surgeons coming out that has some wonderful ideas,
- but until they begin to be able to make sure that
- it's tested according to a protocol that whether it's
- 11 established by FDA or established by the university
- or by lab, then they don't know whether it's going to
- work.
- so you've asked me from before many of the
- cadaver work that we've done, and rightfully so you
- asked me because you wanted to know, you know,
- whether I know what the results are, so even then
- 18 after testing we have great results, okay. I won't
- say great, I'll say reasonable results that fit the
- standard, but when you did not look at all the other
- 21 parameters of what the clinical occasion use it for,
- and it doesn't fit all the clinical cases, it may fit

149 So I put this in just to be clear that I feel, some. 2 I know somebody like Dr. Hynes probably has this 3 experience, unequivocally, because I read his designs, I read his patents, okay. So having seen 5 those, I'm not discrediting him, I'm saying he has the skills, but I have young people who don't have 6 7 the skills and I think that those individuals for us 8 to include as a person ordinary skilled in the art 9 wouldn't be proper. They will develop the skill at 10 the time. It's just a qualification to make it more 11 complete. 12 Okay. Would there -- in your opinion, 13 would there be some number of additional years of 14 designing that could take the place of having 15 experience testing, so for example, where you say 16 two to three years of designing and testing, is 17 there some number of years of just designing that 18 would suffice to qualify that hypothetical person as 19 a person of skill? 20 MR. AMON: Objection; incomplete 21 hypothetical, speculation. 22 I have a wonderful fellow who has done tons

150 of designing, and from his designs the ideas never 2 came to fruition, okay. So I don't want to say that 3 he's not good or not in the field. I can only say that it doesn't, it's like a basic scientist only 5 without being able to apply it. So when we are 6 talking about implant is an applied science, so to go 7 to the applied science, I think having both just 8 makes it complete. It's just like somebody who can 9 do all the testing but can't do any design. 10 Q. Okay. 11 It would not come up with any ideas. 12 the combination of the two. I'm not so sure that two 13 or three years is what's necessary, but in going 14 through a residency, if somebody has been exposed to 15 this, the time that they finish residency is 16 certainly qualified. 17 Ο. Fair enough. How are you doing, sir, 18 okay? 19 I'm okay. 20 We'll go a little bit longer then and then 21 we'll break for lunch. 22 MR. AMON: Jeff, the Court

	151
1	Reporter had asked me during the break
2	how long you expected to go after
3	lunch.
4	(Discussion off the record.)
5	EXAMINATION BY MR. SCHWARTZ:
6	Q. Let's turn to the next page, talking about
7	the Synthes SVS-PR. And you refer in paragraph 79
8	to the SVS-PR I'll just read it: "The SVS-PR was
9	designed to be an interbody spacer that is inserted
10	using a PLIF (posterior) procedure in a direct
11	posterior-anterior direction in the disc space."
12	Did I read that correctly, sir?
13	A. Yes, sir.
14	Q. So it's your understanding that the SVS-PR
15	can be used as a PLIF, correct?
16	A. Correct.
17	Q. And what did you derive that understanding
18	from?
19	A. I've looked at the literature and I've
20	looked at the description and I've looked at the
21	company's guide, so-called surgical instructional
22	guide, and all the labeling for this is that it is

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152
    used as a PLIF implant.
2
               Okay. I'm going to hand you what's been
         Ο.
3
    previously identified as MSD 1106.
4
                         (Handed.)
5
         Ο.
               Is that some of the literature that you
6
    reviewed for purposes of drawing the conclusion you
7
    just mentioned?
8
               Yes, I've seen this. Thank you.
         Α.
9
         Q.
               Okay. Sir, and you'll notice in this
10
    document, just like in the Telamon document we
11
    looked at before, there's a reference on the
12
    Indications on the bottom of the document where it
13
    says: "The vertebral spacer is a vertebral body
14
    replacement device intended for use in the
15
    thoracolumbar spine-T1-L5" -- I'm sorry, "(T1-L5) to
16
    replaced a collapsed, damaged or unstable vertebral
17
    body due to tumor or trauma, (i.e. fracture)."
18
               Did I read that correctly?
19
         Α.
               Yes.
20
               So the vertebral spacer PR is also a
         Q.
21
    vertebral body replacement device, correct?
22
               That's what the paragraph reads.
         Α.
```

153 And so it is also a device as a vertebral 2 body replacement device that could be put in 3 anterior, correct? 4 MR. AMON: Objection; 5 mischaracterizes the document. 6 ahead, Doctor. 7 The last sentence? As a vertebral body replacement device, it 8 could also be put in anteriorly? 10 Α. Yes. 11 And it can also be put in laterally, Ο. 12 correct? 13 MR. AMON: Objection; 14 mischaracterizes the document. 15 There's no mention here of what the 16 indication or the approach is. 17 Ο. Correct. 18 So all I've seen of the SVS-PR has been as 19 the next page really shows, all of the dimensions and 20 so on, are that this is for a posterior PLIF 21 approach. So I do not see where this said this is 22 anterior implantable or lateral implantable device.

154 But it is discussed as a vertebral body O. 2 replacement device, correct? 3 Α. It does say that. 4 And as we talked about before, vertebral Q. body replacement devices can be put in laterally, 5 6 obliquely or anteriorly, correct? 7 That is correct. But I've never seen one Α. 8 of the SVS-PR as a vertebral body replacement. 9 Q. Okay. And it is designed in the last 10 sentence, I'll read the sentence. "The vertebral 11 spacers are designed to provide anterior spinal 12 column support even in the absence of fusion for a 13 prolonged period", correct? 14 That's what it says here but that's a big Α. 15 stretch. But anyway. 16 That's what it says? Ο. 17 That's what it says. Α. 18 Fair enough. Sir, if you would turn to Ο. 19 Page 81 -- I'm sorry, Page 41, paragraph 81, in your 20 opinion. We're still talking about the Synthes PR 21 device.

Yes, sir.

Α.

155 1 The second sentence says: "It does not O. 2 appear from the SVS-PR documents that the implants 3 have any other radiopaque markers near the middle of the implant nor would they need to given that this 5 is a PLIF implant and that the pair of markers at 6 the posterior and distal walls would provide the 7 surgeon with all of the requisite information and 8 positioning information for a PLIF procedure." 9 I read that correctly, right, sir? 10 Α. That's correct. 11 Okay, sir, in the hypothetical, where the 12 SVS-PR is made longer, 41 millimeters, and the 13 surgeon wants to put it in laterally, would that 14 surgeon have a reason to put markers in the middle? MR. AMON: Objection; incomplete 15 16 hypothetical. Vague as to time. 17 This device has several properties that Α. 18 really renders it for a lateral implant to be 19 incorrect. 20 O. Okay. But that's not my question, sir. 21 My question is, if you make it longer, 22 41 millimeters long, and you want it to put it in

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156 laterally, would you have a reason to put two 2 markers in the middle? 3 MR. AMON: Objection; incomplete 4 hypothetical, vague as to time. 5 And listening to your question and trying Α. 6 to answer you appropriately, if some, if a surgeon 7 choose to do this laterally with a longer implant, 8 okay, that surgeon even with a longer implant with 9 the properties of this implant that is given, 10 presented to me in the SVS-PR implant guide or 11 description, because a lot of these other properties 12 a surgeon would not choose to do this in the lateral 13 approach. 14 Not my question, sir. My hypothetical, Q. 15 the surgeon is putting it in laterally. And it's 16 41 millimeters long. Would he have a reason to put 17 two markers in the middle? 18 MR. AMON: Same objection. 19 Would he have reason. Α. 20 Because is a hypothetical and how would a 21 surgeon be able to just put two markers in the

middle.

157 By any means of manufacturing, sir. Ο. 2 Α. But he can't tell somebody to manufacture 3 that because that is not the approved device, it's not even something that you can use custom. 5 just -- I'm --6 Sir, getting, putting aside whether the 7 doctor has a manufacturing means to do it, or owns a 8 manufacturing company that could do it, or whether 9 there is some regulatory prohibition that you 10 testified you're not a regulatory attorney about, in 11 the hypothetical where you have the SVS-PR and you 12 make it 41 millimeters long and the surgeon wants to 13 put it in laterally, would he have a reason to put 14 two markers in the middle? 15 MR. AMON: Objection; incomplete 16 hypothetical, vague as to time. 17 I don't know whether I can speak for Α. 18 another surgeon. I will speak for myself, that I 19 wouldn't put that implant in. 20 But hypothetical, if the surgeon is Ο. 21 putting the SVS-PR in laterally and he has one 22 that's 41 millimeters long, does he have a reason to

158 put two markers in the middle? 2 MR. AMON: Same objection. 3 We go back to somebody who qualifies and who is thinking of safety of his patient, he wouldn't 5 want to do one without having the markers in the 6 middle. 7 Ο. Thank you, sir. In the last sentence that 8 goes from paragraph 41 to 42, I'll read it for the 9 "Inside" -- strike that. record. 10 "Indeed, the SVS-PR has a side aperture 11 often referred to as a visualization window in the 12 medial plane of the implant. These windows are 13 generally designed to help a surgeon visualize bone 14 healing/fusion post-operatively so such 15 visualization windows should not be obstructed by a 16 radiopaque marker passing through." 17 Did I read that sentence correctly? 18 That's correct. Α. 19 Sir, do you believe that a metal wire in 20 that window obstructs the ability of a surgeon to visualize the bone healing? 21

My statement here is merely to imply that

- 1 any additional obstruction is not beneficial for
- something that doesn't serve a purpose. So if
- something doesn't serve a purpose, then you have to
- $^4$  make the educated and the appropriate decision. So
- it isn't to say you should not. It's just merely to
- say it is not beneficial to ask something that
- 7 doesn't serve a purpose.
- 8 Q. So you're not saying that a single wire
- 9 across this visualization window obstructs the
- surgeon's ability to visualize the bone healing?
- 11 A. I didn't say is not. I just say that your
- 12 preference would be not to put anything unless is
- really going to serve a purpose.
- 0. Okay. Sir, I'll ask the question this
- $^{15}$  way.
- Does a single wire in that visualization
- window of the SVS-PR obstruct a surgeon's ability to
- visualize bone healing?
- MR. AMON: Objection; asked and
- answered.
- A. Is just better not to put something unless
- it's going to serve a purpose.

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160
               Sir, you have windows in your house?
               I have windows in my mouse.
          Α.
3
               Do any of those windows have dividers in
          Ο.
4
    them?
5
                          MR. AMON: Objection; relevance.
6
          Α.
               It depends on which house.
          Ο.
               Any house.
8
               You asked me if I have a house.
9
          Ο.
               Sir, have you ever seen a window that has
10
    a divider in it?
11
          Α.
               Yes.
12
               Can you still see out that window?
          0.
13
               But it does obstruct the view.
          Α.
14
          0.
               To the width of the divider?
15
               It just obstructs the view.
16
               But you can still see out the window?
          Q.
17
                          MR. AMON: Objection;
18
                    argumentative.
19
               If it serves a purpose there, then I see
20
    that it makes sense. If it doesn't serve the purpose
21
    to have something that obstructs the view, doesn't
22
    benefit.
```

161 Can you see out a window that has a Ο. 2 divider? 3 MR. AMON: Objection; asked and 4 answered, argumentative. 5 As I've stated, Counsel, it just obstructs the view. If it's not necessary I wouldn't put it 7 in. 8 Is the middle marker unnecessary? 9 MR. AMON: Objection; incomplete 10 hypothetical. 11 Can you qualify that? 12 Are the markers in the center of the 13 implant that's claimed in the '156 patent 14 unnecessary? 15 The '156 patent, the claims are having the 16 middle marker is there to serve a purpose. And the 17 purpose is to allow you to align the implant and to 18 let you know that you are not in any way going to 19 have any potential obliquity and perhaps could cause 20 harm to the patient. So those markers are put there 21 with the defined reason as I said, it has a strategic 22 indication, so they are necessary.

	162
1	MR. AMON: Mr. Schwartz, is this
2	a good time to take a break?
3	MR. SCHWARTZ: Sure. This lunch
4	break?
5	MR. AMON: Yeah.
6	MR. SCHWARTZ: How much time do
7	you think you need? Off the record.
8	(Discussion off the record.)
9	(Proceedings adjourned for luncheon
10	recess at 1:44 p.m)
11	
12	(Change of reporters occured after recess
13	from MARITA PETRERA to PAMELA PALOMEQUE.)
14	
15	
16	
17	
18	
19	
20	
21	
22	

163 EXAMINATION BY MR. SCHWARTZ: 2 Okay, sir, we're back on the record and we O. 3 are going to continue on in your expert report to 4 facilitate some of this discussion. Since we're 5 getting into a new prior art reference, I'm going to 6 hand it to you and it's already been marked. 7 MSD 1005, which for the record is the Michelson 8 patent 5,860,973 also referenced as Michelson '973. 9 I take it, sir, that is the Michelson '973 10 that you opined on in your Declaration at paragraph 11 90 and thereafter? That would be page 45 of --12 Thank you. Make it easy for me. Α. 13 -- Exhibit 2020 in the 506 matter. Ο. I'm 14 just asking if that is the Michelson '973? 15 Α. I'm sorry, yes. Yes, it is, sir. I'm 16 sorry. 17 No problem, sir. So if you would, sir, Ο. 18 look at page 46, the last part of paragraph 90. 19 I'll read that last sentence for the record: "Based 20 upon my knowledge and experience in spine surgery 21 (including my personal experience using lumbar

implants and thoracic implants), I believe that a

164 person of ordinary skill in the art in March 2004 2 (and even today) would recognize that Michelson 3 proposes implants in which the width (or diameter in the case of the dowel designs) is quite large even 5 compared to the largest dimension (the length), 6 thereby providing an implant that is both long and 7 wide to fulfill Dr. Michelson's intended purpose of 8 an oversized spinal implant." 9 Did I read that correctly, sir? 10 Α. Yes, sir. 11 Sir, what I'm wondering is for purposes of 12 your opinion, about the width of Dr. Michelson's 13 implant, whether or not you took into consideration 14 the narrow embodiment that is taught in the '973 15 patent? 16 Α. Can you clarify that for me? 17 I'll say it again, sir. If you look in Ο. 18 the '973 patent -- we can take it in order -- figure 19 19 or figure 18 -- and I'm just making a passing 20 reference just to this, and then figure 19 which is 21 at the bottom of that page and shows three modular 22 implants in the intervertebral space.

Q. And then turn to column 10, beginning at
line 48 which refers to those figures I just pointed
you to. So I am referring to the discussion from

Yes, sir.

Α.

- 5 line 48 to about line 59 where it's discussing that
- 6 alternative embodiment that has a narrower width
- y such that more than one spinal fusion implant 1000
- 8 may be combined in a modular fashion for insertion
- 9 within the disk space.
- Do you see that discussion, sir?
- 11 A. Yes. I'm just reading that right now, sir.
- Q. Okay. I'll let you read that and you let
- me know when you're ready to -- for a question.
- A. (Witness complies.) Yes, sir.
- Q. Okay, sir. So that conclusion that you
- 16 made at the end of paragraph 90 where you're talking
- $^{17}$  about the width that Dr. Michelson proposes as being
- 18 quite large, did you take into consideration the
- 19 narrow embodiment that I just pointed you to?
- 20 A. I take -- I understand what
- 21 Dr. Michelson -- and correctly what he's trying to do
- is to gain as wide a weight-bearing surface as he

- can, so I'm looking at these, as he says modular,
- they're modular meaning that they're individual
- pieces that you add on to gain the full width of what
- 4 he will like to get.
- 5 Q. But he does disclose a narrower width for
- 6 a spinal fusion implant, correct?
- 7 A. He does disclose a modular unit that he --
- 8 that he so calls stacks together to make it -- to
- 9 achieve what he has purported to be a -- his goal is
- 10 to make it a wide implant. That's what he wanted to
- do so that's what he purported, so the individual
- ones, that he adds them together to make sure they
- are an oversized spinal implant for translateral
- 14 insertion.
- Q. Well, he does say may be combined,
- 16 correct?
- 17 A. In his abstract what he says: "Oversized
- 18 spinal implant for translateral insertion into the
- 19 disk space between two vertebrae, a length that is
- 20 greater than one-half of the transverse width of the
- vertebrae and is greater than the depth of the
- vertebrae. The translateral implant of the present

167 invention has the height that's greater," et cetera. 2 So his goal is to make sure that he 3 has a broad surface as he emphasized in his abstract. 4 But he does say may be combined, correct, 5 sir? 6 Α. He does say that. 7 Ο. So he doesn't say must be combined, 8 correct? Α. Correct. 10 Q. He doesn't say shall be combined, correct? 11 MR. AMON: Objection; document 12 speaks for itself. 13 That's correct. Α. 14 And figure 18 is certainly a narrow 15 embodiment of his translateral implant, correct? 16 MR. AMON: Objection; assumes 17 facts not in evidence. Go ahead. 18 As you showed me the figure 18 and the 16, 19 17 and 19, it shows the way that he actually implants 20 it showing the AP and lateral -- I should say the AP 21 and the oblique view to get a better look, so he 22 stacks this so you will have it with a triple width

168 and we don't have any defined numbers on these here, 2 on this page. 3 But the figure 18 implant that is depicted on sheet 7 of 8 is a narrow width translateral 5 implant, correct? 6 MR. AMON: Objection; vague as to 7 "narrow". 8 From what I read, he is -- he's describing 9 one part of his complete implant that he wanted. 10 Q. So that one part is a narrow width 11 implant, correct? 12 But it is used as a total, that's what his Α. 13 intentions are. 14 But it may be used; we've gone through 15 that? 16 MR. AMON: Counsel, if you could 17 let Dr. Yuan finish his answer, 18 please. 19 Were you done with your answer, sir? 20 He actually states, counsel, in the 21 preferred embodiment: The spinal fusion implant has

a height of 8 and 16 with a preferred height being,

```
169
    et cetera; a width in the range of 24 to 32
2
    millimeters with a preferred width being 26
3
    millimeter. I apologize.
4
               If you have a patient emergency, sir, we
5
    can certainly break.
6
         Α.
               That's okay.
                         MR. AMON: This is actually maybe
8
                    more important.
9
                         THE WITNESS:
                                        She got to figure
10
                    this out without asking me. I'm
11
                    sorry, I shut it off.
12
                         MR. SCHWARTZ: No problem.
13
                         THE WITNESS: My apologies.
14
    EXAMINATION BY MR. SCHWARTZ:
15
         Q.
               Were you done with your answer, sir?
16
         Α.
               Yes.
17
               Okay, sir. You just talked about the
18
    preferred embodiment. What I'm asking you about is
19
    the alternative embodiment, not the preferred
20
    embodiment, and I'm just trying to confirm that
21
    figure 18 is an embodiment of a narrow width
22
    implant?
```

170 Α. That's correct. 2 Okay. Thank you, sir. Sir, do you O. 3 understand the concept of incorporation by reference 4 in a patent? That's why I asked the question, sir. 5 Α. I don't mean to smile but I'm not an 6 attorney. I didn't go to law school but would you 7 clarify what you would like me to answer to a simple 8 surgeon? 9 Q. Sure, sir. Maybe we'll back up a little 10 bit. For purposes of the opinion that you rendered, 11 did you consider -- before I talk about what it 12 is -- whether or not there was additional 13 information incorporated into the '973 patent by 14 reference? 15 MR. AMON: Objection; vague. 16 I'm just getting at the basis for your O. 17 opinion now, sir. 18 I know you're going to the basis but the 19 language is what I'm trying to -- I'm trying to 20 understand. 21 Let me phrase it a different way then, Ο.

sir.

- Α. Please.
- 2 When you developed and provided your Ο.
- 3 opinion -- I'm not asking who wrote it -- with
- regard to the '973 patent, did you read any other
- 5 document besides the '973 patent itself?
- 6 I looked at the -- I looked at the other Α.
- 7 patents.
- 8 Ο. Which other patents?
- 9 Which is the Telamon, which is SVS-PR, and Α.
- 10 looked at Baccelli, and also looked at the Frey.
- 11 But you didn't look at any other Michelson Ο.
- 12 patents?
- 13 No, I did not. Α.
- 14 Okay. Fair enough. Q.
- 15 Thank you for making it simple. Α.
- 16 Are you familiar with Dr. Zdeblick, sir? O.
- 17 Yes, I am. Α.
- 18 Are you aware of whether or not he 0.
- 19 implanted a Michelson '973 -- let me strike that.
- 20 In your sentence at the end of paragraph
- 21 92, you say: "However, it is my understanding that
- 22 the implants illustrated in Michelson '973 have

	172
1	never been commercialized and have never been
2	inserted in a live human patient."
3	A. That's as best as I know, yes, sir.
4	Q. Are you familiar with Dr. Zdeblick's work
5	in implanting large threaded fusion cages?
6	A. I know I know Dr. Zdeblick. I'm not
7	I don't have any information what he's implanted.
8	Q. Okay. So you don't know one way or the
9	other what Dr. Zdeblick has done as far as lateral
10	implantations?
11	A. That would be accurate.
12	Q. Are you familiar with the Medtronic
13	Butterfly implant?
14	A. There are so many names. If you show it to
15	me, I would be able to try to answer your questions.
16	Q. I will do that.
17	MR. SCHWARTZ: This will be MSD
18	1021.
19	(MSD Exhibit 1021, Medronic
20	Sofamor Danek Butterfly Fusion System
21	Surgical Technique brochure, marked
22	for identification, this date.)

- Q. Okay, sir, for the record I have handed
- you a document marked MSD 1021 which I will
- 3 represent for the record is a brochure describing
- 4 the Medtronic Sofamor Danek Butterfly fusion system.
- 5 Have you ever seen that document before, sir -- I'm
- 6 sorry, have you ever seen any information about the
- Butterfly fusion system before?
- 8 A. No, I've not.
- 9 Q. Okay. So fair to say when you opined that
- the Michelson '973 had never been commercialized,
- 11 you certainly didn't consider the Butterfly which
- you've now indicated you've never seen before?
- 13 A. That's correct.
- Q. Okay. If I were to represent to you that
- that product was commercialized, would that change
- 16 your opinion?
- MR. AMON: Objection; assumes
- facts not in evidence.
- 19 A. I'm looking at the Butterfly. Dr. Zdeblick
- designed a Z plate, which is a lateral lumbar
- 21 anterior fixation plate, and actually when he
- designed a Z plate, he was taking the concept from

- one of my ideas of using two screws at each vertebral
- level. So he, again, was a fellow of Dr. McAfee, so
- 3 that's how the family tree goes.
- 4 Q. Okay.
- 5 A. So I have not seen him using the Michelson
- 6 component into a disk space, so when you ask me about
- <sup>7</sup> the Butterfly, I know about a Z plate but I've not
- 8 seen him using this cage in the vertebral space.
- 9 Q. I understand, sir. All I was asking was
- does that change your conclusion that the Michelson
- 1973 has never been commercialized?
- MR. AMON: Objection; assumes
- facts not in evidence.
- 14 A. This cage that is put in here was not
- intended to be just a cage.
- 16 Q. Okay, sir.
- 17 A. Okay. So my comment was not a stand-alone
- 18 cage. I haven't seen this either but -- I haven't
- seen either one but here looking at what you just
- showed me, this is really meant to give you better
- 21 fixation of the segment, so what he has is something
- that he can put in and then attach to a fixator

175 device laterally. So this is new to me. 2 Fair enough. So it wasn't considered as O. 3 far as your opinion was presented? 4 Α. That's correct. 5 Sir, I'd like to turn back to the OLIF O. 6 Procedure Manual for a moment. It's in your stack 7 here, marked as MSD 1020. And what I'm specifically 8 curious to get your opinion on, sir, if you turn to 9 figure 4 which is on page number 2 -- well, on the 10 upper left-hand column it's identified as page 11 number 2. It's actually the fourth page of the 12 document. You see figure 4 on the bottom there? 13 Α. Yes. 14 There's that triangle that's identified as Q. 15 the OLIF 25 trajectory? 16 Yes. Α. 17 So that's apparently at least one space O. 18 where Dr. Hynes suggests approaching the vertebral 19 space from the anterior or oblique into the 20 vertebral interdiskal space? 21 MR. AMON: Objection; the 22 document speaks for itself,

176 1 speculation. 2 Α. I've seen this approach, as we talked about 3 before. The soft tissue approach is using that space, but once you get to the dock on that space, 5 then all the implants that you're putting in, you're literally moving implant posteriorly. So also you 7 have commented on this in the past. This is really 8 attempting to go in at a retracted psoas, so the 9 ultimate implant is implanted totally translateral. 10 So the approach in the drawing is telling you that's 11 where you first dock. 12 So is it your understanding that it is 13 safe to approach following that triangle? 14 MR. AMON: Objection; incomplete 15 hypothetical. 16 MR. SCHWARTZ: It's not a 17 hypothetical at all. 18 MR. AMON: It is but --19 This is an approach that is proposed by 20 Dr. MacMillan, I know very well, and Dr. MacMillan at 21 the University of Florida, okay, is one who is a very 22 close friend and also a fellow of mine, so I know his

- 1 approach well. It's an approach that a proposed --
- but this is not too different -- this is not too
- different than what we used to do as an open, of
- 4 going down and then retracting the psoas, but if the
- 5 psoas is very, very big, then in this approach you
- 6 actually cannot see the nerves so that's the reason
- yellow why it just did not become very popular approach for
- 8 surgeon training.
- 9 So it's an approach that you can
- approach the spine but once you do approach the spine
- 11 at the L4-5, there is still other challenges.
- Q. But you can approach the spine in that
- direction following that triangle?
- 14 A. You can approach the spine.
- Q. Thank you, sir. Sir, if you would turn to
- paragraph 106.
- 17 A. Of which document?
- 18 O. I'm sorry, the same Declaration that we've
- been going through, deposition of -- I'm sorry,
- 20 Declaration of Hansen A. Yuan, Exhibit 2020, case
- <sup>21</sup> IPR2013-506?
- In fact let's just go back but we'll stay

- <sup>1</sup> in that document.
- <sup>2</sup> A. Yes, sir.
- O. In fact let's move on to a new document.
- 4 Have I already handed you your Declaration from the
- 5 507 matter?
- 6 A. Yes, I have that.
- Q. Okay. Let's go to that. We're moving
- 8 right along.
- 9 A. That's good.
- Q. Only two more Declarations to go. Let me
- 11 ask you this question so that we avoid duplicating
- 12 effort. For those opinions that you state the same,
- 13 from one Declaration to another, and there are a
- 14 number of them, I'm trying to avoid asking the same
- questions over and over for the exact same
- sentences. Is it fair to say that the answers
- you've given me this morning and this afternoon as
- they relate to the same statements, the answers are
- 19 the same?
- A. The only difference would be they're
- referring to a different so-called set of claims.
- Q. Fair enough. But if the question didn't

179 have a predicate of having to do with a specific 2 claim, the answer is the same, so I don't have to keep asking the same sentence from one Declaration to another? I'm just trying to save time. 5 I understand what you're trying to do and 6 so am I, but I just don't want to miss something 7 because then what my testimony would not be accurate. 8 I understand that, sir. 9 So that's all I want to suggest. 10 Q. Okay. I guess we'll take it in turn as 11 the clock allows. Let's move, if you would, to 12 paragraph 52 in Exhibit 2020 of the case number 507, 13 that last sentence that spills over from page 25 to 14 26. 15 MR. AMON: Sorry, Doctor, you're 16 on page 25, page 52? 17 MR. SCHWARTZ: I'm sorry, yes, 18 page 25, paragraph 52. 19 That last sentence that spills over from 20 25 to 26, where you talk about the forces exerted on 21 the implants, aren't the forces on the implant

identical once it's inserted regardless of the

180 approach? 2 Α. Counselor, actually the answer is no. 3 Ο. Okay. 4 What I would try to clarify a little bit 5 would be if you did an anterior implant, you would 6 cover a much broader surface area and the forces that 7 exerted are -- because you would actually put in a 8 device that's really larger because it can distract, 9 put it in, and let it impact. Now the forces loaded 10 on that implant is going to be less because some of 11 the forces are pushed posteriorly. 12 I'm sorry, are you talking about a 13 different implant because of the approach? 14 Α. No, from a different approach you will put 15 in different implants. 16 Okay. My question -- maybe I wasn't clear 17 then, sir. What I'm asking then for the exact same 18 implant, once it's in the intervertebral space it's 19 experiencing the same loads regardless of how it got 20 there? 21 MR. AMON: Objection; incomplete 22 hypothetical, assumes facts not in

- evidence.
- A. Again, actually the answer is no. Let's
- 3 take an implant that we put in, say, from
- 4 posteriorly. You put in a posterior implant, a PLIF
- 5 implant. Once you put that implant in -- because a
- 6 PLIF implant that you put in -- now you're talking
- about the same implant, all right? That implant that
- you're putting in has a lordosis that's in the front.
- 9 So the load that's on that implant is
- transferred posteriorly, appropriately, but when you
- 11 take that same implant and you put it in laterally,
- 12 the load that's on the implant is no longer
- transferred posteriorly. The load is being
- transferred laterally because the front end of the
- implant is bigger.
- Q. Is that because you're now putting it in a
- different orientation?
- 18 A. Correct, from a different approach but the
- 19 same implant.
- Q. If you put in the same implant so that it
- results in the same orientation in the disk space
- regardless of how it got there, aren't the loads the

182 same? 2 MR. AMON: Incomplete 3 hypothetical. 4 Just a little bit more clarification. 5 give me an example of which implant so we will be 6 exact. 7 Ο. Sure. Let's start with the BAK. You have 8 a lot of experience with that and you can put that 9 implant in from the posterior side or you can put 10 that implant in from the anterior side, correct, the 11 same implant? 12 Α. Okay. 13 So now you put it in posteriorly and you Ο. 14 place it in the disk space. You put it in 15 anteriorly. You place it in the exact same space in 16 the disk space. Doesn't it have the same loads 17 working on it once it's in the space? 18 Again, to qualify that, because you put it Α. 19 in posteriorly, you are not going to distract the 20 space when you're putting it in because you can only 21 put in a smaller implant. 22 So take the same small implant. You

183 put it from anteriorly. You have to drill the 2 cortical rim from the front and also you have to take 3 away some of the anterior longitudinal ligament. have to cut the anterior longitudinal ligament. When 5 you put that cage in, now when you do it from the front, you are going to be able to distract the space 7 more because the anterior longitudinal ligament is 8 partially cut, so now the load that is in there 9 actually is not the same. 10 And how much would you distract putting it 11 in from the front? 12 From the anterior portion? You would 13 distract so that you can literally almost correct the 14 lumbar lordosis, but if you're going to put a cage in 15 from the back, you would rely on the implant to do 16 the distraction for you. 17 Okay. And do you have an estimate of how Ο. 18 much in millimeters, for example, you would 19 distract --MR. AMON: Objection; spec --20 21 Q. -- or a range? 22 MR. AMON: Objection;

184 speculation. 2 It depends here, and I'm not trying to take Α. 3 I'm trying to get there. a long road. If you have a tall disk, then you're not going to distract very 5 much at all but you can't put too big of an implant in anymore. So if it's a collapsed disk, then you can distract almost a couple millimeters. 8 Ο. So --9 So it really varies with other variable, 10 counselor. That's the reason why I'm taking this 11 long route to get there. 12 So a couple of millimeters it could be 13 distracted? 14 It could be. Α. 10 millimeters unusual? 15 Q. 16 10 millimeters for --17 10 millimeters to distract unheard of? Ο. 18 To distract 10 millimeters? Α. 19 Mm-hmm. Ο. 20 You can't distract 10 millimeters. 21 You can't distract 10 millimeters with a Q. 22 collapsed disk?

185 Α. No. 2 Why not? 0. 3 You can distract 10 millimeters if you're going to take out the whole disk space, like with an 5 anterior cage but not with a BAK. 6 Q. Okay. So you can distract 10 millimeters 7 in that circumstance? 8 MR. AMON: Objection; 9 mischaracterizes his testimony, 10 misleading. Go ahead. 11 Α. We are speaking about a BAK cage. 12 0. Okay. 13 How much allowed to distract, so that I've Α. 14 answered you, but to distract -- if you remove the 15 whole anterior longitudinal ligament, you asked me 16 whether you can distract 10. 17 Mm-hmm. Ο. 18 If you remove the whole anterior 19 longitudinal ligament, you can distract more but I 20 wouldn't say 10. I will say you can certainly 21 distract more depending on the amount of bone spurs

and the age of the -- or the amount of eburnation and

186 .t

- degeneration at that level. The more degenerated it
- is, the harder to distract. So when you use the word
- 3 10, that's very difficult to attain.
- 4 Q. What about 5, 5 millimeters of
- <sup>5</sup> distraction?
- MR. AMON: Objection; incomplete
- 7 hypothetical.
- A. Again, depends on the -- here now, it
- 9 depends a little more on the degeneration and the
- bone quality because if the bone quality is bad, then
- anything you put in to spread will just collapse the
- bone so you don't want to do that. So it depends on
- other variables. Can you distract up to 5 in a
- patient with good bone from a degenerated disk, the
- answer is yes, you can.
- 16 Q. Okay. Thank you, sir. Sir, moving
- quickly, paragraph 95 of that same document, which
- is NuVasive 2020 in the 507 case, you say that --
- are you at 95, sir?
- A. Yes, I'm there, sir.
- Q. That sentence you say: "Also the implants
- of Michelson '973 are made of titanium", correct?

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	187
1	A. Yes.
2	Q. Isn't it correct that titanium is just an
3	example in the Michelson disclosure as opposed to
4	the only material that that implant can be made of?
5	A. Can you show me where he describes other
6	Q. I don't know if you have the '973. Do you
7	have it sitting in your stack, sir?
8	MR. AMON: You should.
9	Q. It should be somewhere over here.
10	A. It should be one of these.
11	Q. There it is at the bottom of the stack.
12	A. But it's here.
13	Q. Um?
14	A. I said but it's here.
15	Q. For the record, again that's MSD 1005.
16	So, for example, if you look at column 6, around
17	line 36, I'll read the sentence. Are you with me,
18	sir, so far?
19	A. I'm there.
20	Q. "The translateral implants of the present
21	invention may be made of an artificial material."
22	Correct? I read that correct?

```
188
1
               Go back to the line one more time, please?
          Α.
2
    Which line?
                  20 --
3
               I'm sorry, it's line 36.
          0.
          Α.
               Line 36.
5
          O.
               Are you there now?
6
          Α.
               Yes, I'm there.
7
          Ο.
               "The translateral implants of the present
8
    invention may be made of an artificial material,"
9
    correct?
10
          Α.
               Correct.
11
               And then in column 7, line 39, it says:
12
    "The spinal fusion implant 199 can be made of any
13
    material suitable for human implantation, may
14
    comprise fusion-promoting and/or bioactive material
    to actively participate in the spinal fusion
15
16
    process."
17
               Did I read that correctly?
18
          Α.
               That's correct.
19
               So at least there it says "any material
          Q.
20
    suitable for human implantation", correct?
21
          Α.
               Yes.
22
               And then that last sentence of that
          Ο.
```

- 1 paragraph starting at around line 42: "The implant
- 2 199 can be made of a porous and/or mesh like and/or
- 3 cancellous material or any other material suitable
- 4 for the described purpose."
- Did I read that correctly, sir?
- 6 A. That is correct.
- Q. So is it fair to say that titanium is just
- 8 one example of a material that the Michelson '973
- 9 implant can be made of?
- 10 A. The '973 at that time -- you're a patent
- 11 attorney, so this is patent, but at that time, all we
- had was titanium. So he does say of any other
- 13 material. Bone is; we have used bone. So in this
- particular case here, he's covering the spectrum but
- we've never seen a -- I've not seen -- better to
- qualify, not anybody. I have not seen a Michelson
- implant made of any other material than metal.
- Q. But his description doesn't limit it to
- 19 titanium, correct?
- A. His description here made of a porous, that
- 21 would be -- for it to have the strength would be a
- porous titanium or tantalum. It will be a metal, and

- mesh like again would be titanium at that time, like
- the Harms cage, and cancellous material, that would
- 3 be the so-called window material like the Harms on
- 4 the vertical, and then he does say "any other
- 5 material suitable for the described." So it's really
- $^{6}$   $\,$  more of a metallic material at that time. That's
- 7 what I understand that to mean.
- 8 O. It's not limited to titanium, correct?
- 9 A. Correct.
- Q. And it's not necessarily limited to metal,
- 11 correct?
- 12 A. These words and these sentences from one is
- in the field at that particular time, that's all we
- 14 had.
- Q. Well, at that time you had bone, correct?
- A. We had bone. We had bone before that.
- 0. And bone is cancellous, correct?
- 18 A. No. The bone that we use for cages are all
- 19 cortical. You can't use cancellous. I don't mean to
- 20 correct you but --
- Q. No, no, you're the one testifying, sir.
- Porous materials could certainly include things

191 other than metal, couldn't they, sir? 2 Which ones? Α. 3 Ο. Porous? Α. Ask me that one more time. 5 O. Porous materials could include things 6 other than metals, correct, sir? 7 Give me an example. Α. 8 Ο. Coral? Coral. You wouldn't use a coral implant. Α. 10 Are you saying that -- I'm sorry. Ο. 11 We can go there but a coral implant will 12 just crumble. It just would not be able to take the 13 shear load in the lumbar spine at all. Coral can be 14 used as a graft. 15 Are you unaware of the use of coral 16 implants as intervertebral implants? 17 In 2010, yes. In 2004, no. This one here Α. 18 is in 1996. The answer is no. 19 Okay. What about bovine bone? Q. 20 Bovine bone is readily available and is Α. 21 very strong but the American experience with bovine

bone has been extremely, extremely negative because

192 the bovine bone does just not incorporate and it 2 basically stays as a dead piece and eventually 3 becomes free-floating. So bovine graft is not something that became accepted at all. 5 But it was used? Q. 6 Long before even the -- long before when we 7 even be making implants out of our own allograft 8 bone. 9 Ο. Okay. Okay. So let's move forward about 10 where you're discussing in the same opinion, your 11 Declaration, the Frey publication which starts on 12 page 50, although I want to get to the discussion on 13 page 51. 14 Yes, sir. Α. 15 I know you're going to ask for it so I'll 16 get it. 17 Α. Thank you. 18 I'm handing you what has been previously identified as MSD 1003. 19 20 (Document handed.) 21 MR. NELSON: I'm good with the 22 old ones. It's the new ones I like.

```
193
               Which is the -- just for the record, sir,
          Q.
2
    that MSD 1003 is the Frey publication that you're
3
    opining about?
 4
          Α.
               Yes, sir.
5
          Ο.
               Sir, you mention at the bottom of page 51,
6
    there is no dispute -- I'll wait until you get
7
    there.
8
          Α.
               Okay.
9
          Q.
               "There's no dispute whether Frey briefly
10
    mentions alternative options in which Boomerang
11
    implant can be inserted laterally or anteriorly."
12
    read that correctly, right, sir?
13
          Α.
               Yes, sir.
14
               In fact Frey mentions it at least three
          Q.
15
    times, right?
16
          Α.
               I don't know how many times he mention but
17
    I have it down here he has mentioned it.
18
               That sound about right?
          Ο.
19
               I don't know. Unless you can show me all
          Α.
20
    three.
21
               Sure. Let's go through them then. If you
          Ο.
22
    look on page 11.
```

```
194
         Α.
               Of the patent?
2
               Of the patent?
          O.
3
          Α.
               This is really a patent application
    publication.
5
          O.
               Correct, Frey 550.
6
          Α.
               Page 11?
7
          O.
               Page 11 on the top of it, page 61 on the
8
    bottom.
              The 61 includes the figures.
9
          Α.
               Sorry.
10
          Q.
               So if you --
11
                         MR. AMON: So if you look at the
12
                    bottom, it's that page.
13
                          THE WITNESS: I'm sorry.
14
                         MR. AMON: No problem, take your
15
                    time.
16
          Α.
               I'm on page 61.
17
               On the first sentence, I'll read it:
          O.
18
    "It's also contemplated that disk space D1 can be
19
    accessed and prepared for implant insertion using
20
    any other known techniques and instruments and other
21
    approaches to the disk space such as lateral,
22
    anterior, or anterolateral approaches for inserting
```

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```
195
    implant 1000."
2
               Yes, sir.
         Α.
3
               Right. So at least there he's talking
    about the possibility of putting in this implant
5
    laterally, anteriorly, or anterolateral, correct?
6
                         MR. AMON: Objection; the
7
                    document speaks for itself.
               Yes, it does read that.
8
9
          Ο.
               And then if you turn to the next page, in
10
    paragraph 150 at the bottom --
11
                         MR. AMON: For the record, that's
12
                    page 62 you're referring to.
13
                         MR. SCHWARTZ: 62 on the bottom,
14
                    12 on the top.
15
                         MR. AMON: What paragraph again,
16
                    thank you.
17
               Paragraph 150, sir, do you see that?
         0.
18
         Α.
               Yes.
19
               The last sentence of that paragraph, it
20
    says: "It is also contemplated that the disk space
21
    D1 can be accessed and prepared for implant
22
    insertion using any other known techniques and
```

```
196
    instruments and other approaches to the disk space
2
    such as lateral, anterior, or anterolateral
3
    approaches for insertion of implant 1400."
4
               Did I read that correctly, sir?
5
         Α.
               That's correct.
6
         Ο.
               So that's two times, right?
7
               Two times.
         Α.
               Then if you turn to page 16 on the top, 66
8
         Ο.
9
    on the bottom --
10
               I'm there.
         Α.
11
         O.
               -- paragraph 184.
12
         Α.
               Okay.
13
         Ο.
               The second sentence: "However, there are
14
    aspects of the inventions described herein that may
15
    be utilized or modified for use for a variety of
16
    surgical applications, including but not limited to
17
    spinal surgery for a -- from a unilateral posterior
18
    approach, a lateral approach, an oblique approach,
19
    and through laparoscopic or endoscopic instruments
20
    from any of a variety of angles or approaches to the
21
    spine."
22
               Did I read that correctly?
```

197 Α. Yes. 2 So at least three times he talks about the O. 3 possibility of putting it in laterally or anteriorly, right? 5 Α. Right. 6 Ο. Okay, sir, looking at the last sentence of 7 that paragraph in your report -- I'm sorry, not in 8 the patent. 9 MR. AMON: Which paragraph? 10 MR. SCHWARTZ: It's still 11 paragraph 96 but on page 52. 12 Where you say: "Based upon my knowledge Ο. 13 and experience in spine surgery, including my 14 personal experience using Boomerang-shaped implants, 15 I believe that a person of ordinary skill in the art 16 in March 2004 would have recognized that any 17 proposed modification to Frey's Boomerang implant, 18 hindering its use in the posterolateral TLIF 19 approach, was contrary to Frey's stated objectives 20 and intended purpose for the Boomerang." 21 Did I read that correctly, sir? 22 Α. Yes.

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- Q. But he does state at least three times the
- <sup>2</sup> purpose of putting it in laterally or anteriorly,
- 3 correct?
- 4 MR. AMON: Objection; asked and
- 5 answered.
- 6 A. We see the Declaration and we also see the
- brochures for the Frey implant was the Boomerang
- 8 implant. Those are all described as a device for the
- 9 posterolateral disk space approach, so those are the
- $^{10}$  approaches I've seen and those are the approaches --
- 11 because of his invention and because of his
- Declaration, that's the approach of the device are
- 13 available and that's how we used them and incised
- 14 them.
- Q. In your opinion, sir, are you narrowing
- the scope of what's taught in the Frey application
- based on the procedure manual that you looked at for
- the Boomerang implant?
- A. No, I'm not narrowing. I read and I know
- that they describe all these approaches but there was
- 21 no implant available for us to be using.
- Q. As far as you know?

- A. As far as I know, yes, correct.
- Q. If there was an implant made that was more
- 3 than 40 millimeters long, would that change your
- 4 conclusion?
- 5 MR. AMON: Objection; assumes
- facts not in evidence, incomplete
- 7 hypothetical.
- A. To follow your question, to assume is more
- 9 than 40 millimeters in length, from which approach
- would you be putting it in?
- 11 Q. Laterally or anteriorly or obliquely.
- 12 A. If it's more than 40 millimeter long, then
- the width of this implant would be also a lot wider,
- so that implant would be extremely difficult to do it
- 15 through the approach that we talked about
- posterolaterally because the space, the dimension
- that is there, requires that you need to remove more
- bone and then you also have to key it into a space
- where the nerve has to be retracted. So if it's
- longer and it becomes wider, that approach certainly
- would be not a feasible approach.
- O. Not feasible to put in a concavoconvex

- implant that's longer than 40 millimeters?
- A. A Boomerang implant by Frey, of his design,
- that's what you're describing to me, so I'm following
- $^4$  that train of thought.
- Q. Okay.
- 6 A. So a Boomerang longer and Boomerang wider,
- okay, to put in through a posterolateral approach
- 8 certainly would be not optimum at all because of the
- 9 sides would be compromised because of retraction of
- 10 nerves that are necessary.
- 11 So the TLIF actually has made a space
- 12 bigger than you do a PLIF. A PLIF would be narrower.
- 13 A TLIF gives you a little more room but the room it
- gives you certainly is not extra, extra wide that you
- can go bigger than what the dimension of the
- 16 Boomerang was designed for.
- The second thing is that if you're
- going to make an implant that is going to be a longer
- and therefore wider, according to what we see as his
- claims are, then we are going to have trouble putting
- that in from a lateral approach also because the
- width is going to be wider to get to the certain

	201
1	length.
2	Q. What are you referring to
3	A. Finally
4	Q. I'm sorry, sir.
5	A. And finally, going to the anterior
6	approach, you wouldn't want to be putting in an
7	implant that has a that you can put in a bigger
8	implant of a surface area because you're removing the
9	anterior longitudinal ligament. So to put in that
10	implant either at 40 or under 40 or whatever the size
11	it is, but to go over 40, to seat it on the rim
12	certainly would not be optimum because the chance of
13	it dislodging.
14	And so to put it into the disk, you
15	will like to have more coverage and that implant does
16	not have the full coverage. That implant is designed
17	to leave the anterior longitudinal ligament intact,
18	to allow you to have the stability that it is
19	designed for.
20	So there are other parameters. So
21	even though this description that you can use these
22	various approaches, the implant design would have to

202 be further modified to accommodate. 2 Further modified in what way? O. 3 MR. AMON: Objection; calls for speculation. Go ahead. 5 MR. SCHWARTZ: He's the one that 6 opened the door. 7 Do you have an hour for me to go through 8 one by one? I can. 9 Do you have an hour, sir? 10 Okay. If you have that implant and you Α. 11 want to design it for the lateral approach, you have 12 to modify it both in length and also modify it in 13 width. You do not want the Boomerang because a 14 Boomerang will sit on the rim, if it's going to sit on the rim. 15 16 Otherwise, if you're going to put it 17 in across a lateral approach, you're not going to 18 allow you to be able to be the weight-bearing at the 19 width of the Boomerang as we see it. The length and 20 the width, the ratio will become an issue. 21 To do it from the front is just not 22 the optimal implant and to do it through a TLIF, as I

```
203
    said, it's something of the size that we have now are
2
    made to fit and the approach and is safe. To make it
3
    longer and, therefore, any way wider at all, the
    length and the width would be a challenge to be able
5
    to put into the space and to rotate.
6
          Q.
               But you certainly can --
7
         Α.
               Cannot.
8
                         MR. AMON: Dr. Yuan, let
9
                    Mr. Schwartz ask his question, please.
10
               You can certainly make a Frey implant
11
    that's over 40 millimeters long and fit it in the
12
    interdiskal space; correct?
13
                         MR. AMON: Objection, incomplete
14
                    hypothetical. Go ahead.
15
               For which approach?
16
         Q.
               Any approach?
17
               (Shakes head). I disagree.
         Α.
18
               So under no condition can you put a
19
    Boomerang-shaped implant into a disk space that's
20
    over 40 millimeters long?
21
                         MR. AMON: Objection, asked and
22
                    answered.
```

204 Let me go specifically, as you do, one step 2 at a time, I perceive your question. To do a TLIF 3 approach, to build a Boomerang implant that's going to be longer than 40 millimeter in length, okay, and the width to accommodate that would be an implant 5 that's going to be potentially risk to the nerve and 7 also cause the inability to be implanted and to 8 rotate. 9 But it can be done? 10 I'm a surgeon. I'm just trying to tell you 11 that it is not an implant that you will want to do it 12 because it will do harm to a patient. So if you are 13 asking me can it be done? The answer is I wouldn't 14 do it. 15 Q. Okay. 16 MR. AMON: Dr. Yuan, are you 17 doing okay? 18 THE WITNESS: I'm okay. 19 MR. SCHWARTZ: Let's mark this as 20 MSD 1031. 21 (MSD Exhibit 1031, European 22 Patent number EP 1 290 985 A2, marked

205 1 for identification, this date.) 2 EXAMINATION BY MR. SCHWARTZ: 3 So what I've handed you, for the record, Ο. 4 is a document identified as MSD 1031. It's a European patent application 1 290 985 A2. Did I 5 6 read that correctly, sir? 7 Α. Yes. 8 Ο. I wouldn't expect that you're necessarily 9 familiar with this document but what I'd like to 10 point you to is the last page, figure 19. You see 11 that Boomerang-shaped implant, sir? 12 Yes, I do. Α. 13 And that implant is pretty much going from 14 one end to the other of that vertebral body, 15 correct? 16 MR. AMON: Objection; the 17 document shows what it shows. 18 We're looking at a banana-shaped implant. 19 I wouldn't call it Boomerang. Boomerang would bring 20 it back to what you're talking about. This is a 21 banana-shaped implant. That is not the Boomerang 22 implant that we're referring to in Frey. Do you

206 agree? 2 I'm sorry, sir, I asked you the question. 3 But I'm trying --4 Is that concavoconvex implant that goes from one end of the transverse width of that 5 6 vertebral body to the other? 7 MR. AMON: Objection; outside the 8 scope. 9 I'm looking at a picture that you showed 10 me, Counsel, which is what we will just term in 11 general a banana-shaped implant. 12 Fair enough, sir. 13 So we won't use the word Boomerang implant Α. 14 because there's a name applied to what we've been 15 discussing, just to be exact. I don't want to be --16 Banana-shaped is fine with me, sir. 17 that a banana-shaped implant that goes from one side 18 of the transverse width of the vertebral body to the

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This one illustrates a banana-shaped

implant in a vertebral body, a drawing. There is no

19

20

21

22

other?

dimension.

207 I understand. So in a -- in a large adult Ο. 2 male, L4 to L5, wouldn't that implant be greater 3 than 40 millimeters long? 4 MR. AMON: Objection; outside the 5 scope, speculation. Dr. Yuan --6 MR. SCHWARTZ: Coaching the 7 witness. 8 MR. AMON: That's fine, you can 9 accuse me all you want. Take all the 10 time you need to review the entire 11 document, Dr. Yuan. 12 This drawing here of what they're designing 13 to put an implant in, would make you, if in the lower 14 lumbar, absolutely transpsoas. 15 Q. That's fine, sir. 16 Let me qualify a couple more things just 17 so -- if this is done, not only transpsoas but this 18 is going to be done totally along the path which is 19 the wrong location, both from your anterior oblique 20 approach that you showed me that your KOL, key 21 opinion leaders, showed of the anterolateral which 22 has a space to approach the spine, which I agree with

208 you. 2 This approach that you just showed me 3 here would allow you to impale the whole nerve plexus so it's not in the lower lumbar and this approach 5 would not be used in the upper lumbar because you 6 will have visceral structures. You would have 7 kidneys; you would have ribs, if you're going to go in the thoracic, and then if you're in the upper lumbar, you would have kidney; you're going to have 10 the spleen. 11 So this is a wonderful drawing. 12 a great design drawing but it doesn't make any sense 13 at all on how you would implant through this 14 approach. Turning to the prior page, figure 17, does 15 16 that figure look to you like it's the lower lumbar 17 portion of the spine? 18 Α. Yes. 19 Okay. Thank you, sir. No more questions 20 on that document. 21 Sir, are you familiar with a product 22 marketed as the Guided Lumbar Interbody Fusion

August 22, 2014

	209
1	Device?
2	A. Guided lumbar fusion device. Can you tell
3	me a little more about that?
4	Q. I can do more than tell you, sir. I will
5	show you.
6	A. Thank you.
7	MR. SCHWARTZ: Mark this as MSD
8	1023.
9	(MSD Exhibit 1023, Alphatec
10	Guided Lumbar Interbody Fusion Device,
11	marked for identification, this date.)
12	Q. Are you familiar with that device, sir, as
13	indicated on MSD 1023?
14	MR. AMON: Dr. Yuan, take all the
15	time you need to review the document.
16	Q. If you're not familiar with it, just say
17	you're not familiar with it and we can move on?
18	A. May I ask a question? "Familiar" meaning
19	do I know about this or
20	Q. At the time you were giving your testimony
21	that's memorialized in your Declaration, were you
22	aware of this product?

210 I'm aware of this product. 2 Okay. Is it fair to say that that's a Ο. 3 banana-shaped implant? 4 It isn't a banana-shaped implant. This is 5 a lateral implant. A banana-shaped implant would be 6 one that the -- this isn't a true -- it's a true 7 lateral implant approach from, quote, unquote, a guided lumbar interbody approach by Alphatec. 9 well-aware of this. It's a totally lateral implant 10 but it's a -- this drawing here --11 Are you aware, sir, that NASS 12 characterizes that as a posterior implant and 13 procedure? 14 MR. AMON: Objection; assumes 15 facts not in evidence. 16 MR. SCHWARTZ: I'm asking if he's 17 aware. How could it be assuming facts 18 not in evidence? 19 MR. AMON: Because you're 20 testifying that's what the facts are. 21 It's assuming a fact. 22 I'm a past president of NASS so I know NASS

211 very well. This approach here is a, how they call a 2 posterolateral approach. That's why they may call it 3 posterior, which is not correct. It's a circular guided path going down to the vertebral body and 5 access for stabilization of all of this is maintained 6 from a posterior point to maintain it as stable so 7 you can basically make the move without -- without 8 sliding, but this is totally and truly a lateral 9 approach, but the avenue that you get there is 10 through a curvilinear approach. Incision is 11 posterolateral and then this will approach the lumbar 12 spine totally laterally. 13 Okay. And that's an implant that's Ο. 14 greater than 40 millimeters long, correct? 15 Α. Yes, designed to be. 16 Q. Okay. 17 What date is this implant? 18 Sir, if you would, in that same 19 Declaration, 2020 in the 507 matter, on page 60, 20 which is paragraph 108. 21 Α. Page 60? 22 Right. It's a continuation of paragraph

```
212
    108 from -- starting at page 59.
2
         Α.
               I'm trying to get to where you're reading
3
    from, Counsel.
4
               Sure. I haven't actually started reading
         Q.
5
    yet. What I'd like to do is read from, six lines
6
    from the top, the sentence "even if it were
7
    possible."
8
         Α.
               Yes.
         Q.
               Are you with me?
10
         Α.
               Yes.
11
               So it says: "Even if it were possible, a
         O.
12
    person of ordinary skill in the art in March 2004
13
    would understand the unnecessarily increased level
14
    of risk of greater morbidity in the patient, less
15
    stability in the spine, and increase the chance of
16
    damaging the spinal cord or nerves lying near the
17
    backside of the spine."
18
               Did I read that correct?
19
         Α.
               Yes.
20
         Q.
               Now, there's no spinal cord in the lower
21
    lumbar spine, right, sir?
22
               The spinal cord ends at lumbar 1.
         Α.
```

213 Right. So from L2 to S1 there's no spinal Ο. 2 cord? 3 Α. Right; those are roots. There should be spinal elements. 5 Q. Sir, I'm going hand you what's been previously identified as NuVasive Exhibit 2012, 7 which is the Boomerang VERTE-STACK PEEK Vertebral 8 Body Spacer. Do you see that, sir? 9 Α. Yes, sir. 10 So even in this document that you've been 11 relying on, and actually Medtronic hasn't, it 12 characterizes the Boomerang as a VERTE-STACK PEEK 13 Vertebral Body Spacer, correct? 14 Can you say the whole sentence again? Α. 15 missed one portion. I heard it from the back end. 16 (Whereupon, the pending question 17 was then read back by the Reporter.) 18 You said that Medtronic hasn't? Apologize. Α. 19 Let me restate the question. 20 document characterizes or describes Boomerang as a 21 VERTE-STACK PEEK Vertebral Body Spacer, correct?

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Yes, correct. Thank you.

Α.

- O. And at the back of the document it
- explains that the Boomerang VERTE-STACK PEEK
- 3 Vertebral Body Spacer is a vertebral body
- 4 replacement device, correct?
- 5 A. That's what it states.
- 6 Q. Now, if you look at the diagrams, you can
- <sup>7</sup> take any one of them, but perhaps look at the last
- one, the -- on page 4 of the brochure, at the bottom
- <sup>9</sup> of the page. You see the implant sitting there
- inside of that vertebral body, correct?
- 11 A. That's correct.
- 12 Q. There's certainly space on either side of
- that implant, correct?
- 14 A. Can I qualify, please? Not to challenge
- you but just qualify. We have no information on the
- dimension of the vertebral body. We have no
- dimension of the Boomerang cage that is in this
- 18 drawing. So the question that you just asked, I
- don't know -- for me to answer that would only be
- talking about a drawing with no information.
- Q. Okay. Sir, I'm just asking you, is there
- space on either side of that implant in the

- vertebral disk space?
- A. Not knowing the size of the body, not
- knowing the size of the implant you're using, only in
- 4 the drawing here, which is merely a drawing, for me
- 5 to say that there is space, there is annulus and
- that's where the implant is designed to be implanted.
- What it shows me is an implant is put in the right
- 8 position because it is inside of the annular wall.
- 9 It doesn't tell me any more.
- Q. But there's space on the left and right
- 11 side of that implant, correct, sir?
- A. What is "space"?
- Q. The vertebral body is larger in its
- transverse width than the length of that implant,
- 15 correct?
- 16 A. Now you're talking about length of the
- implant. We don't know the dimension of this
- implant. They can make a small one --
- Q. Referring to the illustration, sir. I
- don't know why you're fighting me on this.
- A. I'm not fighting.
- Q. I'm just pointing to the picture.

- 1 MR. AMON: Dr. Yuan --
- Q. In the picture the transverse width of the
- yertebral body is longer than the length of that
- 4 implant, correct?
- 5 A. I will go back to say that this is an
- 6 illustration. It gives me no information to be able
- 7 to answer you because if you give me the dimension of
- 8 a cage and the dimension of the body, I'm happy to
- 9 answer your question.
- Q. Sir, you've been referring to this
- document all day long. I'm just asking you, is the
- 12 length of that implant smaller than the transverse
- width of that vertebral body?
- 14 A. Counsel, I like to just answer questions
- that's going to be specific and accurate. If you are
- not going to give me numbers, you want me to just
- give you an assumption, then I will not be doing you
- 18 a favor.
- Q. So you can't tell me one way or the other?
- A. I can't tell you unless you clarify and you
- give me the reason and information that I need to be
- able to answer you accurately.

217 I'm just pointing to the illustration, O. 2 sir, and I'm asking you if the implant is smaller 3 than the transverse width of that vertebral body as reflected in that illustration? It's a simple yes 5 or no question, sir. 6 Again, I will go back to say I'm not a 7 lawyer. I'm just trying to be specific and I'm 8 trying to be accurate and to testify to the 9 information. You give me the information, I will be 10 able to answer your question. 11 Okay, sir. I'm going to hand you what was Ο. 12 previously marked as MSD 1113. 13 Α. Thank you. 14 You'll see, sir -- you're familiar with Q. 15 the Zhou reference, which is MSDS 1113, correct, 16 sir? You discuss it in your Declaration, right? 17 MR. AMON: Mr. Schwartz, before 18 you get into the line of questioning, 19 can you take a break before you get 20 into a line of questioning? 21 MR. SCHWARTZ: I'm in the middle 22 of a line of questioning.

218 1 MR. AMON: All right. 2 I'm aware of this document. Α. 3 EXAMINATION BY MR. SCHWARTZ: 4 Okay, sir. So assuming that the 5 statistics reported in this document are accurate as 6 to the geometric sizes of vertebra, you see, sir, 7 where the L4 and L4-5 disk, lower vertebral width 8 for a male, is 55.1 plus or minus 4.1, correct? 9 Can you go to where you're reading this Α. 10 from, sir? 11 Sure. Sir, on page 245, in the center Ο. 12 column where it's L4 and L4-5 disk, the LVW, which 13 is the lower vertebral width, for a male, which is 14 the third indication down. The lower vertebral 15 width on average is 55.1 plus or minus 4.1, correct? 16 Α. That's what it states, yes. 17 So using that number, 55.1 plus or minus Ο. 18 4.1 and referring back to the Boomerang, if that 19 vertebral width is 55.1 and the implant length is 36, 36 is smaller than 55, right, sir? 20 21 Α. Yes. 22 Okay. So there would be a difference of Q.

```
219
    19 millimeters in the width of the transverse -- the
2
    transverse width of the vertebra and the length of
3
    that implant, correct?
4
          Α.
               The number is correct.
5
          Q.
               Thank you, sir.
6
                         MR. SCHWARTZ: Now we can take a
7
                    break.
8
                         MR. AMON: Thank you.
9
                          (3:52 p.m.)
10
                          (A recess was then taken.)
11
                          (4:04 p.m.)
12
    EXAMINATION BY MR. SCHWARTZ:
13
               We're back on the record, sir.
          Ο.
14
    understand you're still under oath, correct?
15
               Yes, sir.
          Α.
16
               I want to start, sir, there were a few
          O.
17
    places in your Declaration where you talk about this
18
    length-to-width proportion for the '334 patent
19
    claims being 2.5 to 1; do you recall that?
20
         Α.
               Yes.
21
               Are you taking the -- strike that.
          O.
22
               Is it your opinion that it's unique to
```

- have a 2.5 to 1 proportion of length to width? 2 Α. We've been talking about the length for 3 sometime, so the length is important. The width is also important because of the space that is 5 available. In particular you're doing this through a minimally invasive approach. 7 In the minimally invasive, why it's so 8 important, because the open approach leaves patient 9 with tremendous mobility, of having large size 10 hernias, and then having the intercostal nerves that 11 are damaged. So the minute you go to something that 12 didn't cut open the womb, you're slowly dilating the 13 womb up, so those neuromas and then the herniations
- And the other reason for going

  minimally invasive, part of what I'm getting to is
- important, you are really limited anatomically a
- 18 certain width in these lumbar segments so I wasn't
- 19 trying to be smart in pointing out the approach you
- showed me of the European one; that that is okay to
- 21 be done truly straight lateral in the upper lumbar.
- The minute you get down to low lumbar,

14

disappeared.

- when you're doing at L3-4, L4-5 and 5-S1 -- 5-1 you
- can't do it -- those levels become very dangerous.
- 3 But with the evolution evolving using monitoring and
- so on, they got us to go there.
- 5 The width is extremely critical
- because of how wide you can get an implant and this
- is really studied to give you the approach, the
- 8 average -- the norm that is a good width.
- 9 Q. You can certainly appreciate that implants
- that were prior art to the NuVasive patents that
- we're talking about also had the same proportion of
- length to width, correct?
- 13 A. Which one?
- 14 O. Well, for example, the Boomerang, it has a
- 2.5 to 1 ratio of length to width, right?
- 16 A. Can you show me that?
- Q. Sure, sir, and this is referring to
- 18 NuVasive Exhibit 2021. You've got a length of 36
- and a width of 13; right, sir?
- A. You got a channel you're going to put
- things through and the channel is a certain dimension
- 22 and allow you to put in -- the length doesn't matter

- so much because you're going to be docked; you're
- ready to go. The width from 13 and if this was 15,
- okay, then it doesn't fit into this hole.
- Now, you showed me this document here,
- 5 which is a Medtronic document, and the NuVasive
- 6 brought this document out. I look at the width, so
- <sup>7</sup> for what I, as a surgeon, have to do is not looking
- 8 at that width. I'm looking at the total width
- 9 because I have to, because that's the slot that I got
- 10 to put it down.
- So if I'm going to put this width in,
- in a curved dimension, then a short channel, then I
- can really make the turn, is okay, but the minute I
- have to go in straight to get both anterior and the
- two posterior PEEKs into the slot, then it's going to
- be tight.
- So same thing I'm looking at, it has
- 18 to go through an annulotomy incision where I
- 19 retracted the nerve and now my retractor is docked at
- a certain width. To add 2 more millimeters, or
- whatever, is going to be something difficult to
- implant, so it is a straight implant. If it was

- going to be laterally curving in, then that would be
- <sup>2</sup> fine.
- Q. Okay. But it does physically have a
- 4 2.5-to-1 width and even if you take into account the
- 5 additional curvature, it likely meets the 2.5 to 1
- 6 as well?
- 7 A. It doesn't. 36, let's assume this is a
- 8 36 millimeter length. Here it is called the width
- 9 because -- we both understand?
- Q. Sure. We're talking about length.
- 11 A. Right. So then you take the 13 and you add
- 2 more millimeters to go down the channel, it's no
- 13 longer 13; it's 15.
- Q. So that's pretty darn close to 2.5 to 1,
- isn't it? 15 would make it -- two and a half times
- 16 15 is --
- A. Do the math. You know the math. You're
- 18 not asking me. I know you know the answer.
- 19 O. 37 and a half.
- 20 A. Okay.
- Q. So it's pretty darn close to 2.5 to one?
- A. As you and I say in the trade, close but no

224 cigar. 2 Does the Telamon meet the 2.5 to 1? Ο. 3 The Telamon certainly does but in the 4 Telamon, we don't have implant of the length that 5 we're referring to, and by the time you get it to the 6 length, as you say, you modify to any length, any 7 width, so if you assume that, you can do anything and 8 then you don't have to have patents, don't need 9 inventions. 10 Q. Thank you, sir. 11 Thank you. 12 I'm going to turn back in your report and 13 this is the 507 report, Exhibit 2020, to page 67. 14 Α. Yes, sir. You see that figure in the middle of your 15 Q. 16 report? 17 Α. Yes. 18 And you represent that image as being a 19 Telamon implant elongated to a length slightly 20 greater than 40 millimeters, correct? 21 Α. Yes. 22 And how do you -- how do you get that that

- image is of an implant slightly greater than 40
- 2 millimeters?
- A. Your question one more time? How did I get
- 4 there?
- <sup>5</sup> Q. How do I know that that implant is
- 6 slightly greater than 40 millimeters?
- 7 A. Okay. Let's go back and look at the depth
- 8 of the vertebral body. The depth of the vertebral
- body as you showed me on the Zhou article.
- Q. Um-hum.
- 11 A. What is the average anterior posterior
- dimension in a male? You know the document well.
- 0. I don't have it memorized, sir.
- 14 A. Yes, you do. I know you do.
- Q. For the record we're referring to MSD 1113
- the Zhou article, Z-H --
- 17 A. Zhou.
- 18 O. Zhou. So we're talking about the -- I
- should give you that copy. Which dimension, using
- Zhou, is the depth that we're referring to here?
- 21 A. I don't know. I would just say that he's
- done these studies so I can say we can look up the

226 depth. 2 Okay. It appears that you've got a --3 you've got a spinal canal depth that's defined and you've also got an upper vertebral depth and a lower 5 vertebral depth, correct, sir? So if you use the 6 lower vertebral depth of a male, L4-L5, that's 38.6 7 plus or minus 3.4; right, sir? 8 Α. Which one are you at? 9 Ο. I'm sorry, the middle column on LVD for a 10 male is 38.6 plus or minus 3.4, correct, sir? 11 LVD --Α. 12 Lower vertebral depth. O. 13 Α. Okay. 14 Well, using that as a starting point, 38.6 0. plus or minus 3.4? 15 16 Α. Okay. 17 Doesn't it look like that implant is Ο. 18 bigger than 40 from your diagram? 19 Again, there's no numbers on the implant. 20 Q. I understand. 21 So it's just an illustration, just what you 22 tried to tell me, so I wouldn't use that to say

- that's accurate. I would merely say rather that's a
- risk of it protruding through the front, but if we're
- looking at these numbers here, you would definitely
- 4 break through the anterior rim; that's all it's meant
- <sup>5</sup> to.
- Q. Understood, but for purposes of me
- <sup>7</sup> understanding your diagram, right, this is your
- 8 report, I have to assume that's something that you
- 9 endorse. The amount that that implant extends out
- would at least not be representative of how much a
- 40 millimeter implant would stick out on a male at
- 12 the L4 level, correct, sir? It would be less than
- 13 that.
- My point is you would have a little more
- 15 space. It might stick out but it wouldn't stick out
- 16 that much.
- 17 A. Now I will use your language again,
- 18 Counsel. The word up here say elongated to a length
- 19 slightly greater. What is slightly and what is
- <sup>20</sup> greater?
- Q. Your language, sir.
- A. Correct, so it's my language. It didn't

- say slightly shorter. It didn't say slightly less.
- It didn't say 40 millimeters, so when you say
- 3 slightly greater, the key that I'm trying to imply is
- 4 that it protrudes anteriorly of the disk space.
- Okay. I'm just trying to get an
- understanding of the proportions of this figure
- <sup>7</sup> because it's somewhat dramatic.
- 8 A. It's meant to show that in the average
- 9 male -- and doing spinal fusion at L4-5 level, 70 to
- 10 80 percent of the patients with degenerative
- 11 spondylolisthesis are females.
- Q. I appreciate that, sir.
- 13 A. And it's only to dramatize the point.
- 14 O. So is it fair to say that for a male at
- the L4-5, the implant would not stick out that much
- if it's slightly greater than 40?
- MR. AMON: Objection; incomplete
- hypothetical, go ahead.
- 19 A. If you take the average male and you
- don't -- you add this to the upper limit, it will
- 21 stick out that far. If you take the average male and
- you use the bottom, then it won't.

- Q. So, for example, to your point, 38.6 plus
- 3.4 is 42 millimeters, correct, sir?
- 3 A. Yes.
- Q. So that would be bigger than a slightly
- 5 greater than 40 millimeter implant; correct, sir?
- A. Did you say it's my words? My words from
- <sup>7</sup> 40 to 42, as you say, is only slightly bigger, if I
- 8 paraphrase your terminology accurately. You have
- 9 used that word.
- Q. Okay, sir. So let's do this. If you're
- inserting a 41 millimeter implant, correct,
- 41 millimeters, and you use the upper end of the
- average, which would be 42 millimeters in depth, the
- 41 millimeter implant would not stick out, correct?
- 15 A. This is just to show that whenever you have
- to penetrate the anterior rim, penetrate the anterior
- 17 longitudinal ligament in any patient, the chance of
- you perforating, protruding through is extremely
- 19 high. That's what it's supposed to show.
- Q. I understand, sir.
- A. And I respect your position, I understand,
- but any amount of protrusion through the anterior

- wall is risky in terms of safety, so this is just
- <sup>2</sup> merely meant as an illustration.
- Q. I understand, sir. But you agree that 41
- 4 is less than 42, right?
- 5 A. To be fair, take a middle range. Why pick
- 6 the lower? I didn't even pick a female. I picked a
- <sup>7</sup> male and 70 percent of the patients we're operating
- 8 on is females. Do we want to look at a female?
- 9 Q. Actually, sir, I'd like to stick with my
- 10 hypothetical. I would like to stick with mine.
- 11 At the outer range male where it's
- 42 millimeters in depth, 41 is less than 42, right,
- 13 sir?
- MR. AMON: Objection;
- mischaracterizes the document.
- A. As we said, if we want to be fair, we pick
- the average of a male and pick an average of a
- 18 female.
- 19 Q. Sir, can we stick with my hypothetical for
- these questions?
- 21 A. I think you like me to answer and give you
- honest answer but for me to agree to something that

Yuan, M.D., Hansen A.

- the -- you are -- you're not trying to deviate but
- 2 you're trying to channel into a question mode that is
- 3 not the norm. I'm only asking for the norm.
- 4 I understand, sir but --
- 5 Stay with the norm.
- 6 -- take it one step at a time because I'm
- 7 running out of time and I know counsel is going to
- 8 tell me I'm out of time pretty soon here. So rather
- 9 than spending a lot of time with your hypotheticals,
- 10 if you'd stick to mine, I'd appreciate it.
- 11 I'm willing to stick to a hypothetical but
- 12 make it fair and make it the norm.
- 13 I see. So but my hypothetical, the outer Ο.
- 14 range male, a depth of 42 millimeters; 41 is less
- 15 than 42, correct?
- 16 I would answer that if this would be the
- 17 norm.
- 18 Okay, sir, and you agree that this
- 19 illustration is an exaggeration, at least in the
- 20 context of a male at the L4-L5 level, correct?
- 21 But not for a female. Α.
- 22 Fair enough. For a male at the L4-5

- level, this illustration is an exaggeration of the
- <sup>2</sup> relative dimensions.
- 3 A. For a female, this more than demonstrates
- 4 the correct accuracy.
- 5 Q. Fair enough, sir. For a male, at the L4-5
- level, the implant in relationship to the size of
- <sup>7</sup> the vertebra is an exaggeration of its length
- 8 relative to the size of the vertebra, correct?
- A. For a male on the upper limits of the norm,
- 10 the norm, it will be sticking out.
- 11 Q. I'm not asking you about sticking out now,
- sir. I'm just asking you the relative size of the
- implant compared to a male, at the L4-5 level, if
- 14 you take 38.6 compared to your slightly greater than
- 40 implant, that implant is an exaggeration of the
- relative size of the implant compared to the
- vertebra, correct?
- 18 A. You take 38.6 and go up to 41, as you use a
- 19 number, that implant will be sticking out.
- Q. And again, sir, I'm not asking if it's
- 21 sticking out. What I'm asking is, the relative size
- of this implant compared to the size of the outline

- of that vertebral body is an exaggeration of the
- size of that implant compared to the size of the
- 3 vertebra, correct?
- 4 A. Not if this is a norm of an adult male. It
- <sup>5</sup> will be protruding as illustrated.
- Q. Sir, you're showing an implant that's
- 7 protruding 30 percent beyond the rim of that
- 8 implant; fair characterization, roughly?
- 9 A. I'm showing here just an illustration to
- demonstrate the point of protrusion.
- Q. I understand that, sir. I'm just asking
- 12 about the relative size.
- 13 A. So unless we're going to pick a norm and be
- 14 fair in the question, then I can answer you honestly
- and appropriately. For you to pick what suits you
- but not the norm and then asking me to agree to you,
- 17 I cannot.
- 0. Sir, I'm allowed to ask hypotheticals and
- 19 I'm entitled to an answer to those hypotheticals.
- 20 So let's start with that as the basis for the
- <sup>21</sup> question.
- Basis of the question is an average male

	234
1	with a depth at average of 38.6 and a 41 millimeter
2	implant is not going to protrude 30 percent of its
3	length, correct?
4	A. That's correct.
5	Q. Thank you, sir.
6	A. Thank you.
7	Q. Whew.
8	MR. SCHWARTZ: Sir, I'm going to
9	mark this as MSD 1052.
10	(MSD Exhibit 1052, diagram,
11	marked for identification, this date.)
12	Q. Sir, I've handed you
13	MR. AMON: Could I have a copy,
14	Counsel?
15	MR. SCHWARTZ: It's the exact
16	replica of the figure that's in his
17	report.
18	MR. AMON: It's been blown up?
19	MR. SCHWARTZ: I'll get you a
20	copy.
21	MR. AMON: Thank you.
22	MR. SCHWARTZ: Can I see it for a

```
235
1
                    second, sir?
2
                          THE WITNESS: Oh, sure.
3
                          (Document handed.)
                         MR. AMON: This was marked as
5
                    1032?
6
                         MR. SCHWARTZ: 1052.
7
    EXAMINATION BY MR. SCHWARTZ:
8
          Ο.
               You've been handed what's been identified
9
    as MSD 1052.
10
         Α.
               Thank you.
11
               Can we agree that's a proportionate
          Ο.
12
    representation of the figure that's in your report?
13
         Α.
               Yes.
14
               Okay, sir, I'm going to hand you cut-out
15
    of that exact implant which I invite you to put on
    top of it to compare the size. Is it the same size,
16
17
    sir?
18
         Α.
               Yes.
19
          Q.
              Okay, sir.
20
         Α.
               Sorry.
21
                    Now, sir, isn't it fair to say that
          O.
               No.
22
    even with your exaggerated implant, it will fit
```

- within that disk space?
- A. Would you want a spine surgeon to do the
- 3 case on your back with that implant?
- Q. I'm not asking you that question, sir.
- <sup>5</sup> I'm asking you does it fit within the disk space?
- 6 A. It doesn't.
- 7 Q. It's within the circumference of that disk
- 8 space, sir?
- 9 A. But if you look at this, posteriorly you
- 10 are invading the spinal canal with that implant
- because the implant that we're putting in here is
- right in the space, and you're looking anteriorly.
- 13 You've already penetrated all the annular ligaments
- and actually abutting against the vein.
- 0. Is it within the circumference of the
- 16 vertebral body?
- 17 A. No, just protruding. I would not do that
- 18 case that way.
- 19 Q. I'm not asking if you would do the case.
- I'm asking you does it fit within the circumference
- of the vertebral body?
- MR. AMON: Asked and answered.

237 It is sitting on the rim and it's just 2 protruding and it's dangerous. 3 So it's sitting on the rim. Where is it protruding? 5 Α. This is the vena structure and that's protruding, and that posteriorly is already in the 7 spinal canal because the spinal canal comes down 8 below. 9 Well, sir, the spinal canal is over here, 10 right? 11 No, no, that's where the nerves are. 12 That's where the nerve structures are sitting, right 13 in this whole space here. This is where your 14 entrance point. No surgeon would leave the corner 15 sticking out there. 16 Q. Okay, sir. How about pointed in the other 17 direction? 18 MR. AMON: Can I have a copy of 19 that one please, Mr. Schwartz? 20 MR. SCHWARTZ: You want to take a 21 break and make a copy? Want to take a

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break?

22

We can take a break and make a

	238
1	copy. I'm trying to move this along.
2	MR. AMON: No need to raise your
3	voice, Mr. Schwartz.
4	MR. SCHWARTZ: I'm not raising my
5	voice, Counsel.
6	MR. AMON: We'll get a copy at
7	the next break.
8	A. In an oblique implant, you don't want the
9	implant sitting on the rim of the vertebral body.
10	That's the reason why an implant of the size and this
11	dimension that you're talking about cannot be used.
12	EXAMINATION BY MR. SCHWARTZ:
13	Q. But, sir, does it sit within the
14	circumference?
15	A. First of all, we don't know the dimension
16	of this vertebral body and, secondly, we don't know
17	here what the length is that we are measuring.
18	Q. I'm just working from your picture, sir.
19	A. My picture is an illustration. I don't
20	have any numbers there to show that.
21	Q. I understand.
22	A. As I said to you, it's an illustration

	239
1 <b>s</b> :	howing when a cage is too long, it will stick out
2 <b>t</b> :	hrough the anterior vertebral body, and whenever you
3 <b>h</b>	ave to take down the annulus at an oblique angle
4 <b>a</b> ;	pproaching from anywhere, posterior, posterolateral,
5 <b>t</b> :	here is risk.
6	Q. Does it fit within the circumference, sir?
7	A. It sits on the rim.
8	Q. It's on the rim. It's not protruding.
9	A. One corner is very close.
10	Q. Very close but not protruding?
11	A. Very close.
12	MR. SCHWARTZ: Thank you, sir.
13	Why don't we take a short break so we
14	can make copies of this picture.
15	MR. AMON: Why don't we keep
16	going?
17	MR. SCHWARTZ: Why don't we take
18	a short break to make copies of this
19	picture.
20	(Whereupon, there was a pause in
21	the proceedings.)
22	MR. SCHWARTZ: This is MSD 1032,

	240
1	sir, I've handed you again just. So
2	we're clear, MSD 1032. Counsel, your
3	copy.
4	MR. AMON: Thank you. And we
5	should mark this second one MSD 1053?
6	(MSD Exhibit 1053, diagram,
7	marked for identification, this date.)
8	EXAMINATION BY MR. SCHWARTZ:
9	Q. The second one, sir, as we talked about is
10	the implant that was sitting on the ground. And now
11	I'm going to hand you what's going to be marked as
12	MSD 1054.
13	(MSD Exhibit 1054, diagram,
14	marked for identification, this date.)
15	Q. On MSD 1054, you see that implant, at
16	least in your report, was slightly greater than
17	40 millimeters, is within the translateral width of
18	the implant but just barely so, right?
19	A. By this drawing, which we have no proper
20	delineation of size, as the illustration, yes.
21	Q. Okay. And it's fair to say, referring
22	back to Zhou, which you have in front of you, that

241 the lower vertebral width of a male at L4-L5 is 55.1 2 plus or minus 4.1, correct? 3 That's correct. 4 So this implant that we've been playing 5 with that spans almost the entire transverse width 6 of the vertebra, if this were a male at L4-L5 would 7 be pretty close to 55 millimeters long, right, sir? 8 MR. AMON: Objection, 9 speculation, incomplete hypothetical, 10 assumes facts not in evidence. 11 MR. SCHWARTZ: And coaching the 12 witness. 13 As I've said, we don't have dimension, 14 accurate dimension on the illustration. So having 15 accurate dimension on this, then that would be 16 meaningful but I would agree with you on the 17 illustration. What you're showing here is an 18 illustration of the cage that you cut out the size of 19 a 40 plus sits within the vertebral space. 20 And if that were a male at L4-L5, that Q. 21 implant would be at least 50 millimeters long, 22 right, sir?

242 Once more, if this was --2 If this was a male at L4-L5, that implant Ο. 3 would roughly be about 50 millimeters long, right? 4 MR. AMON: Objection; incomplete 5 hypothetical, speculation, assumes 6 facts not in evidence. 7 I can't say that because there's no marking 8 for me to be able to measure the length. I can only 9 say that this is shorter than the full transverse 10 width. 11 But only slightly so, right, sir? 12 We're back to your slightly and to my 13 slightly again, so when we say slightly, is this 14 4 millimeter slightly or 5 millimeter slightly? 15 Q. What do you think, sir --16 I don't know. 17 -- 4 or 5? Ο. 18 I think for you and I to guess 4 or 5 19 millimeters shorter, it be totally a guess. 20 wouldn't --21 If it's 4 or 5 millimeters shorter, and in

a male at L4-L5, that would make that implant about

- 50 millimeters long; right, sir? I'm just trying to
- <sup>2</sup> get to relative sizing.
- A. I like to give you relative sizing but I'm
- 4 trying to understand why you're taking this path of
- 5 questioning. I'm trying to understand you so I can
- 6 answer you better.
- 7 O. Fair enough, sir. If we go back to the
- prior figures, 1053, where we said that it was
- 9 sitting on the rim and not protruding, that same
- 10 implant --
- 11 A. Wait, wait. We say this one here is
- just breaking through the annular wall. I said
- sitting on the rim anterior, is just protruding,
- that's what it shows, and if you say the space, yes,
- there's space but here there's no space; it's
- protruding, and then posteriorly the corner is at a
- 17 risky location because it is in the posterior through
- the posterior annular wall.
- Q. Okay, sir, proportionately speaking on a
- male, L4-L5, with an implant that goes the entire
- transverse width, it would be bigger than
- 41 millimeters long; correct, sir? It would be

Yuan, M.D., Hansen A.

- closer to 50 millimeters long?
- 2 Α. Ask that one again.
- 3 The point I'm trying to make, sir, is that
- 4 this length is not, proportionately speaking, for a
- 5 male, L4-L5, 41 millimeters, it's something much
- larger than that; is that a fair estimate?
- 7 I don't have a length of this and I'm not
- 8 purporting it to be anything. You are purporting it
- 9 to be a certain length.
- 10 O. Sir --
- 11 You're the one who proved to me that on
- 12 your first, I'm sorry, illustration which is 1052,
- 13 that this thing here, according to you, okay, is way
- 14 longer than just 40 plus.
- I'm sorry, finish you sentence, sir. 15
- 16 Α. And now you're asking me to take that
- 17 length again. I agree with you that this thing here
- 18 is just an illustration. It is not meant to be
- 19 anything, so even if this just slightly protruding,
- 20 let's take it back to only -- take away 4, 5
- 21 millimeters, that implant there is still risky.
- 22 Fair enough, sir. I'm not asking you Q.

245 about risk and so that's somewhat nonresponsive to 2 my question. Let's try it this way. 3 I want to be responsive, Counselor. 4 A 41 millimeter long implant placed 5 diagonally on an L4-L5 male would fit within the 6 circumference of that male's disk space? 7 We've shown that in the drawing, if this is Α. 8 correct --9 Sir, I think we got to the point that that 10 implant is a exaggeration. I'm trying to ask you 11 generally, a 41 millimeter implant laying in the 12 disk space diagonally of an average male at the 13 L4-L5, which has an average width of 55.1 and an 14 average depth of 34.6, 41 millimeters would fit well 15 within that circumference, correct? 16 That's correct. Α. 17 Ο. Thank you, sir. 18 A. That was easy. Why didn't you ask that 19 first? 20 There you go. Q. 21 MR. SCHWARTZ: We're going to 22 mark this MSD 1028.

```
246
1
                         (MSD Exhibit 1028, US Patent
2
                    number 7,815,682, marked for
3
                    identification, this date.)
4
    EXAMINATION BY MR. SCHWARTZ:
5
         Ο.
               Sir, I've handed you what's been
6
    identified as MSD 1028, which I'll represent for the
7
    record is US patent number 7,815,682 and this is a
8
    patent that at least on the face of it indicates is
9
    assigned to NuVasive, correct, sir?
                         MR. AMON: Take your time to
10
11
                    review the document, Dr. Yuan.
12
               I'm just asking if it's assigned to
         Ο.
13
    NuVasive according to the face of the patent, sir?
14
         Α.
               Yes, it says that.
15
         O.
               If you would, sir, turn to page -- column
16
    4?
17
               I haven't seen this document before.
         Α.
18
               I understand, sir. I'd like to ask you a
         Ο.
19
    specific question with regard to the specific
20
    dimensions of this implant. I'm not sure you need
21
    to study the document to answer the question.
                                                     Ιf
22
    you think you do when I ask you the question, let me
```

```
247
    know that.
2
          Α.
               Okay. What would you like me to look at,
3
    sir?
4
               I'd like you to look at column 4 and lines
5
    43 to 45. You see there, sir, that there's a
6
    description of the dimensions of this implant as
7
    being between 20 and 45 millimeters long, right,
8
    sir, the length ranging between 20 and 45
9
    millimeters?
10
               Just a minute.
          Α.
11
          O.
               Sure.
12
               Okay, sir.
          Α.
13
               So it shows that this implant is described
          Ο.
14
    as having a length ranging from 20 to 45
    millimeters; correct, sir?
15
16
               That's this implant 10?
         Α.
17
          Ο.
               Correct.
18
         Α.
               Yes.
19
               And that implant is a banana-shaped
          Q.
20
    implant, right, sir?
21
          Α.
               Yes, that's what we call banana shape.
22
          O.
               We can move on unless you want to look at
```

```
248
    that some more.
2
                         (MSD Exhibit 1029, US Patent
3
                    number 8,623,088, marked for
                    identification, this date.)
5
         O.
               Sir, you've been handed a document
6
    identified as MSD 1029. I'll represent for the
7
    record that this is United States patent 8,623,8 --
8
    088?
9
               That's correct.
         Α.
10
         O.
               This is another patent assigned to
11
    NuVasive, correct?
12
         Α.
               That is correct.
13
               If you would, sir, turn to column 5 and
         Ο.
14
    ask a very similar question.
15
                         MR. AMON: I'll just object to
16
                    this entire line of questioning as
17
                    irrelevant, beyond the scope.
         O. Column 5 --
18
19
         Α.
               Yes.
20
         Q.
               -- at about line 35. You see, sir, it
21
    describes a length ranging from between 25 and 45
22
    millimeters?
```

249 1 MR. AMON: Objection; beyond the 2 scope and relevance. 3 That's correct. Α. 4 And you see, sir, for example in 5 figure 13, this is an implant that's inserted by I 6 think what you described as a posterolateral 7 approach; is that fair to say? 8 MR. AMON: Objection; assumes 9 facts not in evidence. Dr. Yuan, if 10 you need to review the document to 11 answer that question, go ahead. 12 MR. SCHWARTZ: If you'd like more 13 time to coach the witness, I'll 14 object. 15 I think you answered the question and said 16 that's correct. Right, sir? 17 Looking at the illustration this appears to Α. 18 be a bilateral posterolateral approach which is not a 19 good thing. 20 Okay, sir. Thank you. You say it's not a 21 good thing. Do you think that NuVasive would 22 describe in a patent application something that they

250 thought was unsafe? 2 MR. AMON: Objection; beyond the 3 scope, speculation. 4 I wouldn't know what NuVasive would be 5 thinking about. I'm only looking at it from a 6 surgical point of view and I'm not seeing this device 7 marketed because this requires a bilateral TLIF 8 approach. 9 MR. SCHWARTZ: Mark this as 1030. 10 (MSD Exhibit 1030, MAS TLIF 11 brochure, marked for identification, 12 this date.) 13 Sir, I've handed you what's been marked as 14 MSD 1030. As you just mentioned, that you had not 15 seen this marketed, and I realize that suggests that 16 you're not familiar with this document; is that 17 correct? 18 That's correct. Α. 19 Is it fair to say, if you turn to page 6, 20 where it says what implants are used --21 Α. There's no page on this. 22 I understand. It's the sixth page.

251 the top it says what happens during surgery. On the 2 bottom it says what implants are used. Do you see 3 it, sir? 4 Α. Yes. 5 Q. On the bottom, does that appear to be a very similar implant to what we just looked at in 7 MSD 1029? 8 MR. AMON: Objection; beyond the 9 scope, speculation. 10 Α. I'm not familiar with this implant so --11 I'm just asking if it looks the same or 12 similar to what's represented, for example, in 13 figure 11 of MSD 1029? 14 That's a single implant, that's correct. Α. All right. Thank you, sir. 15 Q. 16 (MSD Exhibit 1018, "Medtronic 17 VERTE-STACK PEEK Stackable Corpectomy 18 Device Surgical Technique", marked for 19 identification, this date.) Thank you, sir. You've been handed a 20 Q. 21 document identified as MSD 1018. I'll represent for 22 you that this is the Medtronic Sofamor Danek PEEK

252 Stackable Colpectomy Device Surgical Technique. Do 2 you see that, sir? 3 Α. Yes. 4 So this describes -- as a person of skill Q. 5 in the art what is it your impression that this 6 document describes? 7 This illustrates a modular stackable cage 8 that is used for a colpectomy, horizontal, 9 multiple-level colpectomy. 10 Q. Have you ever used the VERTE-STACK system, 11 sir? 12 I have used something from Medtronic of a 13 so-called stackable but I don't know this is 14 VERTE-STACK and the material is made out of PEEK. Ι 15 don't know whether the name is a VERTE-STACK. 16 If you could, sir, turn to what appears to Ο. 17 be page 6, step 5 that talks about device insertion 18 and placement. 19 Yes, sir. Α. 20 You see there, sir, it describes the Q. 21 VERTE-STACK device and I'll read the sentence:

"Where you thread the inserter rod into the

253 appropriate hole on the center device for the 2 approach used (anterior, oblique or lateral)." 3 Did I read that correctly, sir? 4 Α. Yes. 5 O. So is it fair to say that this device, the 6 VERTE-STACK device is designed for an anterior, 7 oblique, or lateral approach? 8 Α. Yes. 9 Q. That's all I have on that. One last 10 question about the VERTE-STACK system, sir. You see 11 on the last page the important information on 12 VERTE-STACK's spinal system? The last page. 13 sorry, sir, the second-to-last page where it talks 14 about important information on the VERTE-STACK 15 system, that page? 16 Α. Yes, I'm looking at the page. 17 Okay, sir. You see the first sentence O. 18 says: "The VERTE-STACK spinal system is intended 19 for a vertebral body replacement to aid in the 20 surgical correction and stabilization of the spine." 21 Did I read that correctly? 22 Α. Correct.

254 So VERTE-STACK is a vertebral body O. 2 replacement, correct, sir? 3 Α. Yes. 4 Thank you. Backing up, sir, to the Q. 5 discussion of the Frey reference and actually the 6 Boomerang implant, have you actually used the 7 Boomerang? 8 Yes, I have. Α. 9 Q. Do you know when you first started using 10 it? 11 I couldn't tell you a date. Offhand I Α. 12 couldn't even tell you how many times I've used the 13 Boomerang itself. I've done many TLIFs, and the 14 Boomerang is one of them that I've used. 15 So the only way you've put it in is as a O. 16 TLIF? 17 That's what the brochure directs us Α. Yes. 18 and that's what the guide is designed for. 19 MR. SCHWARTZ: Mark this as MSD 20 1017. 21 (MSD Exhibit 1017, 1/5/2010 NASS 22 memo re: Lateral Interbody Fusion

```
255
1
                    (XLIF, DLIF) of the Lumbar Spine,
2
                    marked for identification, this date.)
3
    EXAMINATION BY MR. SCHWARTZ:
4
               Sir, have you seen this document before,
5
    MSD 1017?
6
         Α.
               No, I've not seen this before but it comes
7
    from NASS. Can I read it?
8
               You may read it, sir.
9
          Α.
               Thank you.
10
          Q.
               Admittedly I'm running out of time.
11
    Unfortunately it's only four pages long.
12
               (Witness reads.) Should I read it all or
13
    you want to ask something?
14
               I was ready to ask questions about it but
15
    you wanted to read it.
16
               I don't want to -- maybe you want -- I
17
    don't want to waste your time.
18
               That sounds great, sir.
          O.
19
               If I need to read it, I will.
20
          Q.
               Okay, sir. I'm referring primarily to the
21
    conclusions that appear to be presented at the
22
    bottom of page 3 and those bullet points.
```

256 You would pick the tail end that I haven't Α. 2 read. 3 Sorry, sir. And I guess, going to the Ο. 4 second-to-last bullet, it says: "XLIF and DLIF 5 should be coded and reimbursed as an ALIF"; is that 6 correct? 7 Α. Yes. 8 Ο. XLIF and DLIF are both what we've been 9 discussing earlier today as transpsoas lateral 10 procedures, correct, sir? 11 Α. Correct. 12 So the NASS apparently indicates at the Ο. 13 next sentence: "The technical execution and 14 surgical principles of LIF are sufficiently 15 analogous to, if not a variation of, ALIF, "correct? 16 Α. Mm-hmm, yes. 17 So NASS has come to the conclusion that a Ο. 18 transpsoas -- strike that -- a transpsoas lateral 19 approach is analogous to, if not a variation of, 20 ALIF, correct? 21 MR. AMON: Objection, the 22 document speaks for itself.

257 NASS here is trying to get reimbursement 2 for the doctors so they are -- the reimbursers will 3 reimburse for an ALIF and to take a quote unquote newer -- not an approach. We say the approach has 5 been there a long time but to take an evolving 6 technology that is beneficial to the patient, they 7 are trying to get approval so both Medtronic and 8 NuVasive gets reimbursed also. So that's what these 9 are, claims here just say reimburse as ALIF. 10 Q. And --11 That's all it's meant for. 12 And that's being used so that insurance 13 companies will reimburse for that procedure, right, 14 sir? 15 That's what it's intended for. 16 And certainly NASS is not intending to 17 commit insurance fraud; they're trying to tell the truth? 18 19 MR. AMON: Objection; speculation 20 as to what NASS is trying to or not 21 trying to do. 22 0. You can answer.

- 1 A. NASS is a multi-disciplinary spine
- organization that's trying to make sure patients that
- need care gets the best care. As you and I have been
- 4 discussing today, the evolution of spinal procedure
- 5 has gone from wide open to less open to minimally
- invasive, giving you better outcome for the patient
- <sup>7</sup> and faster recovery.
- NASS's point here is to say that when
- 9 you do an XLIF or DLIF, the procedure is as demanding
- 10 as that of an ALIF. That's all they're trying to
- <sup>11</sup> say.
- Q. What they're saying though is that it's
- analogous to, if not a variation of ALIF.
- 14 A. It allows you, because of difficulty, the
- time amount and the training of the surgeons, okay,
- it's analogous to that of an ALIF so the
- reimbursement can be coded as an ALIF. This has
- nothing to say about anything technical. This is
- merely a description of an approach to the spine that
- is better than a big open procedure or a
- 21 laparoscopic, which is risky.
- Q. Well, sir, isn't it because of the fact

- that the implant is basically sitting in the same
- place, too, from an ALIF?
- 3 A. Not at all.
- Q. It's sitting in the anterior portion of
- 5 the space, right?
- 6 A. So does the PLIF cage. It clearly says, in
- <sup>7</sup> the last sentence, if you read, that it's not.
- Q. Well, actually the last sentence -- I'm
- 9 sorry, which last sentence are you referring to, the
- 10 last sentence in that bullet or the next bullet?
- 11 A. "XLIF and DLIF, which are anterior
- procedures, should not be confused with posterior
- 13 procedure" --
- Q. Right.
- 15 A. -- "that have similar sounding names, such
- as TLIF, PLIF and GLIF."
- Q. Right. So it's saying XLIF and DLIF are
- 18 anterior procedures?
- 19 A. It's just saying that it's a lateral
- approach, transpsoas to the vertebral body, and they
- 21 want it to be reimbursed as that of an ALIF because
- of the technical difficulty, and the training

- 1 required for the surgeons, it's beneficial to the
- patient. So it is meant to -- it is really meant to
- benefit the patient of able to get a procedure and be
- 4 reimbursed.
- <sup>5</sup> Q. While being accurate in their discussion
- to the insurance company, correct?
- 7 MR. AMON: Objection; the
- document speaks for itself.
- 9 A. It didn't say anything about accurate to
- 10 the insurance company. It just merely said that you
- 11 are using an approach that is safe and it benefits
- 12 the patient.
- Q. Okay, sir, but I thought we got to the
- point where the purpose of this was to make sure
- that the surgeon was reimbursed, correct?
- A. And the company manufacturing it is
- reimbursed, but the purpose, when NASS does allow
- things, is to make sure it benefits the patient
- 19 first.
- Q. I understand that, sir.
- A. That's its one and only purpose. By not
- being approved, not having a code, then the patient

261 don't benefit. 2 MR. AMON: Mr. Schwartz, I'm 3 pretty sure we've over time so I don't 4 know if you want to wrap it up. 5 Q. The entities that are reimbursing are the 6 insurance companies, correct? The insurance 7 companies are the ones paying for these procedures, 8 at least in part? I didn't want to ask a compound 9 question by saying other entities. So the insurance 10 companies are reimbursing at least in part, right? 11 What do you mean by "in part"? 12 As opposed to other entities. Let me 13 strike the question. 14 Reimbursement is done by either the 15 insurance companies, the government, or an 16 individual like the patient, correct? 17 Α. Correct. 18 Okay. And so certainly when NASS is 19 issuing this kind of a statement, it's for the 20 purpose of getting the insurance company or the 21 government to pay for that surgery, correct? 22 MR. AMON: Objection; asked and

262 1 answered. 2 NASS is doing this mainly because of the Α. 3 patients are not covered of whatever insurance they 4 have or they have a self pay. They will not get this 5 procedure which is beneficial to them versus a TLIF procedure because a TLIF procedure is more painful 7 and longer time recovery to a procedure that allows 8 the patient to have the procedure done and be up and 9 be ambulating and recovering quicker and back to 10 activities quicker. 11 NASS here is just saying the technical 12 procedure that you're doing on the XLIF or a DLIF is 13 equivalent in time, skill to that of an ALIF, and you 14 are stabilizing, as you said, the anterior column. 15 Q. Okay. Thank you, sir. We'll wrap up that 16 line. 17 MR. SCHWARTZ: I take it I've run 18 out of time? 19 MR. AMON: I think you're over. 20 Maybe we should ask. 21 THE STENOGRAPHER: Nine minutes. 22 MR. SCHWARTZ: Nine minutes over?

	263
1	THE STENOGRAPHER: Yes.
2	MR. AMON: Let's go off the
3	record for ten minutes. I'm going to
4	ask you, are you passing the witness
5	at this point?
6	MR. SCHWARTZ: I have more to ask
7	but I concede that I'm at seven hours,
8	so we've got to decide if we need more
9	time but I know we agreed that this
10	deposition would be 7 hours.
11	MR. AMON: Just like we did with
12	Dr. Hynes.
13	MR. SCHWARTZ: So that's where we
14	are.
15	MR. AMON: So, Mr. Schwartz, are
16	you passing the witness or not?
17	MR. SCHWARTZ: Well, like I said,
18	I have more to ask.
19	MR. AMON: Well, based on our
20	agreement Dr. Yuan has made
21	MR. SCHWARTZ: Fine. I pass the
22	witness but I'm not done yet, how's

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	264
1	that?
2	MR. AMON: Well, can you state
3	for the record that you're passing the
4	witness and you have no further
5	questions at this time?
6	MR. SCHWARTZ: No, I said I pass
7	the witness based on our agreement
8	that it would go seven hours.
9	MR. AMON: Well, then I'll
10	interpret that as saying you're
11	passing the witness and you've
12	completed your direct
13	cross-examination or
14	cross-examination.
15	MR. SCHWARTZ: Okay, and I have
16	not represented that I've completed
17	but I am willing, for today, to live
18	to the agreement of seven hours.
19	MR. AMON: So we'll go off the
20	record then.
21	MR. NELSON: Jeff, could you
22	clarify

	265
1	MR. AMON: Before we go off the
2	record then, are you going to ask him
3	to clarify the record?
4	MR. NELSON: I can. You have
5	something in mind that I'm not
6	understanding of whether you think
7	you're entitled to more time or not?
8	Could you clarify?
9	MR. SCHWARTZ: Well, sure. We
10	can talk about it in detail if you'd
11	like. I'm not done asking questions.
12	There's three IPRs that are going on.
13	I fully agree and admit that I agreed
14	to seven hours going into this.
15	Now, of course, I had no idea going
16	into this how the questions and
17	answers would go and how much time it
18	would specifically take so there's no
19	way to predict how that would evolve.
20	I think, in fairness, the rules can be
21	read to give me three, seven-hour
22	depositions of Dr. Yuan because we

	266
1	have three procedures going on.
2	That being said, we agreed to
3	seven hours for cross and I'm willing
4	to live with that agreement. I have
5	to go back and decide am I going to
6	ask for another deposition and justify
7	that either to you or to the PTAB, and
8	if we want to talk about it some more,
9	we might want to let Dr. Yuan take a
10	break while we discuss this.
11	MR. AMON: I agree with that.
12	Why don't we let Dr. Yuan take a
13	break.
14	(Whereupon, the witness was then
15	excused.)
16	MR. AMON: Now, Mr. Schwartz, we
17	had an agreement that went both ways
18	where we agreed to be limited to
19	Dr. Hynes to seven hours. We lived by
20	that agreement. And it's a
21	goose-gander situation here where we
22	lived to seven hours; you should be

	267
1	expected and should live to the same
2	seven hour period. If you're now
3	going to renege on the agreement that
4	we had, I'd like to know that now.
5	MR. SCHWARTZ: How am I reneging
6	on the agreement? I just passed the
7	witness to you and I fully agreed on
8	record that I said that I would do my
9	cross for seven hours.
10	MR. AMON: Because you're not
11	you're attempting to leave open the
12	deposition.
13	MR. NELSON: You're saying
14	MR. AMON: Let him speak.
15	MR. SCHWARTZ: How is that not
16	living to my agreement that this
17	deposition went for seven hours? I
18	could not possibly predict in advance
19	that I was going to be debating what
20	the meaning of necessary or rational
21	or motivated was to someone who used
22	those words in their Declaration, and

	268
1	we wasted a lot of time going back and
2	forth on that and we wasted time with
3	him reading his own documents, not
4	just new documents, his own documents,
5	before answering questions.
6	Now, I appreciate on the record
7	you advised him to read the documents,
8	so he went ahead and took your advice
9	and read those documents. That all
10	goes into how long this takes.
11	MR. AMON: You don't need to
12	raise your voice, Mr. Schwartz.
13	MR. SCHWARTZ: I'm just answering
14	your question.
15	MR. AMON: You're getting
16	aggressive and it's intimidating me
17	here so to the extent that you need
18	to want to have a rational
19	discussion without raising your voice,
20	we can do that but to the extent that
21	you're going to insist on pounding the
22	table

	269
1	MR. SCHWARTZ: I didn't pound the
2	table.
3	MR. AMON: That was
4	MR. SCHWARTZ: Mr. Martin, did
5	you see me pound the table?
6	MR. MARTIN: You did not pound
7	the table.
8	MR. AMON: You're going to insist
9	on raising your voice and having a
10	heated discussion, we can end this.
11	To the extent you need to go to the
12	Board, go ahead and do that. As far
13	as I'm concerned, this deposition is
14	closed for purposes of your direct
15	examination of Dr. Yuan.
16	MR. NELSON: Cross.
17	MR. AMON: Cross.
18	MR. SCHWARTZ: So the record is
19	clear, I didn't raise my voice any
20	louder than Mr. Amon just did.
21	MR. AMON: Come on.
22	MR. SCHWARTZ: So let's make sure

	270
1	that the written document accurately
2	reflects that we are generally at the
3	same decibel level.
4	MR. AMON: I disagree with that
5	but that's fine.
6	MR. SCHWARTZ: We agree to
7	disagree.
8	MR. NELSON: So you're going to
9	be done with cross today; you're going
10	to reserve to petition the Board for
11	more days, is that accurate?
12	MR. SCHWARTZ: I agree that I
13	completed my seven hours that we
14	agreed to.
15	MR. AMON: Why don't we take a
16	break.
17	(5:24 p.m.)
18	(A recess was then taken.)
19	(5:47 p.m.)
20	MR. SCHWARTZ: So the record is
21	clear, counsel for NuVasive felt it
22	was appropriate to sit in a conference

	271
1	room with the witness during the break
2	to apparently coach the witness before
3	the redirect begins. So I'm
4	registering an objection, which is
5	plainly against the rules of the
6	Patent and Trademark Office and as far
7	as I'm concerned, this entire redirect
8	should be stricken from the record and
9	it certainly will be if they try to
10	rely on it.
11	MR. AMON: And I would just
12	respond to Mr. Schwartz's statements
13	that the Patent Office has issued case
14	law on this including specifically
15	Focal Therapeutics, Inc. Versus
16	SenorX, Inc, indicating that once
17	cross-examination is completed,
18	defendant counsel is permitted to
19	confer let me put it in for the
20	record, the case number, it's case
21	IPR2014-00116. That defendant counsel
22	is permitted to confer with the

	272
1	witness once cross-examination is
2	completed and the witness has been
3	passed.
4	MR. SCHWARTZ: I'm sorry, could
5	you say that again? You can read it
6	from the record or say it.
7	MR. AMON: I can say it. What
8	part do you need?
9	MR. SCHWARTZ: What's the
10	citation?
11	MR. AMON: IPR2014-00116.
12	MR. NELSON: Paper 19.
13	EXAMINATION BY MR. AMON:
14	Q. Dr. Yuan, do you recall Medtronic counsel
15	putting in front of you Exhibit MSD 1107 mine has
16	notes, I'd rather not. I'm sorry, let me ask my
17	question again.
18	Dr. Yuan, do you remember Medtronic
19	counsel putting in front of you Exhibits 1107, 1106
20	and 2012 and asking you some questions about those
21	exhibits during your deposition?
22	MR. SCHWARTZ: Objection,

	273
1	leading.
2	A. I've seen these three.
3	Q. Okay. And do you recall Medtronic counsel
4	asking you let's use as an example 1107 which you
5	have in front of you Medtronic counsel asking you
6	questions about the statement in the bottom
7	left-hand corner of page 1, the sentence that reads:
8	"The VERTE-STACK Telamon PEEK Vertebral Body Spacer
9	is a vertebral body replacement device intended for
10	use in the thoracolumbar spine (T1 to L5) to replace
11	a collapsed, damaged, or unstable vertebral body due
12	to tumor or trauma (i.e. fracture)."
13	Do you remember him asking you questions
14	about that sentence?
15	A. Yes.
16	Q. And do you remember Medtronic counsel
17	asking you questions about similar statements in
18	Exhibits 1106 and 2012?
19	A. Yes.
20	Q. Okay. Dr. Yuan, as a person of ordinary
21	skill in the art, do you understand there to be a
22	difference between a vertebral body replacement

274 device and an interbody fusion device? 2 MR. SCHWARTZ: Objection; 3 leading, form. 4 The interbody fusion device is a device 5 that has specific -- specific length, specific width 6 because of the different routes of implantation and 7 different markers, different than the vertebral body 8 replacement which means you're replacing the whole 9 segment. 10 When you replace the whole segment of 11 bone, the vertebral body, that is not the disk. 12 is the vertebral body including a disk, above and 13 below. So it's a vertebral body and two motion 14 segments. Let me ask you a fairly simple question. 15 16 As a surgeon of ordinary skill in the art, would you 17 use the Telamon device reflected in Exhibit MSD 1107 18 as a vertebral body replacement? 19 The Telamon is designed as a PLIF implant 20 and the dimensions are way smaller and also the 21 leading edge and the trailing edge, the lordotic

angle is also intended for push approach, not an

275 anterior or lateral approach. 2 From a clinical standpoint could you use Ο. 3 the Telamon implant pictured in MSD 1107 as a vertebral body replacement the way you've described 5 that --6 MR. SCHWARTZ: Objection; 7 leading, form. 8 The Telamon that I'm looking at, MSD 1107, 9 that is both illustrated here and also described in 10 the -- this brochure by Medtronic is clearly defined 11 as a PLIF implant, not a vertebral body replacement. 12 And when you say "PLIF implant" you mean a Ο. 13 PLIF interbody fusion device? 14 That's correct. Α. 15 O. Okay. Would your responses be -- well, 16 strike that. 17 Let me take these one at a time. If I ask 18 you to turn now to Exhibit MSD 1106. 19 Yes, sir. Α. And that is the document referring to the 20 Q. 21 Vertebral Spacer-PR by Synthes, correct? 22 Α. Yes.

- 1 Q. You analyzed this document as part of --
- in forming your opinions in this matter, correct?
- 3 A. Yes, I did.
- Q. As a surgeon of ordinary skill in the art,
- 5 in your opinion could the device pictured in MSD
- 6 1106 be used as a vertebral body replacement device?
- 7 MR. SCHWARTZ: Objection to form,
- 8 leading.
- 9 A. The device in this illustration and also in
- 10 this brochure is designed as a vertebral spacer, and
- vertebral spacer meaning an interbody spacer because
- of the dimensions and because of the contours, and,
- again, this is designed for a posterior lumbar
- interbody approach, the force of the lordotic angle,
- and also because of the sizing.
- Q. Sticking still on MSD 1106, Dr. Yuan, are
- you aware of a Synthes Vertebral Spacer-AR?
- 18 A. Yes.
- Q. And do you know what that device -- how
- 20 that device is different from the Vertebral
- 21 Spacer-PR?
- 22 A. I have not seen one of those devices.

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277 O. Let me see --2 I've only read about it in their Α. 3 descriptions. 4 Dr. Yuan, can I ask you to turn to your Q. 5 Declaration in the '334 matter, please. I'll pull 6 that out for you. I believe that's it. 7 If you could turn to page 43 of this 8 document, paragraph 83, and if you could read that 9 entire paragraph to yourself and let me know when 10 you've done that, please. 11 Α. Page 43 --12 You can just read it to yourself. Ο. 13 Okay. (Witness complies.) Okay. Α. 14 Dr. Yuan, having read paragraph 83, do you Q. 15 have an understanding as to the difference between 16 the SVS-AR device and the SVS-PR device? 17 Α. Yes. 18 What is that? Ο. 19 SVS-PR is much smaller in dimension and I 20 suppose in length and also in width. 21 Is it your understanding that the SVS-AR Q. 22 is an anterior -- is a device designed for anterior

278 insertion? 2 Α. Yes, it is designed for and that is what is 3 stated. 4 You can put that aside, Dr. Yuan. 5 Dr. Yuan, if I could ask you now turn to 6 the Exhibit NuVasive 2012 which is the Boomerang 7 brochure I think. Right there. And, again, I'll 8 just -- to make sure the record is clear, if you 9 turn to the last page, the back page, do you recall 10 Medtronic counsel asking you questions about the 11 statement on page 6, starting: "The Boomerang 12 VERTE-STACK PEEK Vertebral Body Spacer is a 13 vertebral body replacement device? Do you recall 14 questions about that statement? 15 Α. Yes. 16 As a person of ordinary skill in the art, 17 do you consider to be the Medtronic Boomerang 18 VERTE-STACK PEEK device a vertebral body replacement 19 device? 20 MR. SCHWARTZ: Objection to form 21 and leading. 22 The Boomerang is intended and designed, as Α.

279 illustrated by this brochure, that it really is a 2 TLIF approach implant and designed from a 3 posterolateral approach and not as a vertebral replacement, vertebral body replacement. 5 Q. And when you say a TLIF device, do you mean a TLIF interbody fusion device? 7 Α. That's correct. 8 MR. SCHWARTZ: Objection, 9 leading. 10 Now, Dr. Yuan, I want to switch gears a 11 little bit. And do you recall Medtronic counsel 12 asking you questions as to whether -- and I'm going 13 to paraphrase because I don't remember the exact 14 language, but as to whether it would have been obvious for a surgeon to place two medial markers in 15 16 an implant that was going in laterally? Do you 17 recall those questions earlier today? 18 MR. SCHWARTZ: Objection to form; 19 mischaracterizes prior record. 20 Yes, I recall the question. 21 Okay. Now, I want to get a little clarity Q. 22 on your response there. Dr. Yuan, is it your

- opinion that it would have been obvious to a person
- of ordinary skill in the art before March 29th, 2004
- for a person to place two medial markers, radiopaque
- 4 markers in an interbody fusion device that was going
- <sup>5</sup> in laterally?
- 6 MR. SCHWARTZ: Objection to form
- and leading.
- 8 A. Before 2004 there was no lateral implant
- 9 that had two markers in the medial plane.
- Q. So in your opinion would it have been
- obvious to a person, prior to March 2004, to place
- two markers in the medial plane?
- MR. SCHWARTZ: Objection,
- leading.
- 15 A. Not before the patent came out for the
- 16 correct implant.
- 0. What changed after 2004?
- 18 A. After the patent, the '334 patent came out,
- and the '156 patent, that's the marker to tell you
- that you need a medial marker and indicated you need
- two markers to get a better control rotation.
- Q. Was 2004 the approximate time when the

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281
    CoRoent XL implant was launched by NuVasive?
2
                         MR. SCHWARTZ: Objection; form,
3
                    leading.
 4
         Α.
               Yes, after that.
5
               Let met ask one -- hopefully one last
         O.
6
    question. Going back for a second to the devices
7
    that are pictured by MSD 1106, the Synthes VS-PR
8
    device, Exhibit MSD 1107 the Medtronic device, and
9
    the NuVasive 2012, the Boomerang device, Dr. Yuan,
10
    would a surgeon of ordinary skill in 2004 have
11
    understood these devices to be vertebral --
12
    vertebral body replacement devices?
13
                         MR. SCHWARTZ: Objection;
14
                    leading, form, compound.
15
                    A person skilled in the art would not
         Α.
16
    have interpreted any of these as vertebral body
17
    replacements.
18
               In 2004?
         Ο.
19
               In 2004.
         Α.
20
         Q.
               What about today?
21
                         MR. SCHWARTZ: Same objections,
22
                    leading the witness, form.
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		282
1	A.	Not today either.
2		MR. AMON: I have no further
3		questions for Dr. Yuan.
4		
5	EXAMINATI	ON BY MR. SCHWARTZ:
6	Q.	Okay. Dr. Yuan, we're back on
7	cross-exa	mination.
8	A.	Yes, sir.
9	Q.	You understand you're under oath?
10	A.	Yes, sir.
11	Q.	First off, during the break after my
12	cross-exa	mination, you met with Mr. Amon; right?
13	A.	We were in the same room.
14	Q.	And you were talking to each other,
15	correct?	
16	A.	We were talking.
17	Q.	What did you talk about?
18		MR. AMON: I'm going to instruct
19		the witness not to answer that
20		question as calling for work product.
21		MR. SCHWARTZ: So you're not
22		going to let the witness explain what

	283
1	you said to him?
2	MR. AMON: Correct.
3	MR. SCHWARTZ: When you were
4	coaching him before the redirect?
5	MR. AMON: You can characterize
6	it however you want, Mr. Schwartz.
7	EXAMINATION BY MR. SCHWARTZ:
8	Q. Dr. Yuan, these questions that you were
9	presented on redirect
10	A. Yes, sir.
11	Q during the break, did counsel for
12	NuVasive discuss with you this concept of vertebral
13	body replacements?
14	MR. AMON: Again, I'm going to
15	instruct the witness not to answer as
16	calling for work product. Objection,
17	sorry.
18	Q. You're going to take that instruction,
19	sir?
20	A. Yes, sir.
21	Q. You're not going to tell me whether or not
22	counsel talked to you about changing your testimony?

	284
1	MR. AMON: Objection;
2	mischaracterizes, assumes facts not in
3	evidence and, again, I'm going to
4	instruct the witness not to answer the
5	question.
6	Q. Sir, you did change your testimony, right?
7	A. I didn't change my testimony. What was
8	stated in here, you asked me was it written here. My
9	answer was yes. You didn't ask me was this implant
10	actually used, which is what he asked.
11	Q. Okay, sir, are you aware of all surgeons'
12	use of that product, any of those products you've
13	now talked about on redirect?
14	A. Ask me that one more time, Counsel.
15	Q. Are you aware of all uses of those
16	products by all surgeons at any time?
17	A. As a vertebral body replacement?
18	Q. All uses, sir. I'm asking you are you
19	aware of all uses of those products that you just
20	testified about on redirect by any surgeon at any
21	time?
22	A. That is way too broad. I can't answer your

285 question in the way that you shouted it out. 2 So your answer is no; correct? O. 3 Α. No, sir. You're not aware? Q. 5 Α. I didn't say no. 6 O. So are you aware? 7 You qualify and you tell me specifically Α. 8 which --9 Q. No, sir, I'm not going to qualify my 10 question. I'm going to ask my question and I'd like 11 to get an answer; okay? Now my question, sir, is --12 and I'll ask them one at a time -- as to the Telamon 13 represented in MSD 1107, are you aware of all uses 14 by any surgeon at any time of that product? 15 Α. No. 16 Okay. Thank you, sir. And as to the O. 17 Vertebral Spacer-PR represented in MSD 1106, are you 18 aware of all uses at any time by any surgeon of that 19 product? 20 Α. No. And the same for the Boomerang as 21 Ο. 22 represented in NuVasive 2012, are you aware of all

286 uses at any time by any surgeon of that product? 2 Α. No. 3 So you can't state categorically that those three implants have never been used as 5 vertebral body replacements, correct? 6 MR. AMON: Objection; 7 mischaracterizes Dr. Yuan's testimony. 8 What I tried to tell you, what I tried to 9 respond to you, Counsel, is to be as accurate as I 10 can, but these implants, the sizes, the design are 11 designed as vertebral body fusion devices, 12 intervertebral fusion devices. None of these to my 13 knowledge are used as a vertebral body replacement. 14 But you don't know for a fact that no one has ever used them; correct, sir? 15 16 I can tell you to the best of my knowledge 17 it has not been used. 18 But you don't know that as a fact here 19 under oath; correct, sir? 20 MR. AMON: Objection, asked and 21 answered.

Henderson Legal Services, Inc.

I'm under oath.

22

I'm answering as

287 accurately as I possibly can. 2 Okay, sir, but you've already testified Ο. 3 that you don't know -- you're not personally aware of all uses of these devices, correct? 5 MR. AMON: Objection; asked and 6 answered. 7 We are asking as a vertebral body Α. 8 replacement. So the answer is no. 9 Q. Not my question. I'd appreciate if you'd 10 answer my questions. You were certainly willing to 11 answer your counsel's questions. I'd appreciate the 12 same treatment when answering my questions. You 13 seem to like to fight with me when it comes to 14 answering my questions --15 MR. AMON: Argumentative. 16 -- but you're cooperating with your Ο. 17 counsel when he's asking you leading questions. 18 MR. AMON: Mr. Schwartz, ask a 19 question. 20 I'm going to ask you to please answer my Q. 21 questions that I'm asking you, rather than trying to 22 avoid answering them, give me at least the same

288 courtesy that you showed Mr. Amon; okay, sir? 2 I'm going to ask you again, fresh 3 question: Can you state with absolute certainty that no surgeon has ever used the Boomerang implant as a vertebral body replacement? 5 6 MR. AMON: Objection; asked and 7 answered for the fourth time now. 8 MR. SCHWARTZ: I never asked that 9 question before. 10 MR. AMON: Yes, you did. 11 MR. SCHWARTZ: No, I didn't. 12 MR. AMON: Read the record back. 13 Α. You have narrowed it down to a vertebral 14 body replacement, so the answer I can tell you is I 15 can say to the best of my knowledge I know of no 16 surgeon having used it. 17 But to the best of your knowledge you 18 admitted you don't know what all surgeons have done; 19 correct, sir? 20 But you're using all indications. 21 you're talking about vertebral body replacement. 22 Ο. So you can state with absolute certainty

- under penalty of perjury that nobody has ever done
- 2 it?
- A. To my knowledge, under perjury, in all
- 4 statements I can say unequivocally the Boomerang, as
- 5 to the sizing and all is stated here has never been
- 6 used as a vertebral body replacement. It does not
- <sup>7</sup> have the size or the dimension, period.
- Q. Okay. But you're qualifying your answer
- 9 in a way that makes it nonresponsive to my question.
- 10 I'm going to ask the question and I ask you to be
- 11 responsive to my question; okay?
- 12 A. Do my best.
- Q. Again, sir, I'm not asking you to your
- 14 best. I'm asking you as a matter of fact do you
- have the knowledge; okay? Not asking you to your
- best. I'm asking you do you have the knowledge.
- Can you absolutely state that no doctor has
- ever inserted a Boomerang implant as a vertebral
- 19 body spacer?
- A. I'd like to answer your questions also very
- 21 clearly but you leave the thing in broad
- generalities, so it would be specific if there's a

290 Boomerang implant that is demonstrated in front of 2 me, this particular implant, these sizes, and all of 3 these, then I can answer to you unequivocally nobody has ever used it for a vertebral body replacement. 5 Q. Interesting. 6 It's the truth. It hurts. 7 Sir, how can it possibly be the truth if 8 you don't know with absolute certainty what all 9 surgeons have done? 10 I am absolutely certain that this Α. 11 boomerang, the sizes as shown in this brochure, that 12 to the best of my knowledge no surgeon could use this 13 as a vertebral body replacement. 14 And that's to the best of your knowledge? Ο. 15 That's what I'm answering as honest as I 16 can. 17 Despite the fact that it's called a Ο. 18 vertebral body replacement device; correct, sir? 19 Α. When they're saying a vertebral body 20 spacer, it's not a vertebral body replacement. 21 Q. Okay.

Α.

Spacer.

291 Okay, sir, on the last page of the 2 document you just referred to as a vertebral body 3 spacer, back page, last sentence -- actually not the last sentence, it says that: The Boomerang 5 VERTE-STACK PEEK Vertebral Body Spacer is a 6 vertebral body replacement device intended for use 7 in the thoracolumbar spine (T1 to L5) to replace a 8 collapsed, damaged, or unstable vertebral body due 9 to tumor or trauma (i.e. fracture). That's what it 10 says, right? 11 MR. AMON: Objection; document 12 speaks for itself. 13 MR. SCHWARTZ: The document is 14 not talking. 15 MR. AMON: Document reads what it 16 reads, Mr. Schwartz. 17 MR. SCHWARTZ: The document is 18 not reading to me either. 19 They talk about to replace a collapsed, 20 damaged, or unstable vertebral body. The sizing here 21 cannot be used, just doesn't fit. 22 But it says it is a vertebral body Ο.

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292
    replacement device; correct, sir? Those are the
2
    words on the page.
3
               It says it in the Medtronic document here
    but that's not what you can use it for.
5
               That's what it's described as, correct?
         Q.
6
                         MR. AMON: Objection; asked and
7
                    answered at least ten times now.
8
                         MR. SCHWARTZ: Never used those
9
                    words in a question before.
10
                         MR. AMON: Doesn't matter, the
11
                    substance of the question is the same.
12
    EXAMINATION BY MR. SCHWARTZ:
13
               You can answer, sir.
         O.
14
               I've already answered.
15
         Q.
               So you're refusing to answer my question
16
    now?
17
               I didn't say I refuse. I've already
         Α.
18
    answered the question.
19
               The document describes the Boomerang
20
    VERTE-STACK PEEK Vertebral Body Spacer as a
21
    vertebral body replacement device, doesn't it, sir?
22
                         MR. AMON: Objection; asked and
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Yuan, M.D., Hansen A.

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293
1
                    answered.
2
         Α.
               This device here, as one skilled in the
3
    art, in no way can be implanted as a vertebral body
    replacement. It is an interbody spacer.
5
         O.
               Despite what the words on the document
    say?
7
               That's correct.
         Α.
8
                         MR. SCHWARTZ: I'm going to mark
9
                    this MSD 1032.
10
                         (MSD Exhibit 1032, VERTE-STACK
11
                    Spinal System 510(k) summary, marked
12
                    for identification, this date.)
13
    EXAMINATION BY MR. SCHWARTZ:
14
               Sir, you've been handed a document --
         Q.
15
                         MR. AMON: Do you have copies,
16
                    Mr. Schwartz?
17
                         (Document handed.)
18
                         MR. AMON: Thank you.
19
         Q. -- identified as MSD 1032. Can you
20
    identify that for us, sir?
21
         Α.
               VERTE-STACK Spinal System, 510(K) summary.
22
    This is document 32.
```

294 So this a document that indicates the Ο. 2 regulatory approval for the VERTE-STACK Spinal 3 System; is that correct, sir? 4 MR. AMON: Objection; beyond the 5 scope, speculation. 6 Α. Counselor, you showed me another one of the 7 VERTE-STACK Stackable Vertebral Body Replacements. 8 Ο. I'm sorry? 9 You showed me another brochure of the 10 VERTE-STACK Stackable Vertebral Body Replacement, 11 correct? 12 I'm sorry, sir, I'm asking the questions 13 here, not you. 14 I'm reading this because it tells me 15 that -- I understand you ask a question. 16 trying to be combative. I'm just trying to clarify. 17 The VERTE-STACK device may be used 18 individually or stacked together in order to 19 accommodate, because you showed me the VERTE-STACK 20 that is stacked together as vertebral body 21 replacement for colpectomy. That's what I'm asking.

You showed me that and I said yes, that is used for

- 1 vertebral body replacement. So that is using the
- name of VERTE-STACK Spinal.
- Okay, sir, and the Telamon product on
- 4 MSD 1107 uses the VERTE-STACK name as well, correct?
- 5 A. They do.
- Q. And the Boomerang product as identified on
- NuVasive 2012 uses the VERTE-STACK name as well,
- 8 correct?
- 9 A. That's correct.
- Q. Thank you. And if you turn to the last
- page of that document, MSD 1032, the indications for
- use for the VERTE-STACK spinal system is a vertebral
- body replacement device intended for use in the
- thoracolumbar spine (T1 to L5) to replace a
- collapsed, damaged, or unstable vertebral body due
- to a tumor or trauma (i.e. fracture); correct?
- 17 A. That is speaking about the stackable
- vertebral body replacement, not talking about any of
- this one here that you're pointing to.
- Q. Well, wait a minute, sir.
- A. They may call it the same name but it's not
- what you showed me on these so-called illustrations.

296 Okay. Sir, if we could back up a little. Q. 2 On the first page of MSD 1032 --3 Α. Yes, sir. 4 -- if you look at the fourth paragraph under Product Description, actually the third 5 6 paragraph, I'll read the sentence: "The VERTE-STACK 7 device may be used individually or stacked together 8 in order to accommodate the individual anatomical 9 requirements of the vertebral space created by the 10 colpectomy, " correct? 11 That is exactly the other one you showed 12 me, of the vertebral body replacement one. 13 Sir, can you please answer my question? Ο. 14 Can't answer if the question is not Α. 15 germane. 16 Sir, can we please stick to my questions? Ο. 17 My question is did I read that sentence correctly? 18 That's what it said in this paragraph. Α. 19 Thank you, sir. So it's true Q. All right. that the VERTE-STACK device can be used 20 21 individually. It doesn't have to be stacked,

correct?

	297
1	A. The VERTE-STACK can be used individually if
2	it's a vertebral body replacement VERTE-STACK. Not
3	the Telamon. Not the Boomerang.
4	Q. Sir, can we please stick to my questions
5	and not your questions.
6	A. I'm not using my questions.
7	Q. I'm asking you individually, the
8	VERTE-STACK device may be used individually;
9	correct?
10	A. Yes.
11	Q. Thank you. See it goes much quicker if
12	you just answer my question.
13	MR. AMON: There's no need for
14	the sarcasm, Mr. Schwartz.
15	MR. SCHWARTZ: There's no need
16	for coaching the witness, Mr. Amon.
17	MR. AMON: I didn't but you can
18	make that allegation all you want,
19	Mr. Schwartz.
20	MR. SCHWARTZ: But since you
21	won't allow a record to be created as
22	to what was said during your

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1	conference, I have no way of knowing
2	that it was not that, and I can't
3	possibly imagine another reason for
4	you to be meeting with the witness
5	before questioning him other than to
6	tell him the questions or the subject
7	matter of the questions so that you
8	can then prepare him to provide the
9	answer that you wanted.
10	MR. AMON: Are you done on the
11	soap box?
12	MR. SCHWARTZ: There's no soap
13	box.
14	(MSD Exhibit 1041, document which
15	states the CoRoent system was approved
16	by the FDA as a vertebral body
17	replacement device (unidentified),
18	marked for identification, this date.)
19	EXAMINATION BY MR. SCHWARTZ:
20	Q. You've been handed a document identified
21	as MSD 1041. I have a very simple question for you.
22	Hopefully this will go quickly. The CoRoent system

299 was approved by the FDA as a vertebral body 2 replacement device, wasn't it, sir? 3 Α. That's what it says here. Q. Awesome. 5 Α. You're welcome. 6 O. Sir, during your direct you talked about 7 whether or not you thought certain things were 8 obvious. Do you recall that testimony during your 9 redirect? 10 No. Maybe you would qualify for me? Α. 11 You don't remember talking about whether 12 or not something was obvious with Mr. Amon just a 13 few minutes ago? 14 In relationship to what? Α. Well, I believe some of the questions were 15 16 in relationship to the placement of markers. Do you 17 recall now that you had some conversations on redirect with Mr. Amon about obviousness? 18 19 Go ahead and ask your question, Counsel. Α. 20 I'll try to answer. 21 What's your understanding of what Ο.

obviousness means?

	300
1	MR. AMON: Objection; calls for a
2	legal conclusion.
3	MR. SCHWARTZ: He used the words
4	and you used the words so I'm
5	certainly entitled to know what he
6	meant. He testified to it.
7	MR. AMON: I was paraphrasing
8	your questioning and, again, I'm
9	making an objection for the record.
10	Objection; calls for a legal
11	conclusion.
12	A. Could you qualify for me what you would
13	like me to tell you? I don't want to frustrate you.
14	You look frustrated.
15	Q. I have to admit, sir, that you ask me to
16	qualify the words I use but you freely answered them
17	when Mr. Amon asked them. So I would like for you
18	to explain to me what your understanding was, if
19	any, and if you have no understanding, then just
20	tell me that, when you were asked and answered
21	questions about obviousness.
22	A. The question that was asked that I answered

301 was, was it obvious at the time for somebody skilled 2 in the art at a certain date. That was a sentence. 3 So you are asking me to qualify the word obvious? 4 What did you mean by that when you 5 answered that question or what did you understand 6 that word to mean when you answered that question? 7 MR. AMON: Objection; calls for a 8 legal conclusion. May I have my outline? Α. 10 Q. Okay. 11 I'll try to answer counsel's question. 12 So the record will reflect, the witness Ο. 13 asked Mr. Amon to hand him his cheat sheet or expert 14 report --15 You have a copy of it also so... 16 -- to be able to answer my question about 17 obviousness, although apparently he did not need any 18 documentation to be able to answer Mr. Amon's 19 question on redirect about whether or not something 20 was obvious. Go ahead, sir. 21 I'm just trying to use and give you the

correct answer to the best of my ability. That's why

- 1 I asked for the document, so I will give you the
- 2 meaning that you're looking for.
- Q. It's fair to say that you didn't need any
- documents to answer Mr. Amon's question, right?
- 5 A. Counsel, he asked it in a sentence. If you
- asked me in a sentence, I would be able to answer.
- <sup>7</sup> So I'm not a lawyer. I'm just -- I'm a doctor so I'm
- gives just trying to understand. When you ask a straight
- 9 question, I can answer it, but you are asking me to
- qualify the word obvious so I haven't given you the
- definition of what obvious is.
- 12 Q. I'm just asking you what you meant when
- you answered Mr. Amon's question.
- 14 A. I'm going to give it to you. I have to go
- to read a lot of paragraph. You would like me to
- read, because your question to me is law of
- obviousness. So I can read it to all to you,
- 18 Counsel, if you want.
- Q. Sir, I find it interesting you didn't need
- $^{20}$  to read anything to answer Mr. Amon's question. I
- just asked you what did you mean or understand when
- you answered Mr. Amon's question. You didn't have

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1	to refer to any documents to answer his question.
2	Apparently you need to refer to a document to answer
3	mine.
4	MR. AMON: Mr. Schwartz, we can
5	do without
6	MR. SCHWARTZ: Let me finish.
7	MR. AMON: You're abusing the
8	witness.
9	MR. SCHWARTZ: If that's the
10	case I'm not abusing anyone. I'm
11	trying to explain. The witness asked
12	me what an answer was that I wanted.
13	I just want an answer to my question.
14	I don't need you to read from your
15	report. I just want an answer to my
16	question.
17	A. Because you asked me to give you definition
18	of a legal term. I'm just going to give you the
19	accurate interpretation that I understand it.
20	Q. I didn't ask you for a definition of a
21	legal term, sir. All I did is ask you what your
22	understanding of the word was when you quickly

- 1 responded to Mr. Amon's question.
- A. When I responded to him, the question was
- because it was in a sentence and a sentence is
- $^4$  something that I can respond. If you ask me similar,
- 5 I will be able to respond but if you're asking me to
- give you a definition, I'm not a lawyer, didn't go to
- <sup>7</sup> law school. So you're asking me for the content of
- 8 obviousness so I need to give you a response as best
- 9 I can, as accurate as I can. That's why I'm
- 10 responding to you.
- 11 If you would like me to read you these
- paragraphs to describe it, I can.
- Q. Sir, I've simply asked you what your
- understanding of the word was when you answered the
- question. That's my question.
- What was your understanding of that word
- when you answered his question?
- A. Would you like me to tell you?
- 19 Q. I would like you to answer my question,
- $^{20}$  sir.
- 21 A. Okay, sir. It is my understanding that
- assessing the validity of a US patent based on a

- prior art analysis requires two essential steps.
- First, in an IPR proceeding, one must construe the
- 3 terms of the patent claims to understand what meaning
- 4 they would have to one of ordinary skill in the art
- 5 under the broadest reasonable interpretation that is
- 6 consistent with the specification. For purpose of my
- <sup>7</sup> analysis, I've considered Medtronic's proposed
- 8 construction (Petition at Section III.C), and find
- 9 that even under Medtronic's proposed constructions,
- the proposed grounds for rejection are lacking and
- the '156 patent claims are not obvious.
- 12 Second, after the claim terms have been
- construed, one may then assess validity by comparing
- a patent claim to a prior art. For purposes of my
- independent analysis herein, I have assumed that all
- the references cited in the grounds for rejection in
- the PTAB decisions dated February 13, 2014 are using
- 18 the SVS-PR, Telamon, Baccelli and Michelson '973 to
- be prior art. See February 13, 2014 PTAB decision at
- 20 page 19 to 20.
- Even if each of the SVS-PR, Telamon,
- Baccelli, and Michelson's 973 is considered to be a

prior art publication, I find that the proposed 2 grounds for rejection are lacking and the '156 patent 3 claims are not rendered obvious by the proposed combination cited in the grounds for rejection in a 5 PTAB decision dated February 13, 2014. 6 I understand that the teaching of the art, 7 of the prior art is viewed through the eyes of a 8 person of ordinarily skill in the art at the time the 9 invention was made. To assess the level of ordinary 10 skill in the art, I understand one can consider the 11 types of problems encountered in the art, the prior 12 solutions to those problems found in prior art 13 references, the rapidity with which innovations are 14 made, the sophistication of the technology, and the level of education of active workers in the field. 15 16 My opinion as to what constitutes a relevant person 17 of ordinary skill in the art is set forth below. 18 I understand that Dr. Hynes contends the 19 challenged claims are invalid as obvious. A patent 20 claim is invalid as obvious only if the subject 21 matter as a whole of the claimed invention would have 22 been obvious to a person of ordinary skill in the

field at the time the invention was made. This means 2 that even if all the requirements of the claim cannot 3 be found in a single prior art reference that would anticipate the claim, a person of ordinary skill in the field who knew about all this prior art would 5 have come up with the claimed invention. 7 However, I understand that a patent claim 8 composed of several elements is not proof -- is not 9 proved obvious merely by demonstrating that each of 10 its elements was independently known in the prior 11 In evaluating whether such a claim would have 12 been obvious, I considered whether Medtronic's 13 petition or the Declaration of Dr. Hynes presented an 14 articulated reason with a rational basis that would 15 have prompted a person of ordinary skill in the field 16 to combine the elements or concepts from the prior 17 art in the same way as in the claimed invention. 18 understand there is no single way to define the line 19 between true inventiveness on one hand in 20 paragraph -- in brackets (which is patentable) and 21 the application of common sense and ordinary skill to 22 solve a problem on the other hand (which is not

patentable.) For example, market forces or other 2 design incentives may be what produce a change, 3 rather than true inventiveness. 4 It is my understanding that the 5 decision-maker may consider whether the change was merely the predictable result of using prior art 7 elements according to their known functions or 8 whether it was a result of true inventiveness. 9 the decision-maker may also consider whether there is 10 some teaching or suggestion in the prior art to make 11 the modification or combination of elements claimed 12 in the patents-in-suit. Also, the decision-maker may 13 consider whether the innovation applies a known 14 technique that had been used to improve a similar 15 device or method in a similar way. decision-maker may also consider whether the claimed 17 invention would have been obvious to try, meaning 18 that a claimed invention was one of a relatively 19 small number of possible approaches to the problem 20 with a reasonable expectation of success by those 21 skilled in the art. However, I understand the 22 decision-maker must be careful not to determine

- 1 obviousness using the benefit of hindsight and the
- 2 many true inventions might seem obvious after the
- fact. I understand that the decision-maker should
- 4 consider obviousness from the position of a person of
- ordinary skill in the field at the time the claimed
- 6 invention was made and that the decision-maker should
- 7 not consider what is known today or what is learned
- 8 from the teaching of the patent.
- 9 I understand the ultimate conclusion of
- whether a claim is obvious should be based on -- upon
- 11 my determination of several factual decisions.
- 12 First, the decision-maker must assess the level of
- ordinary skill in the field that someone would have
- 14 had at the time the claimed invention was made.
- 15 Second, the decision-maker must decide the scope and
- 16 content of the prior art. Third, the decision-maker
- must decide what difference if any, existed between
- the claimed invention and the prior art.
- 19 It is my understanding that existence of
- one or more objective factors of nonobviousness can
- rebut a showing of obviousness based on prior art.
- These objective factors include:

	310
1	1, commercial success of a product due to
2	the merits of the claimed invention;
3	2, a long-felt need for the solution
4	provided by the claimed invention;
5	Unsuccessful attempts by others to find the
6	solution provided by the claimed invention;
7	And, number 4, copying of the claimed
8	invention by others;
9	5, unexpected and superior results from the
10	claimed invention;
11	6, acceptance by others of the claimed
12	invention as shown by praise from others in the field
13	or from the licensing of the claimed invention;
14	7, teaching away from the conventional
15	wisdom in the art at the time of the invention;
16	8, other evidence tending to slow nonob
17	to show nonobviousness.
18	Independent invention of the claimed
19	invention by others before or at about the same time
20	as the named inventor thought of it and.
21	Other evidence tending to show obviousness.
22	It is my understanding that in order to

- establish the second consideration of nonobviousness,
- 2 NuVasive must show a nexus between the secondary
- 3 consideration and the claimed invention.
- Are you done, sir?
- 5 Α. Yes.
- 6 Q. Okay, sir. So the record is clear, you
- 7 just read paragraphs 15 through 25 from
- Exhibit NuVasive 2020 into the record; is that 8
- 9 right?
- 10 Α. Yes, sir.
- 11 Okay. Sir, one of the things you just
- 12 mentioned in your answer, in paragraph 22, you talk
- about five lines down, "an articulated reason with a 13
- 14 rational basis." Do you see that, sir?
- 15 Α. On page?
- 16 9, paragraph 22, five lines down.
- 17 Α. Yes.
- 18 Okay. So you're using the word rational Ο.
- 19 there, correct?
- 20 Α. Yes.
- 21 I think in some of my earlier questions
- 22 you had difficulty answering them because of the

312 meaning of the word rational. So what did you mean 2 by the word rational in that sentence? 3 MR. AMON: Objection; the 4 document reads what it reads. 5 In this sentence here it means a reasonable 6 basis. 7 Ο. A reasonable basis? 8 As far as -- or a -- reasonable, correct, 9 acceptable basis, that makes sense. 10 Q. Just asking what you meant by it, sir. 11 Thank you. 12 Using that -- using that explanation of 13 what a rational basis is, because I know we had some 14 issues with my questions about whether something was reasonable or unreasonable, so I'll categorize them 15 in terms of a rational basis. 16 17 Did you have a rational basis, before you 18 conducted those two lateral surgeries that we talked 19 about with Dr. McAfee, of proceeding the way you 20 did? 21 MR. AMON: I'm going to object as 22 being beyond the scope of redirect and

313 1 I will move to have this testimony 2 stricken. You can go ahead and 3 answer. 4 We did those two cases because that is 5 the -- that's a reasonable -- it's reasonable. 6 an improved approach, to be less traumatic for the 7 patient, and that we know that it's safe as we talked 8 about before, Counsel. 9 So we did not know obviously what the 10 outcome is going to be totally but we know it was 11 safe and we know that we have done what we can to 12 document that the device will do no harm, but whether 13 it is going to give us the anticipated outcome, 14 that's the portion that we didn't know and that's 15 what we informed the patient and got the patient's 16 permission and the IRB approval, sorry. So 17 to answer you, it is a reasonable time to use those 18 devices in those two patients because the conditions 19 that the patient had at the time. 20 Thank you, sir. Getting to the Q. 21 predictable result that you refer to about three 22 lines from the bottom in that same page,

314 paragraph 22, page 9, three lines up, you talk about a predictable result. Do you see that, sir? 2 3 Α. Yes, sir. 4 Okay. When you were talking to Mr. Amon Q. 5 during redirect, the subject matter of the two 6 markers in the center of the implant came up. 7 you remember that? 8 Α. Yes. 9 Q. Was it predictable that if you put two 10 markers in the center of an implant, you would get 11 the images that you get? 12 MR. AMON: Objection; vague. 13 I'm trying to understand you. I'm not Α. 14 trying to slow you down at all. I'm trying to 15 understand you. Can you magnify that a little bit? 16 Okay, sir, you had question and answer O. 17 about the two markers in the middle of the implant. 18 Do you remember those questions and answers? 19 Α. Yes. 20 And what I'm asking is, putting two Q. 21 markers in the center of that implant, did they

provide a predictable result?

	315	
1	A. Which implant?	
2	Q. The claimed implant?	
3	A. Oh, okay.	
4	MR. AMON: Vague objection;	
5	vague as to time.	
6	A. You're referring to a lateral implant; am I	
7	correct?	
8	Q. Sir, I'm talking about the claim, which if	
9	you're asking me a question, the word lateral	
10	doesn't appear in the claim.	
11	A. A long implant.	
12	Q. Greater than 40 millimeters.	
13	A. Greater than 40 millimeters, okay. So	
14	you're putting it into a greater than 40 millimeter	
15	long implant, okay. Now go ahead and ask your	
16	question. I'm with you.	
17	Q. Is the image that you obtained from those	
18	two markers predictable?	
19	MR. AMON: Same objection.	
20	A. If you put two markers and you take an	
21	X-ray, you can see the two implants. What do you	
22	mean by "predictable"?	

316 Sir, I'm using your words. You just read 2 them into the record. You talked about predictable 3 result. I'm asking you in my question, using your words, what did you mean by "predictable result" in your testimony? 5 6 MR. AMON: Objection; calls for a 7 legal conclusion. 8 What predictable for me means that it's 9 something that is reproducible and something that the -- you know what it will do. 10 11 Q. Okay. 12 MR. AMON: Is there a question 13 pending? 14 MR. SCHWARTZ: I think I do have a question pending but I'll re-ask it 15 16 so it makes the question a little more 17 clear. 18 Thank you. THE WITNESS: 19 EXAMINATION BY MR. SCHWARTZ: 20 Do you get a predictable result in the 21 image that you obtain through radiographic process 22 by viewing the two markers in the center of the

317 claimed implant? 2 MR. AMON: Objection; nonsensical 3 question. 4 When you put two markers, when you take an 5 X-ray, you'll see two markers; you'll see them as 6 So I don't understand what you mean "you get a 7 predictable result." 8 Is that image that you see something you 9 would have expected to see? 10 Α. It's an image but it may or may not be what 11 I expect to see depending on the alignment. 12 Is there something unpredictable about the 13 image that you get when you look at an implant that 14 has two markers in the center? Let me back up a 15 little, sir. 16 Α. Thank you. 17 When you look at a metal object on X-ray, 18 you can see it; correct? 19 Yes, it's radiopaque. 20 And so if you place a marker in a plastic Q. 21 object and then you put that plastic object under 22 X-ray, you can see where that marker is; correct?

318 Α. Yes, you can see it on the X-ray. 2 And you knew that before 2004, correct? Ο. 3 Α. Yes. 4 I mean, back when you first took your 5 first X-ray, you knew that you could see something 6 metal on that X-ray; right? 7 I ask you to qualify. You can see 8 something metal that you implant into a plastic 9 implant on X-ray. 10 Q. Right. 11 That is correct, sir. 12 And you knew that in 2004; right, sir? O. 13 Α. Yes. 14 And in 2003 you knew that? 0. 15 I don't know how far forward. I don't know 16 how far the so-called PEEK implants date exactly and 17 I would have to be guessing. I don't want to do 18 that. 19 Okay. But there were certainly prior art 20 implants in 2003 that were nonmetal implants and had 21 metal markers in them, correct? 22 I don't know if it's correct, but if Α. Okay.

- we did, then my answer to you would be yes.
- 2 Is there something unexpected about being O.
- 3 able to see a marker on an X-ray, sir?
- 4 Α. That isn't what you're asking me. You're
- 5 asking me to go back --
- 6 O. I just asked you a new question, sir.
- 7 Okay, fine. Α.
- 8 Is there something unexpected about seeing Q.
- 9 a metal marker on an X-ray?
- 10 Α. If it's implanted into a vertebral --No.
- 11 particularly into a plastic of some type, yes.
- 12 And that's true even in 2003; right, sir? O.
- 13 If in 2003 we already had either PEEK or Α.
- 14 other plastic implants, then the metal marker that's
- 15 visible by X-ray, the answer is yes.
- 16 And so with that qualification in your Ο.
- 17 answer, putting two markers in the middle, you would
- 18 expect to be able to see them on an X-ray; right,
- 19 sir?
- 20 Right, that's correct. Α.
- 21 And you would have expected that in 2002, Ο.
- 22 correct?

		320
1	A.	Expected that you could see them?
2	Q.	Yes.
3	A.	The answer is yes.
4	Q.	You would be able to tell if they were not
5	lined up	when you looked on that X-ray; right, sir?
6	A.	Correct.
7	Q.	Thank you, sir.
8	A.	Thank you.
9		MR. SCHWARTZ: Why don't you take
10		a short break and see if we can wrap
11		up my recross. Before we take our
12		break, sir, I'll remind you we're
13		still in recross and so the
14		instructions that I gave you earlier
15		about not conferring with counsel
16		during this break still apply. Do you
17		understand that, sir?
18		THE WITNESS: Yes, sir.
19		MR. AMON: And just so the record
20		is clear, they apply again. The
21		indications that Mr. Schwartz gave
22		apply again.

	321
1	MR. SCHWARTZ: Off the record.
2	(7:02 p.m.)
3	(Discussion off the record.)
4	(7:09 p.m.)
5	MR. SCHWARTZ: We're back on the
6	record, sir, and we have no further
7	recross questions.
8	MR. AMON: No further questions.
9	We're done.
10	(7:09 p.m.)
11	
12 *	* *
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