

UNITED STATES PATENT AND TRADEMARK OFFICE

AVANOS MEDICAL, INC.,

Petitioner,

v.

IPR2024-01209

STRATUS MEDICAL, LLC,

Patent 10,966,782

Patent Owner.

DEPOSITION OF MARC A. RUSSO

DATE: Friday, August 22, 2025

TIME: 9:10 a.m.

LOCATION: The Westin - Los Angeles Airport

5400 West Century Boulevard

Pico Boardroom

Los Angeles, CA 90045

OFFICIATED BY: John Canfield

JOB NO.: 7562975

[REDACTED]

A P P E A R A N C E S

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A P P E A R A N C E S (Cont'd)

ALSO PRESENT:

Lauren Phillips, Consultant, Laurence & Phillips IP
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E X H I B I T S

NO.	DESCRIPTION	PAGE
	(*None marked.)	

P R O C E E D I N G S

THE OFFICER: Good morning. My name is John Canfield; I'm the reporter assigned by Veritext to take the record of this proceeding. We are now on the record at 9:10 a.m.

This is the deposition of Marc A. Russo, taken in the matter of Avanos Medical, Inc., vs. Stratus Medical, LLC, on August 22, 2025, at 450 -- excuse me -- 5400 West Century Boulevard, Los Angeles, California 90045.

I am a notary authorized to take acknowledgements and administer oaths in California.

Additionally, absent an objection on the record before the witness is sworn, all parties and the witness understand and agree that any certified transcript produced from the recording of this proceeding:

- is intended for all uses permitted under applicable procedural and evidentiary rules and laws in the same manner as a deposition recorded by stenographic means; and
- shall constitute written stipulation of such.

At this time, will everyone in attendance

1 please identify yourself for the record, beginning from
2 my right.

3 MR. KELLY: Chris Kelly, lead counsel for
4 petitioner Avanos Medical. I'm at Meunier Carlin &
5 Curfman, LLC. And with me remotely is Warren Thomas,
6 also of the firm Meunier Carlin & Curfman, LLC.

7 MR. PHILLIPS: I'm -- excuse me. I'm
8 Matthew Phillips. With me are Dan Higgs and Lauren
9 Phillips. We are with the law firm of Laurence &
10 Phillips IP Law. We represent the patent owner,
11 Stratus, in this case,

12 MR. RUSSO: Associate Professor Marc
13 Andrew Russo.

14 THE OFFICER: Thank you. Hearing no
15 objection, I will now swear in the witness.

16 Mr. Russo, would you raise your right
17 hand, please.

18 WHEREUPON,

19 MARC A. RUSSO,
20 called as a witness and having been first duly sworn to
21 tell the truth, the whole truth, and nothing but the
22 truth, was examined and testified as follows:

23 THE OFFICER: Thank you.

24 You may proceed, Counsel.

25 //

EXAMINATION

BY MR. KELLY:

Q Good morning, Mr. Russo. You understand you're under oath today?

A Yes.

Q And is there anything that would prevent you from providing complete and truthful testimony today?

A No.

Q Have you been deposed before?

A I don't think so.

Q So it sounds like you may not be super familiar with how depositions work; is that right?

A I've got a rough idea, yes.

Q Okay. So because we have a court reporter transcribing your testimony, I'll ask that you try and let me finish my questions before you answer. If at any point you do not understand a question that I'm asking, just ask me to clarify, and I'll do my best to do that. Does that sound good?

A Yes.

Q And your counsel has the right to object to any questions that I ask. So after I ask a question, it's probably helpful if you give him a second to object before you answer. That will help the three of us not talk over each other so the court reporter can

1 transcribe everything.

2 And if at any point you need to take a break,
3 just let me know. We can do that. To the extent we do
4 take breaks during today's cross-examination, do you
5 understand you are not permitted to speak with anyone
6 about the substance of your testimony during those
7 breaks?

8 A Yes, correct.

9 Q What did you do to prepare for today's
10 deposition?

11 A I have read several times my deposition
12 statement, which I have here an unmarked copy.

13 Q Did you review any other documents?

14 A Also the other document, which is the Patent
15 Owner's Response to petition for inter-party's review.

16 Q And there are -- there's four of each of
17 those; right?

18 A I have one copy of each.

19 Q Okay. I'm referring to the Patent Owner
20 Response.

21 A As in, there's four sections to it. Oh, yes.
22 There's -- there's multiple sections to it.

23 Q Well, there's four different Patent Owner
24 Responses, one for each of the IPR numbers. So did you
25 just review one of them?

1 A Yes. I reviewed this one.

2 Q And which one is that?

3 A IPR 2024-01209.

4 Q Okay. Other than the Patent Owner Response
5 document and the copy of your declaration, did you
6 review any other documents to prepare for today's
7 deposition?

8 A Yes. I reviewed a document of related to
9 guidelines on how to conduct the deposition interview,
10 which was provided by counsel.

11 MR. PHILLIPS: And I'm going to instruct
12 the witness not to reveal the content of any
13 conversations we've had or documents we've provided to
14 you.

15 BY MR. KELLY:

16 Q And what was this guideline? Is this, like, a
17 manual for how to engage in a deposition?

18 MR. PHILLIPS: I'm going to give the
19 witness the same instruction.

20 BY MR. KELLY:

21 Q You're telling me that you reviewed a document
22 related to sitting for a deposition; is that right?

23 A Yes.

24 Q Okay. And do you remember the title of that
25 document?

1 A No.

2 Q Okay. And when did you receive it?

3 A I think a number of weeks ago.

4 Q Okay. And did that document contain any
5 information related to the substance of these cases?

6 A No. It was related to what the process is.

7 Q Okay. Did you meet with anyone to prepare for
8 today's deposition?

9 A Yes. I -- previously I met via Zoom with
10 counsel.

11 Q Which counsel?

12 A Counsel to my left.

13 Q Mr. Phillips?

14 A Yes.

15 Q Okay. Did you meet with anyone else?

16 A Mr. Phillips and also Dan, whose surname I
17 forget.

18 Q And other than Mr. Phillips and Mr. Higgs,
19 right, did you meet with anyone else?

20 A No.

21 Q Okay. Are you aware that Peter Crosby was
22 deposed in relation to these IPRs earlier this month?

23 A Yes.

24 Q And have you reviewed a transcript of
25 Mr. Crosby's deposition?

1 A Yes.

2 Q Okay. So when I asked you earlier what
3 documents you reviewed, I would've expected you to
4 include that. So --

5 MR. PHILLIPS: Objection, form.

6 BY MR. KELLY:

7 Q -- other than Mr. Crosby's deposition
8 transcript and your declaration and the Patent Owner
9 Response and the deposition guideline document you
10 mentioned, did you review any other documents?

11 A No.

12 Q Okay. Have you reviewed any e-mails or
13 documents describing Mr. Crosby's deposition other than
14 his transcript?

15 A No.

16 Q And did you discuss Mr. Crosby's deposition
17 with anyone in preparing for today's deposition?

18 A No.

19 Q About when did you receive the transcript of
20 Mr. Crosby's deposition?

21 A Approximately ten days to two weeks ago.

22 Q And about how much time did you spend
23 reviewing that document?

24 A About 45 minutes.

25 Q Total. Okay.

1 Mr. Russo, I'm handing you a copy of a
2 document that has been previously marked Stratus
3 Exhibit 2001. Can you identify this document for the
4 record?

5 A Yes. This is my declaration.

6 Q And if you turn to page 73 of Exhibit 2001, is
7 this your signature on page -- actually -- yes, 73. If
8 you could turn to page 73. Let me know when you're
9 there.

10 A Yes.

11 Q And is this your signature on page 73?

12 A Yes.

13 Q And this document was signed on May 21, 2025;
14 is that correct?

15 A Yes.

16 Q Okay. If you turn back to the cover page of
17 Exhibit 2001, there are four IPR proceedings listed on
18 the cover; correct?

19 A Yes.

20 Q And those are IPR 2024-01209, IPR 2024-01210,
21 IPR 2024-01211, and IPR 2024-01212; is that correct?

22 A Yes.

23 Q And if you turn to paragraph 1 of this
24 document on page 4, I believe you repeated those case
25 numbers in the table following paragraph 1; correct?

1 A Yes.

2 Q Is it correct that your testimony in
3 Exhibit 2001 was prepared for all four of these IPR
4 proceedings?

5 A Yes.

6 Q And so you prepared just one declaration to
7 apply to all four IPR cases; is that right?

8 MR. PHILLIPS: Objection, asked.

9 THE WITNESS: Yes.

10 BY MR. KELLY:

11 Q Okay. So going forward, I will just refer to
12 Exhibit 2001, which I've handed you, as your
13 declaration. Is that okay?

14 A Yes.

15 Q So whenever I say "your declaration," I'm
16 talking about this document, unless I indicate
17 otherwise. Do you understand?

18 A Yes.

19 Q Okay. About when did you start working on
20 your declaration?

21 A It would've been a number of months ago now.

22 Q Do you remember which month?

23 A No. I haven't kept a timeline.

24 Q Well, you finished in May of 2025; correct?

25 A Correct.

1 Q Did you start before March of 2025?

2 A I don't have the start date to mind.

3 Q Do you recall working on your declaration in
4 April of 2025?

5 A Yes.

6 Q And do you recall working on your declaration
7 in March of 2025?

8 A I believe so.

9 Q And do you recall working on your declaration
10 in February of 2025?

11 A I am uncertain as to the exact start date.

12 Q Okay. So for sure throughout March and April,
13 but perhaps not before then?

14 MR. PHILLIPS: Objection,
15 mischaracterizes.

16 THE WITNESS: Not having registered the
17 start date, I can only confirm my awareness of working
18 on this through March and April and May.

19 BY MR. KELLY:

20 Q About how many hours did you spend preparing
21 your declaration?

22 A I would say in total, given that it was done
23 in piecemeal and over a number of components, I would
24 say probably about 20 hours, give or take.

25 Q Okay. And your declaration is 73 pages long;

1 right?

2 A Correct.

3 Q So you wrote about three and a half pages of
4 your declaration every hour; is that right?

5 MR. PHILLIPS: Objection, form,
6 foundation.

7 THE WITNESS: That is not the manner in
8 which that was done.

9 BY MR. KELLY:

10 Q Did you write the words in your declaration?

11 A I -- no. I was interviewed extensively by
12 counsel. They put together a draft, which I reviewed
13 and corrected to ensure that it was the words that I
14 used during the interview -- interview and discussion.

15 Q Did you personally write any of the words in
16 your declaration?

17 A Yes. There were a number of areas where I
18 corrected the things and, thus, inserted words that I
19 directly wrote.

20 Q So you edited the draft that they provided
21 you?

22 A Correct.

23 Q And was there more than one draft of the
24 declaration prepared?

25 A No.

1 Q So you received one draft from counsel; is
2 that right?

3 A Yes.

4 Q Did you --

5 A And then I corrected it.

6 Q And that is the final version that we have in
7 Exhibit 2001?

8 A Yes.

9 Q And it took you about 20 hours to edit the
10 draft they provided you?

11 MR. PHILLIPS: Objection, foundation,
12 mischaracterizes.

13 THE WITNESS: It took a total of 20 hours
14 of discussion and editing. So I included both
15 components in that.

16 BY MR. KELLY:

17 Q Could you turn to paragraph 3 of your
18 declaration?

19 A Yes.

20 Q And in paragraph 3, you state, "I'm being
21 compensated at a rate of 3,000 Australian dollars per
22 hour for my work on these cases, including providing
23 this declaration"; is that right?

24 A Correct.

25 Q Were you paid 60,000 Australian dollars for

1 your work on this declaration?

2 A Was I paid \$60,000 for this declaration? I
3 would have to add up the entire billing that I would've
4 done for that. Some of the work would've been divided
5 into this declaration, some of it would've been divided
6 up into the time spent on multiple Zoom calls, so I
7 wouldn't characterize it as that, no.

8 Q Well, earlier you told me you spent about 20
9 hours editing your declaration; is that right?

10 MR. PHILLIPS: Objection,
11 mischaracterizes.

12 THE WITNESS: No, I did not. I mentioned
13 that there was 20 hours of interviews with counsel,
14 followed by draft, followed by correction.

15 BY MR. KELLY:

16 Q Okay. So if you billed Stratus for all 20 of
17 those hours at a rate of \$3,000 per hour, that would be
18 at least 60,000 --

19 A Correct.

20 Q -- Australian dollars. Okay.

21 Were you paid 60,000 Australian dollars or
22 more --

23 A Correct.

24 Q -- for your work on this case? Okay.

25 Could you turn with me to paragraph 1 of your

1 declaration? And do you see the table here where three
2 different Stratus patents are listed?

3 A You mean on page 4?

4 Q Oh, sorry, I meant paragraph 1 on page 4, yes.

5 A Yes. There are -- there are four patents, not
6 three.

7 Q I believe there's four IPR cases but only
8 three different patents; is that right?

9 A Oh, I see what you're saying. Yes.

10 Q Okay. In preparing your declaration, did you
11 review U.S. Patent No. 10966782?

12 A Yes.

13 Q And in preparing your declaration, did you
14 review the prosecution history of U.S. Patent
15 No. 10966782?

16 A Could you explain what you mean by
17 "prosecution history"?

18 Q It was filed in IPR 2024-01209 as Exhibit
19 No. 1,006. I don't know if that helps.

20 A Right. Yes.

21 Q And you reviewed the entire prosecution
22 history?

23 A Yes.

24 Q Okay. And in preparing your declaration, did
25 you review U.S. Patent No. 10736688?

1 A Yes.

2 Q And in preparing your declaration, did you
3 review the prosecution history of U.S. Patent No.
4 10736688, which was filed in this case as Exhibit
5 No. 1,007?

6 A Yes.

7 Q And in preparing your declaration, did you
8 review U.S. Patent No. 10925664?

9 A Yes.

10 Q And in preparing your declaration, do you
11 review -- did you review the prosecution history of U.S.
12 Patent No. 10736664 filed as Exhibit 1,008?

13 A Yes.

14 Q Do you recall how long those prosecution
15 history documents were?

16 A No.

17 Q Can you give me a guess?

18 A No, other than there was extensive material
19 for both the patents and the prosecution histories.

20 Q And was your review of the patents and the
21 prosecution histories included in the 20-hour estimate
22 of your work that you gave me earlier?

23 A No. Some of that would've been background
24 reading for which I would not have charged the company.

25 Q So you reviewed the prosecution histories of

1 those three patents for free?

2 A For some of it, I did.

3 Q Okay. And you don't recall how long they
4 were?

5 A No.

6 Q Were they more than ten pages long?

7 A Yes.

8 Q Were they more than a hundred pages long?

9 A I cannot recall.

10 Q Okay. Do you recall the substance of those
11 prosecution histories?

12 A In -- in significant detail? No.

13 Q So the prosecution history of U.S. Patent
14 No. 10966782 that was filed as Exhibit 1,006 -- and I
15 believe you told me you reviewed that document; right?

16 A Yes.

17 Q Okay. Can you remember anything that happened
18 during the prosecution of U.S. Patent No. 10966782?

19 A That is also known as the Racz patent?

20 Q No.

21 A No, these are the Stratus patents?

22 Q That's correct.

23 A Correct. No. I briefly went over the Stratus
24 patents.

25 Q The patents or the prosecution histories?

1 A Both.

2 Q Okay. My question is, sitting here today, do
3 you remember anything that happened in the prosecution
4 history of U.S. Patent No. 10966782?

5 A No.

6 Q Same answer for the prosecution history of the
7 688 and 664 patents?

8 A Yes.

9 Q Okay. So you reviewed them, but today you
10 don't remember anything about them?

11 A Correct.

12 Q Okay. Mr. Russo, I've handed you a copy of
13 what's been previously marked as Exhibit 1,001, and this
14 is the 782 patent; is that correct?

15 A Yes.

16 Q If you turn to the second page of the 782
17 patent, do you see a heading that says "Related U.S.
18 Application Data"?

19 A Yes.

20 Q And in the first full paragraph beneath that
21 heading on page 2, do you see three provisional
22 application numbers listed?

23 A Yes.

24 Q And these are Provisional Application
25 No. 61/357894 filed June 23, 2010; Provisional

1 Application No. 61/357886 filed June 23, 2010; and
2 Provisional Application No. 61/347351 filed May 21,
3 2010; is that correct?

4 A Yes.

5 Q And in preparing your declaration, did you
6 review any of those provisional applications?

7 A No, I don't believe I did.

8 Q I'm handing you a copy of what's been
9 previously marked as Exhibit 1,002. And this is the 688
10 patent; correct?

11 A Yes.

12 Q If you turn to the second page of the 688
13 patent, do you again see a heading that reads "Related
14 U.S. Application Data"?

15 A Yes.

16 Q And in the paragraph beneath that heading on
17 page 2, do you see two provisional application numbers
18 listed?

19 A Yes.

20 Q And these are Provisional Application
21 No. 61/280557 filed November 5, 2009, and Provisional
22 Application No. 61/347351 filed May 21, 2010; is that
23 correct?

24 A Yes.

25 Q And in preparing your declaration, did you

1 review either of those provisional applications?

2 A No.

3 Q Okay. Could you turn with me to paragraph 41
4 of your declaration?

5 A Yes.

6 Q And do you see in the bullet points of
7 paragraph 41 that you refer to the references Racz Fitz
8 Lee Young 965 and Scheibe?

9 A Yes.

10 Q And in preparing your declaration, did you
11 review each of those references?

12 A Yes.

13 Q Do you recall reviewing any other prior
14 references?

15 A No.

16 Q And in paragraph 42 of your declaration, you
17 refer to Exhibit Nos. 1031, 1032, 1033, and 1034. Do
18 you see that?

19 A Yes.

20 Q And these are the declarations of Dr. Tucker;
21 is that correct?

22 A Yes.

23 Q And in preparing your declaration, did you
24 review each of those declarations?

25 A Yes.

1 Q Did you review each of them in their entirety?

2 A Yes.

3 Q Other than the lawyers for Stratus Medical,
4 did you speak to anyone else about the substance of your
5 testimony when you were preparing your declaration?

6 A No.

7 Q So other than the lawyers for Stratus Medical,
8 you did not rely on anything that anyone else told you
9 to prepare your declaration; is that right?

10 A Correct.

11 Q During the time period in which you were
12 preparing your declaration, did you speak to Cody
13 Jorgensen at Stratus Medical?

14 A No.

15 Q Mr. Russo, I've handed you a declaration from
16 Cody Jorgensen that has been marked as Exhibit 2016 in
17 these proceedings.

18 A Yes.

19 Q Have you ever seen this document before?

20 A No.

21 Q And in preparing your declaration, did you at
22 any point review this document?

23 MR. PHILLIPS: Objection, answered.

24 THE WITNESS: Sections of this, which are
25 blacked out, were part of the document "Patent Owner's

1 Response to Petition for Inter-Party's Review."

2 BY MR. KELLY:

3 Q But you don't recall reviewing Exhibit 2016;
4 is that correct?

5 A This? No.

6 Q Do you recall reviewing a draft of
7 Exhibit 2016?

8 A No.

9 Q You mentioned that the contents of
10 Exhibit 2016, I understood your testimony to be that it
11 resembles some of what's in the Patent Owner Response
12 Document; is that right?

13 A Correct.

14 Q And you testified earlier that you reviewed
15 the Patent Owner Response Document?

16 A Correct.

17 Q Did you review the Patent Owner Response
18 before you prepared your declaration?

19 A No.

20 Q When did you review the Patent Owner Response?

21 A About -- about ten days ago.

22 Q Okay. So before ten days ago, you had not
23 reviewed the Patent Owner Response Document?

24 A Correct.

25 MR. PHILLIPS: Objection, answered.

1 BY MR. KELLY:

2 Q Okay. During the time period in which you
3 were preparing your declaration, did you speak with
4 Peter Crosby?

5 A No.

6 Q At any point, have you spoken to Peter Crosby
7 about the testimony in your declaration?

8 A I have not.

9 Q Have you spoken to Peter Crosby at any point
10 in relation to the IPR proceedings addressed in your
11 declaration?

12 A I have not.

13 Q Have you corresponded with Peter Crosby by e-
14 mail or other means in relation to the IPR proceedings
15 addressed in your declaration?

16 A I have not.

17 Q Have you communicated with him in any other
18 way in relation to these IPR proceedings?

19 A I have not.

20 Q Mr. Russo, I've handed you a declaration from
21 Peter Crosby that has been marked as Exhibit 2006 in
22 these proceedings. Have you ever seen this document
23 before?

24 A Yes.

25 Q And when did you first see this document?

1 A About ten days ago.

2 Q So in preparing your declaration, you did not
3 review this document?

4 A Correct.

5 Q Do you recall reviewing a draft of this
6 document in preparing your declaration?

7 A No, I did not.

8 Q And in preparing your declaration, did you at
9 any point review information or materials that were
10 provided to you by Mr. Crosby?

11 A I did not.

12 Q Okay. I think I handed you earlier a copy of
13 Exhibit 1,001, which is the 782 patent. Do you see
14 that?

15 A Yes.

16 Q And do you see that one of the named inventors
17 is Robert Wright?

18 A Yes.

19 Q During the time period in which you were
20 preparing your declaration, did you speak with
21 Dr. Robert Wright?

22 A No.

23 Q At any point, have you spoken to Robert Wright
24 about the testimony in your declaration?

25 A I have not.

1 Q Have you spoken to Robert Wright at any point
2 in relation to the IPR proceedings that are addressed in
3 your declaration?

4 A I have not.

5 Q When was the last time you spoke with
6 Mr. Wright?

7 A Now, that would be one to one and a half years
8 ago. Closer to -- closer to a year ago, I believe.

9 Q Do you recall the nature of that conversation?

10 A We were discussing another colleague in the
11 world of pain medicine in Australia.

12 Q And I think in your declaration you testified
13 that you first met Robert Wright at a conference; is
14 that right?

15 A Yes.

16 Q Do you recall what year that was?

17 A I think it would've been around about 2012,
18 possibly 2013, around that vintage.

19 Q And today, how would you describe your
20 relationship with Dr. Wright?

21 A He is a professional colleague who has
22 relocated to Australia, and he works in Queensland in a
23 pain clinic. I work in New South Wales. And
24 approximately every second year, he would attend a
25 conference that I would also attend.

1 Q Is he a personal friend?

2 A He's somebody I feel -- I feel friendly
3 towards, although I do not socialize with him. So
4 personal friend, no, but we have one common interest,
5 which is the -- the writings of Hunter S. Thompson, the
6 journalist. He's the only person I know who likes him
7 beside me.

8 Q Well, now you know three, sitting here today.
9 I'll spare you my "Fear and Loathing in Las Vegas"
10 impersonations.

11 If Robert Wright described you as a personal
12 friend at a conference, would you believe that to be
13 inaccurate?

14 A No.

15 Q Okay. Let's turn to your declaration. And I
16 know I've handed you a lot of documents.

17 A Yeah, that's okay.

18 Q So right now we're going to be looking at your
19 declaration, which is Exhibit 2,001. So if you want to
20 stack up the other ones, that's fine.

21 A Right.

22 Q We'll keep those handy for later.

23 A And I may intermittently stand, as I have some
24 acute back pain. So I will stand and sit and don't
25 worry about it.

1 Q You do whatever you need to do to be
2 comfortable. Totally understand.

3 Okay. So we're obviously going to refer to a
4 lot of technical and medical terminology today, and I'm
5 not a doctor, so I have a few questions to make sure
6 we're on the same page about what the terms we're going
7 to refer to today mean.

8 So let's start at paragraph 75 of your
9 declaration. And if you could just read that paragraph,
10 and let me know when you're done.

11 A Read it out loud or read to myself?

12 Q You can read it to yourself.

13 A Yes.

14 Q In paragraph 75, you indicate that "ablation"
15 means the removal or destruction of tissue; is that
16 correct?

17 A Yes.

18 Q For the purposes of our conversation today,
19 whenever you use the term "ablation" on its own, I will
20 assume you're referring to your definition in
21 paragraph 75, unless you tell me otherwise. Is that
22 okay?

23 A That would be fine, although "ablation" refers
24 to alteration of function via removal or destruction of
25 tissue. So there is a longer version of the definition

1 of "ablation." I've used the short version here.

2 Q And, sorry, could you explain that one more
3 time, just so I could understand what you mean?

4 A "Ablation" refers to the alteration of
5 function of something. And the way to alter function
6 and ablate the ability of a -- for example, a nerve to
7 function, is usually by removal or destruction of
8 tissue.

9 Q So if you're removing or destroying tissue but
10 you're not altering a function, you would consider that
11 not to be ablation?

12 A If you're removing or destroying tissue, that
13 would depend on whether it ablates the function by its
14 action. So you could -- you could ablate a -- a skin
15 tag, and you could do that via removing it, but its
16 function isn't relevant.

17 Q Okay. In paragraph 75, you also indicate that
18 "thermal ablation" means the destruction of tissue
19 through the application of heat; is that right?

20 A Correct.

21 Q So same thing. For the purposes of our
22 conversation today, whenever you use the term "thermal
23 ablation," I will assume you're referring to your
24 definition in paragraph 75, unless you tell me
25 otherwise. Is that okay?

1 A Correct.

2 Q And also in paragraph 75, you indicate that
3 "RF ablation" means the destruction of tissue using heat
4 generated from RF energy; is that correct?

5 A Yes.

6 Q So for the purposes of our conversation today,
7 whenever you use the term "RF ablation," I will assume
8 you are referring to your definition in paragraph 75,
9 unless you tell me otherwise. Okay?

10 A Yes.

11 Q If you would, please turn to paragraph 78 in
12 your declaration and read that paragraph, and let me
13 know when you are done.

14 A Yes.

15 Q And at the bottom of page 19, going on to
16 page 20, you indicate that "RF neurotomy" means RF
17 ablation of nerves; is that correct?

18 A No. I said that I practiced RF ablation of
19 nerves.

20 Q And that portion of the sentence reads, you
21 practiced, quote, "RF ablation of nerves," comma, "or,"
22 in quotation marks, "RF neurotomy"; correct?

23 A Correct.

24 Q So I read that sentence to mean that "RF
25 neurotomy" is RF ablation of nerves; is that incorrect?

1 MR. PHILLIPS: Objection, form.

2 THE WITNESS: RF ablation of nerves and
3 RF neurotomy, yes.

4 BY MR. KELLY:

5 Q Okay. So for the purposes of our conversation
6 today, whenever you use the term "RF neurotomy," I will
7 assume you mean RF ablation of nerves, as you've said
8 here in paragraph 78, unless you tell me otherwise.

9 A Yes.

10 Q Is that fair?

11 Earlier, I think you told me that "RF
12 ablation" means the destruction of tissue using heat
13 generated from RF energy; right?

14 A Correct.

15 Q So if RF neurotomy is the ablation of nerves,
16 then would you consider the tissue being ablated to be
17 nerve tissue?

18 A Yes.

19 Q Okay. If you could refer now to paragraph 76
20 of your declaration, if you look on page 19, that
21 portion of paragraph 76 in the -- I think it's the third
22 sentence of paragraph 76, you refer to RF ablations for
23 treatment of tumors; is that correct?

24 A Yes.

25 Q So when RF energy is used to ablate a tumor,

1 then the tissue that is being destroyed is tumor tissue;
2 is that right?

3 A Yes.

4 Q And it's your opinion that tumor tissue is
5 different from nerve tissue?

6 A Yes.

7 Q So if RF energy is being used to ablate tumor
8 tissue, then you would not consider that to be RF
9 neurotomy?

10 A Correct.

11 Q Okay. If you look towards the end of
12 paragraph 76 in your declaration, you indicate that RF
13 ablations of the heart to treat arrhythmias are
14 performed by cardiologists. Do you see that?

15 A Yes.

16 Q So when RF energy is used for cardiac
17 ablation, then the tissue that is being destroyed is
18 cardiac tissue; is that right?

19 A Yes.

20 Q And, again, if RF energy is being used to
21 ablate cardiac tissue, you would not consider that to be
22 RF neurotomy?

23 A No, because there are nerves that run in the
24 heart. So it depends on whether the cardiologist is
25 specifically ablating heart tissue or wishing to

1 interrupt the nerves in the heart tissue.

2 Q Okay. So there are types of cardiac ablation
3 that are not neurotomy and types of cardiac ablation
4 that are neurotomy? Is that what you're saying?

5 A Correct.

6 Q Okay. What types of cardiac ablation are not
7 neurotomy?

8 A Where you're wishing to alter the elasticity
9 of the cardiac tissue. So by applying radiofrequency
10 energy, you can shrink it or make it tighter, and that
11 can alter the function of the heart.

12 And then at other times you're wishing to
13 interrupt the electrical nervous system of the heart,
14 what's called the Purkinje fibers. And then that is
15 specifically doing a neurotomy, but at the same time
16 there's surrounding heart tissue around the nerves at
17 the same time. So it's a bit of a mixed beast.

18 Q Are the devices used for cardiac ablation that
19 is not neurotomy versus cardiac ablation that is
20 neurotomy different?

21 A The devices aren't different, but the settings
22 that are used, the electrical settings would be
23 different.

24 Q What electrical settings would be different?

25 A I'm not an expert on this, not being a

1 cardiologist, but they have power settings, time
2 settings, and they would choose the relevant power
3 setting and time setting for what they wanted to
4 achieve.

5 Q Okay. So for cardiac ablation that is not
6 neurotomy, you would have perhaps one power and time
7 setting for the device. And for cardiac ablation that
8 is neurotomy, you would use the same device but have a
9 different power or time setting?

10 A Yes.

11 Q Okay. And how -- I think, we'll get to this
12 later, but my understanding of RF neurotomy as it
13 relates to the spine is that the device is inserted
14 percutaneously near the spine, toward the nerve; right?
15 So through the skin?

16 A Yes.

17 Q So in cardiac ablations, how does the device
18 get to where it's going?

19 A Endoluminally, so it's done through the
20 arterial system.

21 Q Okay. So how does that work? There's
22 a -- you're not just sticking the device through the
23 patient's skin and into the heart; right? There's a --

24 A Correct.

25 Q Okay --

1 MR. PHILLIPS: Objection, compound.

2 BY MR. KELLY:

3 Q Could you help me understand, like ...

4 A Generally, the femoral artery in the groin is
5 cannulated, and then a catheter with an active tip is
6 traversed upwards under fluoroscopy to the heart, and
7 then either placed adjacent to or embedded in the
8 component of the heart tissue that is of relevance to be
9 treated.

10 Q And that pathway is true for both types of
11 cardiac ablation we talked about earlier?

12 A Yes.

13 Q Okay. Okay. I have some questions for you
14 about your background and experience. So let's start at
15 paragraph 9 of your declaration.

16 A Yes.

17 Q And in paragraph 9, you indicate you have a
18 Bachelor of Medicine and Bachelor of Surgery from The
19 University of Sydney, Australia; is that right?

20 A Yes.

21 Q And in paragraph 11, you indicate that you
22 also received a Diploma of Anesthesia from Royal College
23 of Anesthetists in London; is that right?

24 A Yes.

25 Q Could you pronounce "anesthetist" for me? I

1 don't know how to say ...

2 A "Ah-NEE-tha-tist."

3 Q Anesthetist. Okay.

4 Other than your Bachelor of Medicine, Bachelor
5 of Surgery, and Diploma of Anesthesia, have you received
6 any other undergraduate or postgraduate degrees?

7 A Yes. I have both a FANZCA and a FFPMANZCA.

8 Q Could you spell that for me?

9 A F-A-N, zed, C-A, Fellow of the Australian and
10 New Zealand College of Anaesthetists.

11 Q And --

12 A And F-F-P-M-A-N, zed, C-A, Fellow of Pain
13 Medicine, Australian and New Zealand College of
14 Anaesthetists.

15 Q Sorry, one more time. F-F-M ...

16 A "FIPM," F-P-M-A-N, zed, C-A [sic], Fellow of
17 Pain Medicine, Australian and New Zealand College of
18 Anaesthetists.

19 Q Got it. And these are degrees?

20 A Yes.

21 Q And who awards these degrees?

22 A The -- FANZCA is awarded by the Australia and
23 New Zealand College of Anaesthetists, and the FFPMANZCA
24 is awarded by the Faculty of Pain Medicine.

25 Q And both of these relate to anesthesia?

1 A No. The -- the FANZCA relates to anesthesia,
2 and the FFPMANZCA relates to pain medicine training.

3 Q And -- oh, okay. Sorry, I see you referenced
4 these in paragraph 12 and 14 of your declaration?

5 A Correct.

6 Q Okay. Do you have any engineering degree?

7 A No.

8 Q And do you hold any professional engineering
9 licenses or certifications?

10 A No.

11 Q So based on your declaration, it sounds like
12 you were practicing anesthetist from 1993 to 1999; is
13 that right?

14 A Yes.

15 Q So before 1999, you were not a pain medicine
16 specialist; is that right?

17 A Correct.

18 Q And when did you begin your training in pain
19 medicine?

20 A 1998.

21 Q And how did you begin that training?

22 A I did a fellowship in my last year of
23 anesthetic training at Sir Charles Gairdner Hospital
24 Pain Medicine Unit in Perth, and subsequent to that, sat
25 the Faculty of Pain Medicine's exam.

1 Q And following that training, when did you
2 become a full-time pain medicine specialist?

3 A Full-time and -- with cessation of anesthesia
4 was around about 2003, 2004.

5 Q So in the 2000 --

6 A 2003, I think.

7 Q So in the 2003 timeframe, you gave up
8 anesthesia practice?

9 A Correct.

10 Q Okay. When you transitioned from being a
11 practicing anesthesiologist to being a pain medicine
12 specialist, what types of procedures did your pain
13 medicine practice include?

14 A Essentially, just about all practices. So
15 pain medicine contributes consults in the rooms working
16 with a multidisciplinary team, involving psychologists,
17 physiotherapists, exercise physiologists, psychiatrists,
18 nurses, occupational therapists, and in addition,
19 performing pain medicine procedures. And I practiced
20 almost -- almost the full gamut of interventional pain
21 medicine procedures.

22 Q Can you give me some examples of pain medicine
23 procedures that you performed?

24 A Medial branch blocks, medial branch
25 radiofrequency neurotomy, sacroiliac joint injections,

1 epidural injections, spinal cord stimulator implants, et
2 cetera.

3 Q And do you -- have you ever performed pain
4 medicine procedures for the sacroiliac joint?

5 A Yes.

6 Q Am I saying that right?

7 A Sacroiliac joint, yes.

8 Q Okay. And so you performed those procedures
9 also as part of your pain medicine practice?

10 A Yes.

11 Q And have you ever performed pain medicine
12 procedures on other parts of the body, like the knee?

13 A Yes.

14 Q And could you describe those?

15 A So specifically, the type of procedures that
16 are done and that I did related to the knee?

17 Q Yeah. And to be more clear, I heard you
18 mention that you had performed medial branch blocks and
19 neurotomies; right? And you just mentioned that you had
20 performed neurotomy on sacroiliac joints. So I'm just
21 curious where else in the body other than those two have
22 you performed neurotomy procedures?

23 A So neurotomy procedures are also performed
24 related to nerves around the knee. They're called
25 genicular nerves, and that is genicular radiofrequency

1 neurotomy. And there is a different type of neurotomy
2 termed "pulsed radiofrequency neurotomy," and pulsed
3 radiofrequency neurotomy is applied both to spinal
4 nerves in the dorsal root ganglion as well as peripheral
5 nerves through the body.

6 Q Could you say that last part about pulsed RF
7 neurotomy one more time? It's applied where?

8 A Pulsed radiofrequency neurotomy is applied to
9 spinal nerves, and in addition to that, applied to other
10 nerves around the body. It's a different form of
11 neurotomy to thermal radiofrequency neurotomy.

12 Q So it's not ablation?

13 A That's an interesting point. So pulsed
14 radiofrequency neurotomy changes the function of the
15 nerve. It ablates the ability of the nerve to pass a
16 pain signal, but it does not ablate the ability of the
17 nerve to pass sensation or motor signals. It is
18 differential in its capacity, and, thus, it can be done
19 on peripheral nerves that are important that thermal
20 radiofrequency neurotomy could not be performed on.

21 Q So in a pulsed RF neurotomy, the tissue is not
22 being destroyed; is that right?

23 A Well, that's interesting. Pulsed
24 radiofrequency neurotomy causes a temporary break in the
25 lining of the nerve, which then allows ions to go from

1 outside the nerve to inside the nerve and engage the
2 production of proteins inside the nerve that then blocks
3 pain. So it produces a temporary break, but those ion
4 channels close over after 48 to 72 hours. That is
5 called "electroporation."

6 Q So is that -- for lack of a better term, is
7 that, like, a temporary ablation?

8 A No. It has an effect that lasts longer than
9 thermal ablation. So pulsed radiofrequency neurotomy
10 has an effect of up to a year and a half, but typically
11 thermal radiofrequency neurotomy lasts nine to twelve
12 months. They are two quite different mechanisms of
13 action, although delivered through the one machine.

14 Q Okay. When did you perform your first RF
15 neurotomy procedure on a human patient?

16 A That would've been 1998.

17 Q And in what part of the body did you perform
18 this procedure?

19 A That would've been the medial branch of the
20 spinal nerve, would've been the dorsal root ganglion.

21 Q And is the dorsal root ganglion illustrated in
22 your declaration, in the -- I recall there being several
23 images of your declaration.

24 A If you turn to page 24, figure 1, you'll see a
25 picture, lateral view of the spine, and the right half

1 of that, you can see semi-circular hole. That is where
2 the dorsal root ganglion lives.

3 Q Could you point it to me? Okay. Got it.

4 A I can -- if you then go to figure 3 on
5 page 27, you will see the spinal nerve coming out of the
6 hole and the dorsal root ganglion is tucked just inside
7 the hole. It is a swelling of the nerve.

8 Q So is -- when you refer to "neurotomy of the
9 facet joints," does that include neurotomy of the dorsal
10 root ganglion, or is this different?

11 A So dorsal root ganglion is performed via
12 pulsed radiofrequency neurotomy.

13 Q Okay. And that's what you were doing in 1998?

14 A As well as thermal radiofrequency neurotomy of
15 the medial branch.

16 Q Okay. So when did you first perform a thermal
17 RF ablation on a human patient?

18 A 1998.

19 Q Okay. And that would've been on the medial
20 branch?

21 A Yes.

22 Q Okay. And for that thermal ablation in 1998,
23 do you recall what device you used?

24 A In the Sir Charles Gairdner Hospital, there
25 was a Radionics unit, and there was also another unit.

1 The manufacturer, I cannot recall. There were two
2 units.

3 Q Okay. And do you recall generally the
4 characteristics of that Radionics device?

5 A Yes.

6 Q Did it -- so, for example, did it have a
7 removable RF probe?

8 A Yes.

9 Q And was it straight or bent?

10 MR. PHILLIPS: Objection, form.

11 THE WITNESS: Back then we had straight,
12 and we may have also had bent ones, but we tended to
13 bend them ourselves. We used to put a custom bend in.

14 BY MR. KELLY:

15 Q So the physician would bend the device?

16 A If they needed to.

17 Q Okay. And were the characteristics of the
18 other device you mentioned using whose name you couldn't
19 remember roughly the same?

20 A Yes. The Radionics was very engineer-like and
21 clinically unfriendly. The other unit was slightly more
22 modern and slightly less -- slightly more user friendly.

23 Q What made it more user friendly? Do you
24 remember?

25 A Had less knobs.

1 Q Knobs on the device or the generator?

2 A Knobs on the generator.

3 Q Okay. And at that time, Radionics was making
4 both the needle and the generator; is that right?

5 A Yes.

6 Q Okay. But you would use a different generator
7 for one device versus the other?

8 MR. PHILLIPS: Objection, form.

9 THE WITNESS: I think there were just two
10 units available. I don't believe one was chosen over
11 the other for any particular reason.

12 BY MR. KELLY:

13 Q Okay. So changing our focus from the
14 beginning of your practice to the full scope, I
15 understand you've been a practicing pain medicine
16 specialist for about 25 years?

17 A Correct.

18 Q Okay. I'm interested in the types of
19 procedures you've performed over your career, and mostly
20 I'm interested in the ones that involve thermal RF
21 ablation.

22 So as a starting point, I understand from your
23 declaration that you have experience performing RF
24 neurotomy procedures for both facet joints and
25 sacroiliac joints?

1 A Yes.

2 Q And those are thermal RF neurotomy procedures?

3 A Yes.

4 Q Okay. Where else on the body have you
5 performed thermal RF neurotomy procedures?

6 A I've also performed that over the sensory
7 articular branches to various joints such as a shoulder
8 joint, to a lesser extent, hip joint.

9 Q And I think -- did you mention earlier you've
10 done it on the knee?

11 A Yes.

12 Q Okay. Any other areas you can think of?

13 A No. Those are the main ones.

14 Q And when these procedures are performed,
15 whether it's the shoulder or the hip or the knee, that
16 dictates where the device is being inserted into the
17 body?

18 MR. PHILLIPS: Objection, form.

19 THE WITNESS: I'm not sure I understand
20 your question.

21 BY MR. KELLY:

22 Q Well, if the -- so, for example, when we
23 talked about endocardial lesions earlier, you explained
24 that in that example, the device has to be inserted
25 through a catheter in the groin in order to get to the

1 heart; right?

2 A Correct.

3 MR. PHILLIPS: Objection,
4 mischaracterizes.

5 BY MR. KELLY:

6 Q So in that example, the device is not being
7 inserted through the skin at the heart. It's being
8 inserted elsewhere in the body; right?

9 A Correct.

10 Q Okay. So for when you're performing thermal
11 RF neurotomies on the shoulder or the hip or the knee,
12 the device is being inserted percutaneously proximal to
13 where the nerve you're targeting is?

14 A Correct.

15 Q Okay. Other than pulsed RF neurotomy
16 procedures, have you ever performed an RF ablation
17 procedure that was not an RF neurotomy procedure?

18 A Sorry, just say that again?

19 Q So other than -- you told me earlier that you
20 had experience with pulsed RF neurotomy --

21 A Yes.

22 Q -- right? And I think you indicated that that
23 is -- maybe doesn't fall within the category of RF
24 ablation?

25 A Correct.

1 Q Okay. So other than pulsed RF neurotomy, have
2 you ever performed an RF ablation procedure that was not
3 RF neurotomy?

4 A No.

5 Q Okay. And you mentioned at the start of your
6 career around 1998, you were using the Radionics device
7 and one other that you couldn't remember; right?

8 A Yes.

9 Q Over the course of your career as a pain
10 medicine specialist, about how many different types of
11 RF ablation needles have you personally used?

12 A RF ablation needles, did you say? Over ten, I
13 would say.

14 Q Over the course of 25 years?

15 A Yes.

16 Q And did all those needles have roughly the
17 same characteristics as the Radionics needle?

18 A Well, it depends what you mean by
19 "characteristics." Each had a needle. Each had a tip.
20 Each had a hub. They -- they are the characteristics
21 that are familiar and across the board. But
22 surprisingly, once you have it in your hand, there are
23 many subtle differences between the different needles.

24 Q What are some of the differences that jump out
25 to you?

1 A The tensile strength of the shaft, which means
2 that a stiff shaft cannot be manually curved whilst in
3 the body, whereas a flexible shaft can have a curve put
4 on it. So to an experienced practitioner, different
5 needles feel different.

6 Q Did you ever use a needle that did not have a
7 removable RF probe?

8 A No.

9 Q And have you used both straight and curved tip
10 needles?

11 A Yes.

12 Q Have you ever used a cool tip needle?

13 A No.

14 Q Are those not used for the types of procedures
15 you perform?

16 MR. PHILLIPS: Objection, form.

17 THE WITNESS: They can be used.

18 BY MR. KELLY:

19 Q But you've never used one?

20 A No. They're not cost effective.

21 Q Okay. We've been going an hour. You want to
22 take a quick break?

23 A I'm fine.

24 Q You want to keep going? Okay.

25 If you could turn to paragraph 4 of your

1 declaration.

2 A Yes.

3 Q And you indicate here that you previously
4 served as an expert witness on behalf of Stratus; is
5 that correct?

6 A Yes.

7 Q And were you retained by Stratus Medical in
8 that case?

9 A I was retained by a law firm.

10 Q Do you recall the law firm?

11 A No.

12 Q And that law firm represented Stratus Medical?

13 A Correct.

14 Q Okay. Do you recall when you were first
15 approached by the law firm to participate in the
16 Australia litigation that you mentioned in paragraph 4?

17 A Do I recall being approached by them?

18 Q No, when.

19 A When? Again, not the exact date, no.

20 Q Do you remember the year?

21 A It would've been 2019, possibly very late
22 2018.

23 Q So you first got involved in the Australia
24 case in either late 2018 or early 2019?

25 A I believe so.

1 Q Okay. And this was a patent case in the
2 Federal Court of Australia; is that right?

3 A Correct.

4 Q And as part of your work for Stratus in the
5 Australia litigation, did you provide an expert report?

6 A Yes.

7 Q Do you recall generally the subject matter
8 that you opined on in that expert report?

9 A Yes.

10 Q What was it?

11 A It was related to describing the nature of the
12 NIMBUS needle and the nature of the Diros needle and
13 what similarities or differences were between the two.

14 Q And that's the same NIMBUS needle that you
15 referenced in this declaration Exhibit 2,001?

16 A Yes.

17 Q About when did you complete that expert
18 report?

19 A In 2019.

20 Q And do you know if that report was submitted
21 to the Australian court?

22 A I believe it was.

23 Q Would that have been in 2019 also?

24 A I believe so.

25 Q And have you provided a copy of your expert

1 report from the Australia litigation in these U.S. IPRs?

2 A Sorry, just ask that question again?

3 Q Have you provided a copy of the expert report
4 that you prepared for the Australia litigation in these
5 U.S. IPRs?

6 A No.

7 Q When you were preparing your declaration in
8 these U.S. IPRs, did you rely at all on your expert
9 report from the Australia litigation?

10 A No.

11 Q Did you refer to it?

12 A No.

13 Q So for the avoidance of doubt, when you were
14 editing your declaration in the U.S. IPRs, you never
15 looked at your declaration from the Australia
16 litigation?

17 A Correct.

18 Q Okay. Other than for your work on the IPR
19 proceedings you're testifying in today and the Australia
20 litigation we just discussed, have you ever advised or
21 consulted for Stratus Medical?

22 A Yes.

23 Q And what was the nature of that consulting?

24 A They are designing their own radiofrequency
25 generator, and I was consulted on what I thought a good

1 radiofrequency generator should look like, and I
2 provided my opinion.

3 Q And when did you provide those consulting
4 services?

5 A That would've been about four years ago.

6 Q And were you paid for those services?

7 A No, but I think I was taken out to dinner.

8 MR. PHILLIPS: Okay. I'm going to
9 designate this portion of the transcript as
10 confidential.

11 [REDACTED]
12 [REDACTED]
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1 [REDACTED]
2 [REDACTED]
3 BY MR. KELLY:

4 Q Did you receive any other benefits as a result
5 of your consulting services that you provided to
6 Stratus?

7 A No.

8 Q Have you ever provided consulting services to
9 Biomerics?

10 A No.

11 Q Have you ever provided consulting services to
12 Nimbus Concepts?

13 A I think Nimbus Concepts is a company that is
14 making the generator. And if so, that who -- is who
15 asked me for my opinion on what would make a good
16 generator. I think it was Nimbus Concepts rather than
17 NIMBUS, but I'm not certain.

18 Q So your consulting on the generator, you said
19 that was four years ago?

20 A Yes.

21 Q So that would've been in the 2021 timeframe?

22 A Thereabouts.

23 Q Other than your consulting work on the
24 generator and your work in the legal proceedings we've
25 discussed, have you provided any other advising or

1 consulting services to Stratus?

2 A No.

3 MR. PHILLIPS: Okay. I want to clarify
4 that -- I want to designate as outside counsel only
5 everything in the transcript regarding Dr. Russo's
6 testimony concerning the RF generator.

7 BY MR. KELLY:

8 Q Other than for your work on the IPR
9 proceedings you're testifying in today and the Australia
10 litigation, have you ever served as an expert witness in
11 relation to subject matter that included RF ablation?

12 A No.

13 MR. KELLY: Okay. Let's take a break.

14 THE OFFICER: The time is 10:26 a.m., and
15 we are off the record.

16 (Off the record.)

17 THE OFFICER: The time is 10:51 a.m.
18 We're back on the record.

19 I'll also add, Counsel, just so everybody
20 knows, we are still confidential.

21 MR. PHILLIPS: I don't know. Depends
22 what the next topic is.

23 MR. KELLY: Well, I think -- are we on
24 the record now?

25 THE OFFICER: We're on the record. All I

1 meant to say was that we have yet to de-designate out of
2 confidentiality.

3 MR. PHILLIPS: Okay. Understood.

4 MR. KELLY: Okay. I think we can de-
5 designate now.

6 MR. PHILLIPS: All right. I'll designate
7 again if necessary.

8 MR. KELLY: Okay. And, Matt, for the
9 avoidance of doubt, my expectation is that when the
10 transcript is returned to us, you guys will mark the
11 part that you believe to be confidential before we file
12 it with the board.

13 MR. PHILLIPS: Yes.

14 MR. KELLY: So you'll have an opportunity
15 to parse out what parts of it need to be redacted.

16 MR. PHILLIPS: Okay. That'll work.

17 MR. KELLY: Okay.

18 [REDACTED]
19 [REDACTED]
20 //

21 //

22 //

23 //

24 //

25 //

1 [REDACTED]
2 [REDACTED]
3 BY MR. KELLY:

4 Q Okay. If you would, Ms. Russo, could you turn
5 to paragraph 89 of your declaration.

6 THE OFFICER: And just so I can confirm,
7 Counsel, you are de-designating?

8 MR. KELLY: Yes.

9 MR. PHILLIPS: Yes.

10 THE WITNESS: Eighty-nine? Yes.

11 BY MR. KELLY:

12 Q And paragraph 89 appears just below the
13 heading "History of RF Neurotomy." Do you see that?

14 A Yes.

15 Q And in paragraph 89, you refer to an article
16 entitled "A History of the Development of Radiofrequency
17 Neurotomy"; correct?

18 A Yes.

19 Q And you're a co-author of this article; right?

20 A Yes.

21 Q And the other authors -- well, let me hand you
22 a copy of this article.

23 A Yes.

24 Q So Mr. Russo, I've handed you a copy of what's
25 been previously marked Exhibit 2,004. Do you see that?

1 A Yes.

2 Q And is Exhibit 2,004 the article you
3 referenced in paragraph 89 of your declaration?

4 A Yes.

5 Q And you're a co-author of this article; right?

6 A I'm the co-author and principal author.

7 Q And the other co-authors are Danielle
8 Santerelli, Robert Wright, and Chris Gilligan; is that
9 right?

10 A Yes.

11 Q And the Robert Wright listed on the article is
12 the same Robert Wright who's an inventor of the Stratus
13 patents; is that right?

14 A Yes.

15 Q Okay. And you mentioned you were the
16 principal author of this document?

17 A Correct.

18 Q What does that mean?

19 A It means that I wrote 90 to 95 percent of
20 this. Danielle Santerelli is an employee of mine who
21 assists me in collating references and shepherding
22 journal articles through the publication process, and
23 she proofreads.

24 Robert Wright and Chris Gilligan were added.
25 Chris Gilligan obtained one of the photos for me on

1 page 3900 and provided review of my paper, and Robert
2 Wright provided details of his NIMBUS needle and
3 provided me with figure 3, which appears on page 3903.

4 Q Do you recall if Robert Wright wrote any
5 portions of the article?

6 A No. I interviewed him to obtain the details
7 that I then wrote up.

8 Q So the information in the article that relates
9 to Dr. Wright's work you obtained by interviewing
10 Dr. Wright himself?

11 A Correct.

12 Q Okay. I have some questions for you about the
13 testimony you've provided on the history of RF
14 neurotomy. So let's keep your declaration Exhibit 2,001
15 and the article Exhibit 2,004 handy, because we'll refer
16 to both of them. Okay?

17 A Yes.

18 Q Why don't we start at paragraph 96 of your
19 declaration. Let me know when you're there. Do you see
20 that?

21 A Yes.

22 Q And in paragraph 96, you indicate the first
23 clinical application of an RF lesion in spinal facet
24 pain was reported in 1974 by renowned American
25 neurosurgeon Dr. C. Norman Shealy; is that right?

1 A Yes.

2 Q So 1974 is the first time we see ablation of
3 nerve tissue using RF energy in a clinical setting; is
4 that right?

5 A Yes.

6 Q Okay. And the story with respect to that
7 procedure starts a few years before that when Dr. Shealy
8 meets with Dr. Rees; is that right?

9 A Yes.

10 Q And I gather from paragraph 97 that before
11 Shealy developed his RF technique, he met with Dr. Rees
12 in 1970 and learned about Dr. Rees's percutaneous
13 rhizolysis technique; is that right?

14 A Yes.

15 Q And you indicate in paragraph 97 that Shealy
16 reported an unacceptably high incidence of hematoma
17 formation using Rees's technique; is that right?

18 A Yes.

19 Q And is your understanding that is what drove
20 Shealy to investigate another way of treating back pain?

21 A Correct.

22 Q Okay. And in paragraph 98, you describe how
23 Shealy "devised the technique of percutaneous RFD
24 denervation of the facet joints by medial branch nerve
25 neurotomy"; right?

1 A Correct.

2 Q And you indicate that Shealy derived this
3 technique from principles used with gasserian ganglion
4 thermal RF; is that right?

5 A Yes.

6 Q Is gasserian ganglion thermal RF a form of RF
7 ablation?

8 A Yes.

9 Q Could you explain to me what gasserian
10 ganglion thermal RF is?

11 A There is a condition called trigeminal
12 neuralgia, which produces quite horrendous facial pain.
13 The trigeminal nerve can be attempted to be ablated by
14 inserting a needle to the forward projection of the
15 trigeminal root, which is known as the gasserian
16 ganglion. And you can perform a radiofrequency lesion
17 in an attempt to interrupt the amount of pain the
18 patient experiences. That was pioneered by the
19 neurosurgeons Wall and Sweet in the 1960s.

20 Q Could you say that again, the names of the ...

21 A The pioneering neurosurgeons Wall, W-A,
22 double L, and Sweet, S-W-E-E-T.

23 Q And around what time was this procedure
24 developed?

25 A In the 1960s. It would be approximately the

1 mid-1960s.

2 Q Okay. And in this procedure, the needle is
3 being used to ablate the trigeminal nerve? Do I
4 understand that right?

5 A Correct.

6 Q Okay. And the ablation occurs by RF energy
7 emitted from the needle?

8 A They would've been using, not the modern type,
9 but the original type that was used back then, yes.

10 Q Okay. So is this a form of RF neurotomy,
11 since nerve tissue is being ablated?

12 A Yes.

13 Q Okay. And where -- help me understand, just
14 as a lay person, where the trigeminal nerve is in the
15 body.

16 A You sort of go this way for that, go this way
17 for that, and have them meet, it'll be just in front of
18 the brain. So it's after the -- after the trigeminal
19 root exits the brain, and then it sits inside a part of
20 a small aerial cavern.

21 Q Okay. So where are the needles inserted into
22 the body for that procedure?

23 A Either inside the mouth this way or inserted
24 this way through the cheek.

25 Q And you can do either one?

1 A Correct.

2 Q Have you ever performed one of these
3 procedures?

4 A No. My institution, the neurosurgeons wish to
5 do the procedure, so I did not do it.

6 Q And what is the -- could you describe the
7 device that they would've been using at that time to
8 perform the gasserian ganglion thermal RF?

9 A Would've been a device produced by Cosman. I
10 think Cosman & Company would've been the manufacturer.
11 And back then, I'm -- I suspect it would've been -- it
12 wasn't part of my research, so it's not contained in my
13 paper, but it would've been a -- a solid one-piece unit.

14 Q When you say "one piece," you mean no
15 removable probe?

16 A Correct.

17 Q Okay. So how is the RF energy transmitted
18 through the device?

19 A From a connector at the end of the device onto
20 the machine.

21 Q Okay. But it's still a needle; right?

22 A At the other end --

23 Q Yes.

24 A -- the needle.

25 Q Okay. And the RF energy is emitted from the

1 tip of the needle?

2 A Correct.

3 Q Okay. If we look ahead to paragraph 99, you
4 indicate that Shealy then works on designing an RF
5 neurotomy device with Eric and Bernard Cosman; correct?

6 A Yes.

7 Q And are -- I think this is the same Cosman
8 that you just mentioned manufactured the device for
9 gasserian ganglion thermal RF?

10 MR. PHILLIPS: Objection, form.

11 THE WITNESS: Yes.

12 BY MR. KELLY:

13 Q Okay. And at that point, the -- so we're
14 still in the early 1970s, and at that point the Cosmans
15 had already founded Radionics; is that right?

16 A Yes.

17 Q And you indicate in paragraph 99 that the
18 Cosmans had built the first commercial RF lesion
19 generator in the 1950s; is that right?

20 A Yes.

21 Q And the RF technology the Cosmans worked on in
22 the fifties in the sixties, was that not for neurotomy?

23 A The very first use of their machine is -- is
24 not known to me, for what purpose it was produced.

25 Q Well, I mean we just talked about that it was

1 used for gasserian ganglion thermal RF in the sixties;
2 is that right?

3 A Yes. But they first produced their device in
4 the 1950s. Now, what radiofrequency was performed in
5 the 1950s that they developed it for is not known to me.

6 Q Okay. So you're not sure what the Cosman
7 generator was used for prior to 1970s?

8 MR. PHILLIPS: Objection, form.

9 THE WITNESS: No. I said the original
10 use for which they first built the machine would've been
11 for a medical use.

12 BY MR. KELLY:

13 Q Okay.

14 A Now, which of those early indications it was
15 first used for is not known to me.

16 Q Okay. Do you know of any use of the Cosman RF
17 generator prior to this work with Shealy in the 1970s?

18 A Yes, gasserian ganglion radiofrequency
19 neurotomy --

20 Q Okay. Do you know of any other -- sorry.

21 A -- as well as percutaneous cordotomy.

22 Q Sorry, could you say that again?

23 Percutaneous?

24 A Percutaneous cordotomy, C-O-R-D-O-T-O-M-Y.

25 Q So prior to the seventies, the Cosman

1 generator was used for percutaneous cordotomy and
2 gasserian ganglion thermal RF; correct?

3 A Yes.

4 Q Do you know of any other uses?

5 A No.

6 Q Could you describe percutaneous cordotomy to
7 me?

8 A It's the placement of a very fine needle
9 to -- inside the spinal cord, specifically to the
10 lateral spinothalamic tract, and it is done usually for
11 patients dying of terminal cancer. And a -- a lesion is
12 made in the spinothalamic tract to interrupt pain that
13 is coming from below the neck to provide pain relief for
14 a palliative cancer patient. Highly effective, but at
15 the risk of death, paralysis, stroke, and other serious
16 complications.

17 Q And is percutaneous cordotomy a type of RF
18 neurotomy?

19 A Yes.

20 Q And what is the nerve tissue that's being
21 ablated in percutaneous cordotomy?

22 A The spinal cord, a part thereof of the spinal
23 cord.

24 Q Are there any other names for that nerve?

25 A The -- the spinal cord has various tracts or

1 bundles of nerve fibers. The relevant nerve fiber for
2 this is the lateral spinothalamic tract.

3 Q So would it be -- would it be accurate to say
4 in a percutaneous cordotomy procedure, the lateral
5 spinothalamic tract nerve tissue is ablated?

6 A Yes.

7 Q Okay. And looking back in paragraph 99 of
8 your declaration, it indicates the device that Shealy
9 and the Cosmans develop is the SRK-Shealy Rhizolysis
10 Kit; is that right?

11 A Yes.

12 Q And was this kit made commercially available?

13 A Yes.

14 Q Around what time would that have been?

15 A The 19 -- early 1970s.

16 Q And it was used for RF neurotomy of medial
17 branch nerves?

18 A Yes.

19 Q Do you know whether it was used for RF
20 neurotomy of other nerves at that time?

21 A Also for percutaneous cordotomy.

22 Q Okay. If we look at the paragraphs 100 to 103
23 in your declaration, it looks like the Shealy Cosman SRK
24 device is then refined and modified throughout the
25 seventies and the eighties; is that fair?

1 A Yes.

2 Q And in paragraph 103, you indicate in the
3 early 1980s, "Sluitjer developed refined techniques for
4 cervical, thoracic, lumbar, and sacral spinal pain
5 syndromes using percutaneous RF techniques." Do you see
6 that?

7 A Yes.

8 Q And your understanding is that Sluitjer is
9 using some derivative of the SRK needle when he is
10 refining these techniques?

11 A More or less, yes.

12 Q So he's not changing the device. He's
13 changing the manner in which the device is used?

14 A No. He also introduced 22-gauge needles as
15 a -- for some procedures. They were available earlier
16 but tended not to be used as much.

17 And he produced monographs. He was one of the
18 first people to produce monographs of teaching for
19 doctors.

20 Q I'm sorry, what does that mean?

21 A So a "monograph" is a how-to guide on how to
22 perform the procedure that previously had not been
23 present.

24 Q Okay. And in paragraph 107, you referenced
25 "cooled radiofrequency ablation." Do you see that?

1 A Yes.

2 Q And so chronologically we're now well past the
3 seventies and the eighties; right?

4 A Correct.

5 Q Okay. And it says here in paragraph 107,
6 "Cooled radiofrequency ablation was first developed in
7 the late 1990s for use in the cardiac field for
8 arrhythmia management"; correct?

9 A Yes.

10 Q And do you know who developed cooled RF
11 ablation for cardiac applications?

12 A No.

13 Q And paragraph 107 also says that "Cooled RF
14 ablation found application in tumor ablation as a method
15 to enlarge tumor destruction volume"; is that right?

16 A Yes.

17 Q And do you know who developed cooled RF
18 ablation for tumor applications?

19 A No.

20 Q So the cooled RF ablation technique was
21 developed for cardiac and tumor ablation and then later
22 applied to RF neurotomy; is that right?

23 A Correct.

24 Q And roughly when was cooled RF introduced for
25 RF neurotomy?

1 A Would've been around 2014, plus or minus.

2 Q And paragraph 107 of your declaration says,
3 "Cooled RF technology was first introduced into the pain
4 management field via custom-designed equipment for
5 treatment of sacroiliac joint pain." Do you see that?

6 A Yes.

7 Q What custom-designed equipment are you
8 referring to here?

9 A I'm referring to the -- I think it was
10 actually called "cooled" -- in Australia it was called
11 "cooled RF." It may have had a different name outside
12 of Australia. It was provided by a -- a single company
13 who -- who made it.

14 Q Do you recall the manufacturer?

15 A No.

16 Q And you said this would've been around 2014?

17 A Yes.

18 Q And so the cooled RF needles were commercially
19 available for RF neurotomy in 2014?

20 A Yes.

21 Q Okay. Let's refer back to your article.
22 That's Exhibit 2,004. And could you find the heading
23 "Tined Needle Designs" on page 3,902?

24 A Yes.

25 Q And in the paragraph below the heading "Tined

1 Needle Designs," you refer to Dr. Robert Wright;
2 correct?

3 A Yes.

4 Q And, again, this is the same Dr. Wright whose
5 named as an inventor on the Stratus patents?

6 A Yes.

7 Q And in this section that has the heading
8 "Tined Needle Designs," you are describing the
9 development of the NIMBUS device that is now sold by
10 Stratus; is that right?

11 A Yes.

12 Q And if I read from Exhibit 2,004, beginning at
13 the bottom of page 3902, you state here that in 2006 the
14 Canadian-based Baylis Medical Company asked Wright to
15 evaluate their internally cooled RF electrode for
16 sacroiliac joint denervation. And the temperature
17 safety study he performed was presented at the 2007
18 Spine Intervention Society Annual Meeting; is that
19 right?

20 A Yes.

21 Q And this sentence cites to footnote 61. Do
22 you see that?

23 A Yes.

24 Q So if we turn to footnote 61 at the end of
25 your article.

1 A Yes.

2 Q This references a paper by Wright and others
3 entitled "In Vivo Temperature Measurement During
4 Neurotomy for Sacroiliac Joint Pain Using the Baylis
5 Synergy Probe."

6 A Yes.

7 Q Is that correct? Okay.

8 So if we turn back to page 3902 of your
9 article, in the second sentence after the titled
10 needle -- in the "Tined Needle Designs" heading, you
11 refer to an internally cooled RF electrode that
12 Dr. Wright evaluated. Do you see that?

13 A Yes.

14 Q And that is the Baylis Synergy Probe; is that
15 right?

16 A Yes.

17 Q And so Dr. Wright was evaluating this probe in
18 the 2006 to 2007 timeframe?

19 A Yes.

20 Q Okay. So earlier you told me that you thought
21 that cooled RF was introduced for neurotomy in 2014; is
22 that right?

23 A Commercially available, certainly in my
24 country --

25 Q Okay.

1 A -- yes, around 2014.

2 Q So was the probe that Dr. Wright was
3 evaluating in the 2006/2007 timeframe, was this not
4 commercially available?

5 A I don't think it would've been commercially
6 available in 2006.

7 Q How about 2007?

8 A I would need to find out when it was
9 commercially available in the United States. I think it
10 was likely to have been released in the United States
11 before other countries in the world.

12 Q Would it have been -- is your understanding
13 that it was commercially available before 2014?

14 A Quite possibly.

15 Q Okay. So you're not sure when the first
16 cooled RF neurotomy device was introduced in the United
17 States commercially?

18 MR. PHILLIPS: Objection, form.

19 THE WITNESS: I would need to look that
20 up.

21 BY MR. KELLY:

22 Q So you don't -- sitting here today, you don't
23 know?

24 A I'm uncertain of the exact date of its
25 release.

1 Q On the next page of your article labeled 3903,
2 you indicate that after Wright evaluated the Baylis
3 Cooled RF Probe, he started trying to conceive an
4 alternative to that device; is that right?

5 A Yes.

6 Q And the article indicates that Wright's work
7 on this alternative device began in 2009?

8 A Yes.

9 Q And during that period, Dr. Wright was
10 benchmarking the lesion created by the cooled RF device;
11 is that right?

12 A Okay. Where are you obtaining that from? I
13 don't -- can't see any benchmarking word --

14 Q Oh, sorry.

15 A -- in my paper.

16 Q It says on page 3903, it says, "Wright was
17 trying to conceive of an alternative device that could
18 match the lesion created by the internally cooled
19 electrode."

20 A Yes.

21 Q So he was benchmarking that internally cooled
22 electrode?

23 A I see what you mean by the use of
24 "benchmarking." Yes, if I understand you correctly.

25 Q Okay, let's turn to paragraph 5 of your

1 declaration.

2 A Yes.

3 Q And you state here, "I wrote a preface to a
4 practice guide entitled 'Robert E. Wright,
5 Radiofrequency Ablation and Interventional Pain
6 Management Using RF Multi-Timed Expandable Electrode,
7 First Edition,' which preface is provided herewith as
8 Exhibit No. 2,003." Do you see that?

9 A Yes.

10 Q I've handed you a copy of what's been
11 previously marked Exhibit 2,003. Do you see that?

12 A Yes.

13 Q And this is a copy of your preface in the
14 practice guide that you refer to in paragraph 5; is that
15 right?

16 A Yes.

17 Q And other than your preface, Exhibit 2,003
18 excludes the rest of the practice guide; is that right?

19 A Yes.

20 Q Mr. Russo, I've handed you a copy of what's
21 been marked Exhibit 1051. Do you see that?

22 A Yes.

23 Q And could you compare the cover pages of
24 Exhibit 1051 and Exhibit 2,003, and let me know if you
25 believe they're the same.

1 A No, they're not.

2 Q What's the difference?

3 A There is a mirror -- mirror reversal of the
4 picture.

5 Q On the cover?

6 A Yes.

7 Q Okay. If you could refer to the copyright
8 page of both Exhibits 2,003 and 1051. Is the ISBN
9 number on the copyright page the same?

10 A Yes.

11 Q So is Exhibit 1051 a complete copy of the
12 practice guide that you refer to in paragraph 5 of your
13 declaration?

14 A Let's go to the back. Well, assuming
15 nothing's been left out, I would say yes.

16 Q Well, take a second to flip through it and see
17 if you identify anything that appears to be missing.

18 A Not that I can see.

19 Q Okay. Let's turn to page 5 of Exhibit 1051.

20 A Which is the full book?

21 Q Yeah. You can set aside 2,003 now.

22 A Which page, sorry?

23 Q Page 5 of Exhibit 1051.

24 A Yes.

25 Q And do you see a table entitled "Monopolar

1 Comparison"?

2 A Yes.

3 Q And this table is comparing different
4 monopolar RF neurotomy devices; is that right?

5 A Yes.

6 Q And the leftmost column indicates
7 characteristics of the NIMBUS device; is that right?

8 A Yes.

9 Q And the column adjacent to that indicates
10 characteristics of a cooled RF neurotomy device;
11 correct?

12 A Yes.

13 Q And the first row of the Monopolar Comparison
14 Table indicates that the lesion volume for the NIMBUS
15 device and the cooled RF device; right?

16 A Yes.

17 Q And the table indicates that the lesion volume
18 for the NIMBUS device and the cooled RF device are
19 nearly the same; right?

20 MR. PHILLIPS: Objection, form.

21 THE WITNESS: Yes.

22 BY MR. KELLY:

23 Q And if I refer back to your history of RF
24 neurotomy article where you mentioned that Dr. Wright
25 was trying to match the lesion created by cooled RF, it

1 would seem from this table that he did a good job; is
2 that fair?

3 MR. PHILLIPS: Objection, form.

4 THE WITNESS: That's a very broad
5 coverage. Any comparison is only as relevant as the
6 baseline criteria with which the comparison was
7 performed. So missing from this is, for example, the
8 duration of time applied. Missing from this is the
9 tissue in which the study was performed. So without
10 those details, it is difficult to make an overall
11 comparison.

12 BY MR. KELLY:

13 Q If you look at the copyright page of 1051.

14 A Yes.

15 Q This indicates the copyright is held by
16 Stratus Medical, LLC?

17 A Yes.

18 Q So this is a Stratus book; right?

19 A It is copyrighted by Stratus Medical. I
20 believe the author of the book is Robert Wright, with
21 contributions from a variety of different doctors.

22 Q So is the information in the Monopolar
23 Comparison Table on page 5 reliable?

24 MR. PHILLIPS: Objection, form.

25 THE WITNESS: The reliability is

1 determined by going to the source with which this has
2 been constructed. Then one can parse through that,
3 P-A-R-S-E, and form an opinion about reliability. I
4 don't look at a green dot or a red dot as adequate for
5 my own purposes.

6 BY MR. KELLY:

7 Q Is this adequate for anybody?

8 A Yes, in that it is a pictorial summary to
9 inform people.

10 Q So this Monopolar Comparison Table in the
11 Stratus book at the very least would indicate how
12 Stratus believes the NIMBUS device compares to other RF
13 neurotomy devices; right?

14 MR. PHILLIPS: Objection, form,
15 foundation.

16 THE WITNESS: No. I don't believe that
17 the introduction was written by an employee of Stratus
18 Medical. My understanding is that Dr. Wright and fellow
19 doctors wrote the chapters. I believe that the
20 introduction was written by Dr. Wright.

21 BY MR. KELLY:

22 Q Are you aware that Stratus Medical sells this
23 book on its website?

24 A Yes.

25 Q So is Stratus Medical selling a book with

1 unreliable information in it?

2 A I have no reason to believe so.

3 Q Okay. So we can trust that the table on
4 page 5 entitled "Monopolar Comparison" provides an
5 accurate comparison of the NIMBUS device to other RF
6 neurotomy devices?

7 A For the specific specifications of the study
8 in which it was conducted.

9 Q Could you turn to your preface at the
10 beginning of Exhibit 1051?

11 A Yes.

12 Q And in the last paragraph, the first sentence
13 reads -- and I believe these are your words -- "I
14 commend Dr. Wright and his co-authors for producing this
15 excellent monograph."

16 A Yes.

17 Q "It will have pride of place on my bookshelf
18 and will be compulsory reading for my fellows and
19 trainees."

20 A Yes.

21 Q "I commend it to you wholeheartedly, with the
22 universal caveat that there is no universal truth, for
23 our understanding of science and medicine is continually
24 evolving."

25 A Yes.

1 Q Okay. So you're praising the contents of this
2 book in the preface?

3 A Yes.

4 Q So what I'd like to know is whether or not the
5 comparison of the devices on page 5 is accurate and
6 reliable.

7 A And the way to answer that question is to go
8 to the source of documentation that produced that table.

9 Q We can't assume that it's reliable and
10 accurate because Stratus is publishing it in their own
11 book?

12 A I would not use the relevance of the
13 copyright. I would use the expertise of the author
14 writing the introduction.

15 Dr. Wright is certainly an expert in
16 radiofrequency neurotomy. He's certainly an expert in
17 his own needle that he invented. And I would expect
18 that if we went to the source, we would be able to see
19 the nature of the tissue in which this comparison was
20 conducted, the times that it was applied for, the
21 temperatures that were applied for, et cetera.

22 Q But the source is not indicated here; is that
23 right?

24 A Correct.

25 MR. PHILLIPS: Objection, form.

1 BY MR. KELLY:

2 Q So at the very least, Dr. Wright didn't feel
3 the source was necessary to convey --

4 A Lesion volume, and there is a small No. 3
5 attached to that. So I would need to determine if we
6 are referencing reference 3 as regards to that. So that
7 may be the source.

8 On page 12, there is reference 3, Cedeno,
9 Vallejo, Kelley, Tilley, Kumar, comparisons of lesion
10 volumes and shapes produced by a radiofrequency system
11 with a cooled, a protruding, or a monopolar probe,
12 published in "Pain Physician" in 2017.

13 So it would appear that this is, in fact,
14 independent research that has been conducted by doctors
15 other than Dr. Wright and published in a peer-reviewed
16 journal.

17 Q And it would seem Dr. Wright is relying on
18 this study? Is that your opinion?

19 A Correct.

20 Q So if the information in the study cited in
21 footnote 3 is consistent with what is in the Monopolar
22 Comparison Table on page 5 of the book, is it your
23 opinion that the table would be accurate?

24 A Correct.

25 Q Okay. So the table on page 5 indicates that

1 the lesion volume for NIMBUS is 601 millimeters squared.
2 And I think -- is your opinion that that's a typo?

3 A In what sense?

4 Q Well, it says "millimeters squared" instead of
5 "millimeters cubed."

6 A I see what you mean. I would believe so, yes.

7 Q Okay. And it indicates that the lesion volume
8 for cooled RF is 595 millimeters squared, or presumably
9 cubed; is that right?

10 A Yes.

11 Q Okay. So the lesion volume for cooled RF in
12 NIMBUS is basically the same; is that right?

13 MR. PHILLIPS: Objection, form.

14 THE WITNESS: Yes.

15 BY MR. KELLY:

16 Q And in the second row, there's a heading that
17 says "Perpendicular Placement." Do you see that?

18 A Yes.

19 Q And this indicates whether a perpendicular
20 approach can be used with the devices that are reflected
21 in the table; is that right?

22 A Yes.

23 Q And the table indicates that the NIMBUS device
24 allows for perpendicular placement; correct?

25 A Yes.

1 Q And the table also indicates that the cooled
2 RF device allows for perpendicular placement; correct?

3 A Yes.

4 Q In your opinion, why is it that the NIMBUS
5 device and the cooled RF device allow for perpendicular
6 placement, but the other probes in the Monopolar
7 Comparison Table do not?

8 A It is to do with the shape of the lesion that
9 is produced from the other three. So they do not
10 protrude -- the lesion isotherm does not protrude
11 significantly from the tip. If you, therefore, place
12 the tip perpendicular, you'll get a tiny point source of
13 lesion, but you will not get any sizable lesion, because
14 it will be all proximal.

15 Q So you're saying for the 18-gauge PE, 16-gauge
16 mono, and 18-gauge mono, the lesion doesn't have the
17 right shape? Is that what you're saying?

18 A Correct.

19 Q Okay. And what is the difference between the
20 right shape and the wrong shape?

21 MR. PHILLIPS: Objection, form.

22 THE WITNESS: The right shape is a shape
23 that will ablate the nerve in question. And for a
24 perpendicular approach, you need a particular shape.
25 For the parallel approach, you need a particular shape.

1 BY MR. KELLY:

2 Q So what is the difference between the shape
3 that you need for the perpendicular approach and the
4 shape you need for the parallel approach?

5 A The shape that you need for a parallel
6 approach should be an ovoid lesion that pans out at its
7 maximum distance from the midpoint of the active tip,
8 active component of the needle, whereas the
9 perpendicular approach is aiming to create a -- a base
10 at the tip that expands outwards and then will get
11 smaller as it goes proximal up the shaft.

12 Q Okay. So in the -- I think what you're saying
13 is for the lesion that you need for the perpendicular
14 approach, it needs to extend distally relative to the
15 needle, further than the --

16 A Distally and outwards.

17 Q Okay. So the lesion in this table, the lesion
18 for the 18-gauge PE, 18-gauge mono, and 16-gauge mono,
19 that lesion does not extend distally enough to allow for
20 perpendicular placement, based on the table; is that
21 right?

22 A Correct.

23 Q And the lesion for the NIMBUS device and the
24 cooled RF device extends distally enough to allow for
25 perpendicular placement; is that right?

1 A Correct.

2 Q Do you recall earlier identifying November
3 2009 as the earliest relevant date for the Stratus
4 patents?

5 A Yes.

6 Q And if you want a cite, you mentioned this in
7 paragraph 72 of your declaration, if you want to double
8 check.

9 A Yes.

10 Q So before November 2009, the NIMBUS device was
11 not commercially available; right?

12 MR. PHILLIPS: Objection, foundation,
13 form.

14 THE WITNESS: I don't believe it was
15 available in 2007 or 2008.

16 BY MR. KELLY:

17 Q Was it available in 2009?

18 A The commercial release date of the NIMBUS
19 would've been 2009 or 2010.

20 Q In what country?

21 A United States, I believe.

22 Q Well, I think you indicated in your "History
23 of RF Neurotomy" article that Wright was working on
24 developing the NIMBUS beginning in early 2009; correct?

25 A Yes.

1 Q So it doesn't seem right that he would've been
2 able to get that product commercially available by the
3 end of 2009?

4 A No, correct. Likely correct.

5 Q So do you know when the NIMBUS device was
6 first made commercially available?

7 A Commercially available? No. I don't have the
8 release date.

9 Q Okay. Would it have been after the relevant
10 dates of the Stratus patents?

11 A Yes.

12 Q Okay. So some point, I think in paragraph 72,
13 you say the relevant dates of the Stratus patents span
14 November 5, 2009, through May 4, 2011?

15 A Yes.

16 Q So your understanding is that the NIMBUS
17 device was not commercially available until after May 4,
18 2011?

19 A Yes.

20 Q Okay. So before the relevant dates, meaning
21 before November 5, 2009, was a cooled RF neurotomy
22 device commercially available?

23 A Yes.

24 Q And could you give me an example of a cooled
25 RF neurotomy device that was available before 2009?

1 A The Baylis device.

2 Q And based on the Monopolar Comparison Table on
3 page 5, that Baylis device would allow for perpendicular
4 placement; is that right?

5 A Yes.

6 Q So it was known in the art that cooled RF
7 probes allowed for perpendicular approach to be used
8 before 2009?

9 A No, because I believe the cooled RF was first
10 developed for the sacroiliac joint, and it was promoted
11 for the sacroiliac joint. I think it was only a number
12 of years later that it then began to be promoted for
13 facet joint radiofrequency neurotomy.

14 Q Well, I'm not asking about what the device was
15 promoted for. I'm just asking about what a person of
16 ordinary skill in the art at the time of the invention
17 would've known. So the question is, would a person of
18 ordinary skill at the time of the invention have known
19 that cooled RF probes allowed for a perpendicular
20 approach to be used?

21 A No. There was no evidence to suggest that at
22 that time.

23 Q When do you believe a person of ordinary skill
24 would've become aware that a cooled RF probe could be
25 used for a perpendicular approach?

1 A When it started to be used for that purpose,
2 which was a number of years after its initial release.

3 Q Dr. Russo, I've handed you a copy of an
4 exhibit marked Petitioner's Exhibit 1055.

5 A Yes.

6 Q Do you see that?

7 A Yes.

8 Q And have you seen this document before?

9 MR. PHILLIPS: Objection, scope.

10 THE WITNESS: I don't recall the color
11 scheme. I recall seeing information on the Synergy
12 System when it came out.

13 BY MR. KELLY:

14 Q So if we look at the cover of Exhibit 1055,
15 this appears to be published by Baylis Medical --

16 A Yes.

17 Q -- is that right?

18 And it identifies that it's directed to the
19 Synergy System?

20 A Yes.

21 Q And is it your understanding this is the same
22 Synergy System that is referenced in your "History of RF
23 Neurotomy" article?

24 A Yes.

25 Q And the cover of this document indicates that

1 it's a user guide for effective denervation in the
2 treatment of chronic sacroiliac joint pain; is that
3 right?

4 A Yes.

5 Q And appears to have been published in
6 September of 2008?

7 A Yes.

8 Q Can you think of any reason that Baylis
9 would've published a user guide for its Synergy System
10 in September of 2008 if the device was not commercially
11 available?

12 A No.

13 MR. PHILLIPS: Objection, scope.

14 BY MR. KELLY:

15 Q Could you turn to page 5 of Exhibit 1055?

16 A Yes.

17 Q And you see the heading "Internally Cooled RF
18 Systems"?

19 A Yes.

20 Q And if you look into the first paragraph under
21 that heading on page 5, you'll see a sentence that
22 begins, "As a result," comma. Let me know when you see
23 that.

24 A Yes.

25 Q And this says, "Internally cooled electrodes

1 can produce much larger lesions compared to non-cooled
2 electrodes."

3 A Yes.

4 Q Do you see that?

5 Do you agree with that statement?

6 MR. PHILLIPS: Objection, scope.

7 THE WITNESS: Yes.

8 BY MR. KELLY:

9 Q And if you skip ahead to page 6, and you see
10 an image labeled figure 4?

11 A Yes.

12 Q And that image is entitled "Spherical Lesions
13 Allow Perpendicular or Oblique Placement Towards the
14 Target Location"; is that right?

15 A Yes.

16 MR. PHILLIPS: Objection, form,
17 mischaracterizes.

18 BY MR. KELLY:

19 Q And above that figure, in the paragraph above
20 figure 4, do you see a sentence beginning, "A portion"?

21 A No. Where is this?

22 Q This would be the third sentence in the
23 paragraph above figure 4.

24 A Oh, hold on. Hold on.

25 Q Okay. In this -- in here, the Baylis User

1 Guide states, "A portion of this lesion can project
2 distally from the probe, heating tissue that might
3 otherwise be difficult to access. These distinct lesion
4 characteristics allow perpendicular electrode placement
5 towards the target." Do you see that?

6 A Yes.

7 Q And is that consistent with your understanding
8 of cooled RF neurotomy needles?

9 MR. PHILLIPS: Objection, scope.

10 THE WITNESS: Yes.

11 BY MR. KELLY:

12 Q And if you look at page 7 of this document,
13 there's a heading that says "Spherical Lesions." Do you
14 see that?

15 A Yes.

16 Q And here the user guide states, "The spherical
17 shape of the lesion allows perpendicular, oblique, or
18 parallel approaches towards the target structure. The
19 distally projecting portion of the lesion will form
20 around ridges and within crevices on irregularly shaped
21 surfaces." Do you see that?

22 A Yes.

23 Q And is that consistent with your understanding
24 of cooled RF neurotomy needles?

25 MR. PHILLIPS: Objection, scope.

1 THE WITNESS: This is a general
2 statement. I think it depends on size of crevice and
3 size of irregularly shaped surface. I can imagine
4 irregularly shaped surfaces in which it will not do this
5 and minor irregularly shaped surfaces in which case it
6 would do this. So it would depend.

7 BY MR. KELLY:

8 Q So based on this document, is it fair to
9 assume the Baylis Synergy System was commercially
10 available before the relevant dates of the Stratus
11 patents?

12 MR. PHILLIPS: Objection, scope.

13 THE WITNESS: At least in one country.

14 BY MR. KELLY:

15 Q Okay. So the device described in the Stratus
16 patents was not the first device to enable the
17 perpendicular approach to be used; is that right?

18 MR. PHILLIPS: Objection, scope.

19 THE WITNESS: The perpendicular approach
20 that the Synergy System User Guide is promoting is
21 specifically the sacroiliac joint.

22 BY MR. KELLY:

23 Q So the device described in the Stratus patents
24 was not the first device to enable the perpendicular
25 approach to be used for the sacroiliac joint; is that

1 correct?

2 MR. PHILLIPS: Objection, scope.

3 THE WITNESS: Correct.

4 BY MR. KELLY:

5 Q And the perpendicular approach was already
6 made possible using cooled RF at the time of the
7 invention; right?

8 MR. PHILLIPS: Objection, form.
9 Objection, scope.

10 THE WITNESS: Yes.

11 BY MR. KELLY:

12 Q Okay. Now, I think you told me earlier that
13 this user guide appears to be focused on the sacroiliac
14 joint?

15 A Yes.

16 Q Is that right?

17 Okay. Mr. Russo, I've handed you a copy of
18 what's been previously marked Petitioner's Exhibit 1015.
19 Do you see that?

20 A Yes.

21 Q And did you review this document when you were
22 preparing your declarations?

23 A No.

24 Q Were you aware that it was cited by Avanos in
25 at least one of its petitions?

1 A Not particularly, no.

2 Q If you look at the cover of this patent
3 publication, do you see that the assignee is Baylis
4 Medical Company?

5 A Yes.

6 Q And if you would just take a minute to scan
7 through the figures of this patent, and you don't have
8 to memorize them, but just kind of take a chance to
9 familiarize yourself with them.

10 A Yes.

11 Q Okay. And if -- well, just looking at the
12 figures, do you recognize this as a cooled tip RF
13 neurotomy device?

14 MR. PHILLIPS: Objection, scope.

15 THE WITNESS: It's not particularly
16 clear. I would have to spend quite some time reviewing
17 this in detail.

18 BY MR. KELLY:

19 Q All right. Well, let's turn to paragraph 36
20 of the publication. Let me know when you're there.

21 A This is the patent publication?

22 Q Yes, of Exhibit 1015.

23 A Mine only goes to page 20.

24 Q Oh, sorry, paragraph 36 there, notated in the
25 document.

1 A It starts, "With -- with reference first to
2 figure 1-A"?

3 Q Yes.

4 A Right.

5 Q And in paragraph 36 of Exhibit 1015, the
6 publication states, "With reference to -- with reference
7 first to figure 1-A, a device of the present invention
8 may generally comprise an electrosurgical instrument or
9 device 100."

10 And then it says, "As shown in the embodiment
11 of figures 1-A to 1-C, the electrosurgical instrument or
12 device 100 may be a probe 100. However, in other
13 embodiments, the electrosurgical instrument or device
14 100 may be a cannula, a catheter, or any other elongate
15 member capable of delivering energy to a target site
16 within a patient's body."

17 And then it says, "For the sake of clarity,
18 the term 'probe' is used throughout the specification to
19 describe any such device." Do you see that?

20 A Yes.

21 Q Skip ahead to paragraph 45.

22 A Yes.

23 Q And the first sentence of paragraph 45 states,
24 "In some embodiments, probe 100 may be cooled. In some
25 specific embodiments, probe 100 may be cooled by the

1 internal circulation of a cooling fluid." Do you see
2 that?

3 A Yes.

4 Q So at least some of the embodiments in this
5 publication are cooled RF probes; is that right?

6 MR. PHILLIPS: Objection, scope.

7 THE WITNESS: I haven't read the sections
8 where they get to radiofrequency.

9 BY MR. KELLY:

10 Q Okay.

11 A So far I've only got to 45, which talks about
12 an embodiment of internal circulation of cooling fluid.
13 So that is all I know from this patent. That's all I've
14 been directed to.

15 Q Let's look at paragraph 79. And paragraph 79
16 states, "Embodiments comprising a cooled probe within a
17 cannula may be advantageous in that pre-existing cannula
18 may be used in conjunction with such embodiments of a
19 cooled probe. Examples of such cannula include the
20 Baylis Pain Management Radiofrequency Cannula of Baylis
21 Medical Company, Montreal, Canada." Do you see that?

22 A Yes.

23 Q And if you skip ahead to paragraph 84, refers
24 to a generator 608 that "may produce various types of
25 energy. For example, microwave, ultrasonic, optical, or

1 radiofrequency electrical energy. In some embodiments,
2 the generator 608 may produce radiofrequency electrical
3 current." Do you see that?

4 A Yes.

5 Q So this is describing a cooled RF probe;
6 right?

7 MR. PHILLIPS: Objection, scope.

8 THE WITNESS: It is describing producing
9 radiofrequency electrical current with cooling.

10 BY MR. KELLY:

11 Q So you don't think this is a cooled RF probe?

12 MR. PHILLIPS: Objection, scope.

13 THE WITNESS: It says, "Probe refers to
14 any embodiment of elongate member."

15 BY MR. KELLY:

16 Q So what do you understand the patent to be
17 describing?

18 MR. PHILLIPS: Objection, scope.

19 THE WITNESS: A device to produce cooling
20 along an elongate member that conducts radiofrequency
21 electrical current. I've yet to see where in this
22 patent it says what it's for.

23 BY MR. KELLY:

24 Q Okay. Let's look to paragraph 71. And look
25 at the top of page 7, which is roughly the middle of

1 paragraph 71. There's a sentence that begins, "In these
2 embodiments, a lesion 502." Let me know when you see
3 that.

4 A I'm searching.

5 Q So it'd be right --

6 A Oh, right at the top?

7 Q Yeah.

8 A "In these embodiments, a lesion 502" --

9 Q Yes.

10 A -- "may form wherein the lesion forms
11 substantially distal to the distal face."

12 Q And so here in paragraph 71, Exhibit 1015,
13 states, "In these embodiments, a lesion 502 may form
14 wherein the lesion forms substantially distal to the
15 distal face 107, for example, such that the majority of
16 lesion 502 is located distal to the distal face 107 of
17 the probe, and the shape of the lesion 502 may be
18 substantially rounded." Do you see that?

19 A Yes.

20 Q And if you skip ahead, the next sentence
21 begins, "In use, such a probe 100 may be positioned such
22 that it is oriented substantially perpendicular or
23 generally upstanding to the target site or surface of
24 the tissue to be lesioned; i.e., such that the tissue to
25 be lesioned is generally distal to the probe 100,

1 whereby the lesion may extend distally from the probe
2 100 to the target tissue."

3 A Yes.

4 Q And then it states further, "This can provide
5 significant advantages in a region of the body such as
6 the sacroiliac region." Do you see that?

7 A Yes.

8 Q So this is describing using a cooled RF
9 neurotomy probe to perform neurotomy in the sacroiliac
10 region.

11 A No, it's not --

12 MR. PHILLIPS: Objection --

13 THE WITNESS: -- it's not. It's --

14 MR. PHILLIPS: -- scope.

15 THE WITNESS: -- it's referring to
16 forming a lesion over the sacroiliac region. It's yet
17 to describe a neurotomy. Is it lesioning the bone? Is
18 it lesioning the muscle adjacent to the bone? Is it
19 lesioning the nerves that traverse the -- the sacrum on
20 the way to the sacroiliac joint? I've yet to see any
21 statement as regards what is the target tissue.

22 BY MR. KELLY:

23 Q Let's look in paragraph 94. And I'm at the
24 top here in the sentence beginning, "For example."

25 A Yes, I've got it.

1 Q And here it states, "For example, if the
2 target tissue is a nerve, the probe may be positioned
3 such that the probe is substantially perpendicular or
4 generally upstanding relative to the nerve."

5 A Yes.

6 Q So the target tissue can be a nerve; right?

7 MR. PHILLIPS: Objection, scope.

8 THE WITNESS: Yes.

9 BY MR. KELLY:

10 Q Let's look in paragraph 123.

11 A Yes.

12 Q And let's look at the last sentence of
13 paragraph 123.

14 A Is that "Because lesions"?

15 Q Yes. And if you want, you can just read this
16 sentence into the record.

17 A "Because lesions formed by this method may
18 reach tissue that lies within grooves or other
19 indentations within a bone or directly on the surface of
20 a bone, this method may be particularly useful for
21 lesioning of the nerves of the medial branch of the
22 dorsal ramus at the cervical region of the spine."

23 Q So this is describing RF neurotomy of the
24 medial branch using a cooled RF probe?

25 A Of the --

1 MR. PHILLIPS: Objection, scope.

2 THE WITNESS: -- of the cervical region,
3 yes.

4 BY MR. KELLY:

5 Q Okay. And the publication says you can do
6 this using a perpendicular approach; correct?

7 MR. PHILLIPS: Objection, scope.

8 THE WITNESS: It doesn't connect here the
9 comment about the -- medial branch of the dorsal ramus
10 cervical spine. It doesn't connect that directly with a
11 perpendicular approach. That appears to be missing from
12 that paragraph.

13 BY MR. KELLY:

14 Q Okay. Let's look at paragraph 120.

15 A Yes.

16 Q And so we're now just three paragraphs before
17 the part we just referenced.

18 A Yes.

19 Q And paragraph 120 begins, "A method of
20 treating cervical/neck pain in accordance with one
21 embodiment of the present invention will now be
22 presently described."

23 MR. PHILLIPS: Objection, form.

24 BY MR. KELLY:

25 Q Do you see that?

1 A Yes.

2 Q And in the next paragraph on the next page,
3 paragraph 121, there's a sentence that begins, "The user
4 may insert the introducer apparatus percutaneously into
5 the patient via a lateral approach such that the
6 longitudinal axis of the cannula is substantially
7 perpendicular or generally upstanding; for example, at
8 an angle of about 80 degrees to about 100 degrees
9 relative to the target site; i.e., the centroid of the
10 articular pillar. In other words, the longitudinal axis
11 of the cannula may be substantially perpendicular or
12 generally upstanding to the anterior posterior axis of
13 the body as shown in figures 11-A and B, which show AP
14 views of a portion of the cervical spine." Do you see
15 that?

16 A Yes.

17 Q Let's look at figures 11-A and B.

18 A Yes.

19 Q And do these figures appear to be illustrating
20 a perpendicular approach to ablating medial branch
21 nerves?

22 MR. PHILLIPS: Objection, scope.

23 THE WITNESS: Yes.

24 BY MR. KELLY:

25 Q Okay. So Exhibit 1015 describes a cooled RF

1 neurotomy probe that can be used for ablating medial
2 branch nerves using a perpendicular approach --

3 MR. PHILLIPS: Objection --

4 BY MR. KELLY:

5 Q -- is that correct?

6 MR. PHILLIPS: -- objection, scope.

7 THE WITNESS: Yes.

8 BY MR. KELLY:

9 Q And before, we talked about the Baylis User
10 Guide, which described using a cooled RF probe to ablate
11 sacroiliac joint nerves using a perpendicular approach;
12 is that right?

13 A Yes.

14 MR. PHILLIPS: Objection, scope.

15 BY MR. KELLY:

16 Q And the Baylis User Guide was published in
17 2008; correct?

18 A Yes.

19 Q And Exhibit 1015 was published, if you look at
20 the cover, on February 1, 2007. Do you see that?

21 A Yes.

22 Q So both of these documents were published
23 before the relevant dates of the Stratus patents; right?

24 A Yes.

25 Q So before the relevant dates for the Stratus

1 patents, it was known that you could use a cooled RF
2 probe to ablate medial branch nerves and sacroiliac
3 joint nerves using a perpendicular approach; correct?

4 MR. PHILLIPS: Objection, scope.

5 THE WITNESS: I would make a distinction
6 between what somebody writes in a patent and gets
7 patented and what is known to either be effective or be
8 safe. So I would agree that the patent discloses the
9 use of a device to do medial branch radiofrequency
10 neurotomy using a perpendicular approach, but I would
11 not say in 2007 there were any clinicians conducting
12 that.

13 BY MR. KELLY:

14 Q Have you investigated whether there were any
15 clinicians conducting that procedure in 2009 or earlier?

16 A There's very limited use of the cooled RF
17 probe in the cervical spine. Typically, only certain,
18 shall we say aficionados who are convinced of its
19 widespread benefit perform that. The vast majority to
20 this day choose not to use that device for that purpose,
21 for a very specific and very -- in my opinion, very good
22 reason.

23 Q But you would agree that in 2007 the Godara
24 patent application discloses that it's at least possible
25 to perform that procedure?

1 MR. PHILLIPS: Objection, scope.

2 THE WITNESS: Correct.

3 BY MR. KELLY:

4 Q Okay. So the NIMBUS device was not the first
5 device that made it possible to perform a perpendicular
6 approach neurotomy on medial branch nerves; right?

7 A It is the first device that has found
8 acceptance amongst the pain community on a regular
9 basis.

10 The problem with the cooled device is the
11 lesion is too big, and as a result, you run the risk of
12 transference of heat onto the spinal nerve root and then
13 spinal nerve root damage. This does not occur with the
14 NIMBUS needle.

15 Q So the issue with cooled RF is that the lesion
16 is too big? Is that what you're saying?

17 MR. PHILLIPS: Objection,
18 mischaracterizes.

19 THE WITNESS: At times, the lesion can be
20 not made in a sufficiently controlled manner. And in a
21 small space, which is the cervical spine, you've got
22 only a few millimeters before it's got too big and
23 you've got issues to occur. It is a large, large area
24 which has the major nerves going that way as opposed to
25 this way that allows safety in the sacroiliac joint.

1 And I'm sure that's why cooled RF was first developed
2 for the sacroiliac joint, because it was simply the
3 safest application of it.

4 BY MR. KELLY:

5 Q If you look back at the Stratus book,
6 Exhibit 1051, and we look back at our Monopolar
7 Comparison Table on page 5.

8 A Yes. Yes.

9 Q This suggests that the lesion volume for a
10 cooled RF neurotomy probe is actually a touch smaller
11 than the NIMBUS device; is that right?

12 A Essentially the same for the specifications of
13 the study of those authors.

14 Q So the Stratus book would not suggest that the
15 lesion produced by a cooled RF device is too big; right?

16 A I want to put a caveat here in that we are
17 looking at lesion volume, which is the net total volume
18 of tissue. When it comes to then performing a
19 radiofrequency neurotomy, not only of a nerve, but
20 avoiding more major nerves, it's the shape and the
21 controllability of producing the lesion that is, in
22 fact, even more important than the lesion cubic
23 millimeter size. And it's that that determines where
24 you would use cooled RF and where you would choose to
25 use NIMBUS.

1 Q So --

2 A So the figures -- the -- the lesion volume
3 size might be the same for the criteria that those
4 authors studied, but that does not mean that they are
5 interchangeable.

6 Q So is it the shape of the lesion volume
7 produced by the NIMBUS device, not its size that would
8 distinguish it from a cooled RF device?

9 MR. PHILLIPS: Objection, form,
10 mischaracterizes.

11 THE WITNESS: There are -- there are two
12 aspects to -- there are really three aspects to
13 performing a radiofrequency lesion. What is the volume
14 of tissue that is coagulated? What is the temperature
15 that is produced in the coagulation zone? Is it
16 sufficiently at 90 degrees to produce destruction of the
17 nervous tissue? And what do the isotherms look like?

18 So as you go out away from the
19 coagulation zone, you'll have a lower temperature,
20 70 degrees. And then you go another millimeter, you'll
21 have a lower temperature again, 60 degrees. And so on
22 and so forth until you get to body temperature. So we
23 look at the isotherm profile, which indicates how close
24 you can get to a major nerve and be safe. So that is a
25 factor besides the lesion size and the lesion shape.

1 BY MR. KELLY:

2 Q Well, the lesion size is not any different,
3 right, based on the Monopolar Comparison Table?

4 MR. PHILLIPS: Objection, form.

5 THE WITNESS: Sorry, are you saying that
6 the lesion shape is the same between cooled RF and
7 NIMBUS? Is that your proposal to me?

8 BY MR. KELLY:

9 Q No. I'm asking -- earlier you told me that
10 cooled RF was not preferred because the lesion was too
11 big; is that right?

12 A Correct.

13 Q Okay. And it sounds like the problem isn't
14 actually that the lesion is too big, it's that it's not
15 the right shape, which is a different issue; right?

16 A Partially yes and partially no. There, it's
17 related to the isotherm profile.

18 Q So the problem is the isotherm profile, not
19 the size --

20 A For -- for cervical.

21 Q Okay. Let's look at -- let's look at
22 paragraph 117, your declaration.

23 A Yes.

24 Q And in this paragraph you state, "My view and
25 I believe the view of others working in the RF neurotomy

1 field is that the NIMBUS device was a," quote, "'game
2 changer' in the RF neurotomy field. The NIMBUS device
3 enabled interventional pain specialists, including
4 myself, to use a different and, for many reasons,
5 superior anatomical pathway to reach the medial branch
6 through positioning near the facet joint." Do you see
7 that?

8 A Yes.

9 Q When you refer to a "superior anatomical
10 pathway," what do you mean?

11 A I'm referring to the ability to place the
12 needle in an oblique position to target the eye of the
13 Scottie dog and perform a radiofrequency lesion.

14 Q Is that the perpendicular placement that you
15 described beginning in paragraph 119?

16 A As regards medial branch radiofrequency
17 neurotomy, yes.

18 Q Okay. So the superior anatomical pathway that
19 you say the NIMBUS device provides, you could actually
20 achieve that pathway using a cooled RF device; right?

21 A Yes, except the fact that the NIMBUS gives you
22 optionality, which the cooled RF device does not give
23 you.

24 When we have a patient, they don't have normal
25 anatomy, they have arthritis, which is why they have

1 arthritis of their facet joint, which is why it hurts.
2 So they will have things called "osteophytes."
3 Osteophyte is bone growth, and that bone growth can be
4 in all different positions. So when I take an x-ray
5 during the procedure, I'm looking at the anatomy, I'm
6 looking at where the osteophytes are, and I determine
7 which pathway is going to give me the greatest chance of
8 success. Do I wish to place the lesion parallel down
9 the side of the spine quite close to the major nerve
10 root in the -- what's called traditional format? Or do
11 I wish to do it in the perpendicular position?

12 With the NIMBUS, I can do both. With the
13 cooled RF, I can only do the perpendicular eye of the
14 Scottie dog. Because if I go down the side, I -- and I
15 will create a lesion that will extend onto and damage
16 the nerve root. So I've only got one option for cooled
17 RF. And in many centers the cost of it was cost
18 prohibitive, so essentially it was as if it didn't
19 exist.

20 Q Why is it that the NIMBUS device gives you
21 that optionality?

22 A Because you can place it perpendicularly, or
23 you can place it parallel.

24 Q Well, I guess that's what I'm asking. Why is
25 it that you can place it perpendicular or parallel?

1 What is the characteristic of the device that allows for
2 that?

3 A That essentially --

4 MR. PHILLIPS: Objection, compound.

5 THE WITNESS: -- the physical structure
6 of it is predominantly a two-dimensional shape. It
7 produces a three-dimensional lesion, but it's a two-
8 dimensional shape. So you can place it that way down
9 the side, or you can place it any way perpendicular.

10 BY MR. KELLY:

11 Q Okay. Let's look at the image below
12 paragraph 121 in your declaration.

13 A Yes.

14 Q Okay. And so this is a depiction roughly of
15 the lesion generated by the NIMBUS device; is that
16 right?

17 A Yes.

18 Q And where did this picture come from?

19 A That one was taken either from Rob Wright's
20 original work or possibly from a Stratus publication.

21 Q And your understanding is that this is an
22 accurate depiction of the NIMBUS's lesion shape?

23 A Yes.

24 Q Okay. Is the shape of the lesion that's shown
25 here in figure 8 related to this optionality that you

1 just described?

2 A I don't think I understand the question.

3 Q Well, is it the shape of the lesion that
4 allows you to use a parallel or perpendicular approach
5 with the NIMBUS device?

6 A Partially.

7 Q In what way?

8 A The lesion is sufficient -- sufficiently large
9 to work parallel, in which case you are relying
10 predominantly on the longitudinal and horizontal
11 dimensions of the lesion, and perpendicularly you are
12 primarily interested in the cross-sectional area of the
13 bottom of that lesion.

14 Q Okay. And I think my understanding of what
15 you're showing here in figure 8 is that -- well, I'll
16 just read from paragraph 121 in your declaration. You
17 state, "The presence of the NIMBUS device tines results
18 in RF energy being applied across a larger area compared
19 with traditional RF neurotomy needles"; right?

20 A Yes.

21 Q So if the tines of the NIMBUS device are
22 retracted, for example, and you were to activate the
23 device, then the lesion shape would be similar to what
24 you show here for a traditional neurotomy needle on the
25 left?

1 A If you had an 18 gauge versus the 18 gauge of
2 the NIMBUS? Yes.

3 Q So it's the tines that provide the desirable
4 lesion shape?

5 A Yes.

6 Q Okay. And it looks to me like the lesion
7 shown in figure 8 projects distally from the main tip of
8 the needle; right? So not the tines, but the main tip.

9 MR. PHILLIPS: Objection, form.

10 THE WITNESS: It projects from both the
11 shaft, the needle, and the tines.

12 BY MR. KELLY:

13 Q Well, what I mean is the lesion includes an
14 area that is distal from the main tip of the needle;
15 correct?

16 A Yes.

17 Q Okay. And the fact that the device creates a
18 lesion distal from the tip is due to the deployment of
19 the tines; right?

20 A Yes.

21 Q Okay. So if the tines are only deployed one
22 millimeter, for example, then you're not going to get
23 the lesion shown in figure 8; right?

24 MR. PHILLIPS: Objection, foundation.

25 THE WITNESS: Most likely.

1 BY MR. KELLY:

2 Q Okay. How far would the tines have to be
3 deployed to generate a lesion that resembles what's
4 shown in figure 8?

5 A Most likely 50 to 100 percent of their full
6 deployment.

7 Q What's the full deployment?

8 A Is when the spin collar is locked on.

9 Q How far are the tines deployed as a
10 measurement of distance?

11 A I would have to pull up the -- the exact
12 dimensions, but eyeballing it, it's around about
13 3 millimeters or so, maybe 4 millimeters.

14 Q Let's look at paragraph -- or let's look at
15 page 1 of Exhibit 1051. That's the Stratus book. And
16 do you see a heading that says "Lesion Geometry"?

17 A Yes.

18 Q Okay. And this is depicting, again, the
19 geometry of the NIMBUS device's lesion; right?

20 A Yes.

21 Q And would you agree that the lesion shown here
22 on page 1 of Exhibit 1051 is substantially the same as
23 the lesion depicted in figure 8 of your declaration?

24 A Yes.

25 Q Okay. And in the first image in the Stratus

1 book of the NIMBUS lesion geometry, it appears to
2 measure the length of the lesion as being
3 11 millimeters. Do you see that?

4 A Yes.

5 Q And based on this image, which also shows the
6 tines, how far out do you think the tines are deployed
7 in that image?

8 A It's unclear whether it's exactly to scale or
9 pictorial, but they extend approximately half further
10 than the length of the active tip. So if I had to
11 eyeball it, I'd probably say something like
12 7 millimeters.

13 Q Okay. And the lesion that's generated by the
14 NIMBUS device, it extends distally from the main tip of
15 the needle, but not so distally from the tip of the
16 tines; is that right?

17 A Correct.

18 Q Okay. So the length of the tines when
19 deployed dictates the length of the lesion?

20 A Well, that's not the only thing. It's -- it
21 is related to the length of the tines and the angle of
22 the tines in relation to the main uninsulated tip of the
23 needle.

24 Q Okay. Here's what I'd like to understand. If
25 the tines are not deployed all the way, for example,

1 only one millimeter, then you do not get the NIMBUS
2 lesion geometry that's shown here on page 1 of
3 Exhibit 1051; right?

4 A Probably not.

5 Q Okay. And, in fact, if the tines are deployed
6 in any direction other than distal from the tip of the
7 needle, you're not going to get this lesion geometry,
8 either; right?

9 A That exact lesion geometry -- you'd get
10 a -- you'd get a different lesion geometry.

11 Q So what would happen if the tines projected
12 outward perpendicularly from the tip of the needle?

13 A Dependent on the length of the tines. You may
14 have a continuous globular lesion. You may have
15 separate individual lesions.

16 Q But you're not going to get a lesion that
17 helps you with perpendicular placement for medial branch
18 neurotomy; right?

19 MR. PHILLIPS: Objection, foundation.

20 THE WITNESS: Interesting question as to
21 whether you could alter this and still produce something
22 that would be useful. That's an unknown factor. I
23 don't think anyone's studied that.

24 BY MR. KELLY:

25 Q I'm just asking for your opinion based on how

1 the lesion is dictated by the location of the tines.

2 MR. PHILLIPS: Objection, foundation.

3 THE WITNESS: I'm -- I'm uncertain. I
4 would leave open possibilities here.

5 BY MR. KELLY:

6 Q Well, I think you told me earlier, in order to
7 use an RF neurotomy needle employing a perpendicular
8 approach, the needle has to produce a lesion that is
9 distal from the needle's tip' right?

10 A But that's not what you're asking me. You're
11 asking me should there be a change in the geometry of
12 the tines, would there be the possibility of a useful
13 lesion being made or not? And my answer to you is that
14 would entirely depend on the nature of the alteration of
15 the geometry. In some scenarios, yes, and in some
16 scenarios, no, because we must, by your question,
17 encompass all sorts of possibilities of geometry
18 alteration. So I cannot make a simple answer yay or
19 nay.

20 Q But if I told you that the lesion generated by
21 the device was not distal to the device's tip, then you
22 would assume you couldn't use it with a perpendicular
23 approach; right?

24 MR. PHILLIPS: Objection, foundation,
25 form.

1 THE WITNESS: So your question is if
2 there were no tines and you just had the NIMBUS needle
3 without the tines? Is that your question?

4 BY MR. KELLY:

5 Q Well, let me start over. The key feature of
6 the NIMBUS lesion geometry is that the lesion is distal
7 to the tip of the needle; right?

8 MR. PHILLIPS: Objection, form.

9 THE WITNESS: That is one of the benefits
10 of it, yes.

11 BY MR. KELLY:

12 Q And that is the feature that allows the needle
13 to be used in a perpendicular approach; right?

14 A Yes.

15 Q Okay. So if you modify the needle such that
16 the tines deploy in a different direction and the lesion
17 is not produced distal to the tip, then it would no
18 longer be usable for a perpendicular approach; right?

19 MR. PHILLIPS: Objection, form, scope.

20 THE WITNESS: No, because you could
21 have -- as I sit here now thinking, you could have tines
22 that do not project beyond the tip of the needle but are
23 more of a 45-degree angle rather than the 20-degree
24 angle shown here. And that would mean that you would
25 still form a base, but it would not be as -- as

1 horizontally long. So I would disagree with that
2 statement.

3 BY MR. KELLY:

4 Q But isn't the horizontal length what you need
5 for a perpendicular approach?

6 A No. It's width.

7 Q Well, let's make sure we're talking about the
8 same thing. If we look at the first picture under
9 NIMBUS lesion geometry --

10 A Yes.

11 Q -- in the Stratus book, there's a measurement
12 that says "11 millimeters."

13 A Yes.

14 Q To you, is that length or width?

15 A I call that "length."

16 Q That's length. Okay. If that length was
17 2 millimeters, would the needle be effective for
18 perpendicular placement?

19 A Potentially, yes.

20 Q Let's look back at paragraph 121 of your
21 declaration and the picture of the traditional neurotomy
22 needle.

23 A Yes.

24 Q For the traditional neurotomy needle, how far
25 does that lesion extend beyond the distal tip of the

1 needle?

2 A A very small amount.

3 Q How much?

4 A Maybe no more than one millimeter, one and a
5 half millimeters.

6 Q Okay. So if the lesion only extends one or
7 one and a half millimeters from the distal tip, then
8 it's not suitable for perpendicular placement; right?

9 MR. PHILLIPS: Objection, form.

10 THE WITNESS: Correct.

11 BY MR. KELLY:

12 Q Okay. So if we retract the tines in the
13 NIMBUS needle to a point where the lesion only extends
14 one and a half millimeters from the distal tip of the
15 device, it's no longer useful for the perpendicular
16 approach; right?

17 A No. It depends on the angle of the tines.
18 The -- the wider the tines are apart, the more there'll
19 be a base, the three point -- so in other words, it's
20 the 3.5 millimeters that is important in the
21 perpendicular, because that is what is adjacent to the
22 bone, and that's where the nerve is.

23 Of the 11 millimeters, probably the first
24 proximal 8 millimeters is pointless, useless. It's
25 burning a little bit of soft tissue. It's doing no

1 good. It's the 3.5-millimeter base that you're
2 interested in.

3 Q Okay. So what's important, then, is the angle
4 at which the tines deploy from the tip of the needle?

5 A If you start short --

6 MR. PHILLIPS: Objection,
7 mischaracterizes.

8 THE WITNESS: -- if you start shortening
9 the times for whatever reason you wish to, you would
10 then want to start widening the tines.

11 BY MR. KELLY:

12 Q Okay. Where I'm -- what I'm getting at is
13 that in order for the needle, the NIMBUS needle to be
14 effective for perpendicular placement, the tines have to
15 be at a certain distance outward from the needle and at
16 a certain angle. They do not work at all distances and
17 all angles; right?

18 MR. PHILLIPS: Objection, form, compound.

19 THE WITNESS: There would be a range of
20 distances and angles that would all form acceptable
21 coagulation levels. And beyond those particular
22 parameters, there would be another group of parameters
23 in which it would not be good.

24 BY MR. KELLY:

25 Q Okay. So there's a set of parameters for the

1 filaments that are deployed from the end of the needle
2 that provide a lesion shape that renders the needle
3 suitable for perpendicular placement; right?

4 A Yes.

5 Q But outside of those parameters, the needle
6 would not be suitable for perpendicular placement?

7 A Yes.

8 MR. KELLY: Okay. All right. I think we
9 can take another break.

10 THE OFFICER: The time is 12:31 p.m., and
11 we are off the record.

12 (Off the record.)

13 THE OFFICER: The time is 1:24 p.m., and
14 we're back on the record.

15 Go ahead, Counsel.

16 BY MR. KELLY:

17 Q Welcome back, Mr. Russo. Let's refer to
18 paragraph 83 of your declaration, Exhibit 2,001.

19 A Eighty-three.

20 Q Yes. And could you read aloud the first two
21 sentences of paragraph 83 for me?

22 A "Although I have and had before the relevant
23 dates a general awareness of the use of RF ablation
24 techniques in the cancer and cardiology fields, as an
25 interventional pain specialist, I did not have detailed

1 knowledge of the techniques or technologies used in
2 those other fields, and I did not keep up to date with
3 developments in the use of RF ablation techniques in
4 those other medical fields. In my view, the literature
5 and technologies used in those other clinical fields are
6 not and were not before the relevant dates relevant to
7 the practice of RF neurotomy, as the applicable
8 anatomical and clinical considerations are not the
9 same."

10 Q Thank you. Earlier today, you testified that
11 cooled RF technology was adopted from cardiac and tumor
12 ablation and applied to neurotomy; right?

13 A Correct.

14 Q Isn't that an example of cross-pollination
15 between RF neurotomy and other types of ablation?

16 A That would depend on how similar the cooled RF
17 cardiac and the cooled RF neurotomy were. They're using
18 the same method. If, in fact, the devices look similar
19 and the generators look similar and the parameters look
20 similar, then I would say, yes, cross-pollination. And
21 if, in fact, they're very, very different across all
22 those three perspectives, then I would say not so much.

23 Q Well, we know that cooled RF technology was
24 used in tumor ablation before neurotomy; right?

25 A Correct.

1 Q So the application of cooled RF technology
2 from tumors to neurotomy is cross-pollination, is it
3 not?

4 A Correct.

5 Q So it's not true that technology used in
6 cardiac or tumor RF ablation is necessarily irrelevant
7 to RF neurotomy; right?

8 A Not necessarily irrelevant? Correct.

9 Q Okay. If you turn to paragraph 76 of your
10 declaration, and could you read aloud the last sentence
11 of paragraph 76?

12 A The last sentence?

13 Q Yes.

14 A "As a result, there has historically been
15 little to no crosstalk between or cross-pollination of
16 the various fields in which RF ablations are performed."

17 Q So we just talked about how cooled RF
18 technology is an example of cross-pollination amongst
19 the various fields in which RF ablations are performed;
20 right?

21 MR. PHILLIPS: Objection,
22 mischaracterizes.

23 BY MR. KELLY:

24 Q Yes or no?

25 A Sorry, just ask that question again?

1 Q Well, I believe you just testified that cooled
2 RF technology is an example of cross-pollination between
3 other types of RF ablation and RF neurotomy; right?

4 MR. PHILLIPS: Same objection.

5 THE WITNESS: Yes.

6 BY MR. KELLY:

7 Q Okay. Isn't that inconsistent with the
8 sentence in paragraph 76?

9 A No, because I'm referring to clinicians,
10 clinical behavior, clinical interaction. I think it's
11 obvious that if you are wanting to do radiofrequency
12 neurotomy, you would go to an engineer who has previous
13 experience with radiofrequency energy. So the engineer
14 may well have done a device in one field, and that's the
15 engineer you would go to because he's a radiofrequency
16 engineer. I'm referring to clinicians and how they
17 interact, to -- to make it clearer.

18 Q Okay. And is that also true with respect to
19 your statement in paragraph 83 where you say, "In my
20 view, the literature and technologies used in those
21 other clinical fields are not, and were not, before the
22 relevant dates relevant to the practice of RF neurotomy,
23 as the applicable anatomical and clinical considerations
24 are not the same"?

25 A Correct. That's my opinion.

1 Q So you're saying there's no cross-pollination
2 between clinicians but not necessarily engineers?

3 A Correct.

4 Q Okay. If you would, let's turn to paragraph
5 216 of your declaration.

6 A Yes.

7 Q And in paragraph 216, you quote a passage from
8 the Racz reference that appears at column 2, lines 30 to
9 38 of Racz. Do you see that?

10 A Yes.

11 Q I'm handing you a copy of what's been
12 previously marked Exhibit 1,009. And this is the Racz
13 reference; correct?

14 A Yes.

15 Q Let's turn to Racz at column 2 around line 27.

16 A So at which page?

17 Q Column 2, line 27. It's a paragraph beginning
18 "Stimulation and high frequency."

19 A Yes.

20 Q And do you see here Racz discloses,
21 "Stimulation and high frequency electrodes having
22 expandable and flexible curve tips are known." Do you
23 see that?

24 A Yes.

25 Q And just below this, Racz gives an example of

1 the Radionics TEW Electrode Kit and the Radionics ZHK
2 Electrode Kit; correct?

3 A Yes.

4 Q Are you familiar with the features of the
5 Radionics TEW Electrode Kit?

6 A No.

7 Q And are you familiar with the features of the
8 Radionics ZHK Electrode Kit?

9 A No.

10 MR. KELLY: Okay. Okay. We have no
11 further questions on cross.

12 MR. PHILLIPS: Okay. We need a short
13 break.

14 MR. KELLY: Sure.

15 MR. PHILLIPS: And then we can do the
16 redirect.

17 MR. KELLY: Okay.

18 THE OFFICER: The time is 1:32 p.m., and
19 we are off the record.

20 (Off the record.)

21 THE OFFICER: The time is 1:52 p.m.
22 We're back on the record.

23 Go ahead, Counsel.

24 //

25 //

EXAMINATION

BY MR. PHILLIPS:

Q Good afternoon, Dr. Russo. First of all, thank you very much for appearing here. I know you've made a very long trip to be here.

Just before the last break, you were asked about the use of cooled RF ablation as a possible instance of cross-pollination between cardiac ablation and RF neurotomy. Do you remember that?

A Yes.

Q Are you aware of any other instances of cross-pollination between RF neurotomy and other forms of RF ablation?

MR. KELLY: Objection, form.

THE WITNESS: Let me have a think. Other forms of -- no, not specifically.

BY MR. PHILLIPS:

Q If there were any instances of cross-pollination between RF neurotomy and other forms of RF ablation, would you be aware of them?

MR. KELLY: Objection, form.

THE WITNESS: Yes, I would, both from my clinical experience and from my historical detective work that led to that paper that I published in "Journal of Pain Research."

1 BY MR. PHILLIPS:

2 Q Okay. You were asked some questions this
3 morning about cardiac ablation. Do you remember that?

4 A Yes.

5 Q Are needles used during cardiac ablation
6 procedures?

7 A No.

8 Q Let's take a look at the Godara patent. It
9 is -- I think it's --

10 A You'll have to remind me which one that is.

11 Q I think it's Exhibit 1015.

12 A Yes, I have it here.

13 Q Okay. Now, Mr. Kelly read to you a number of
14 sentences from this document and asked you if he had
15 read them correctly. Before today, had you ever read
16 this document from cover to cover?

17 A No.

18 Q Before today, had you ever studied this
19 document?

20 A No.

21 Q Before today, did you ever form any opinions
22 about the disclosure in this document?

23 A No.

24 Q I'm going to ask you some questions about the
25 use of cooled RF devices, and in particular, using a

1 perpendicular approach to approach a nerve using a
2 cooled RF device. Are there any drawbacks to using a
3 cooled RF device with a perpendicular approach?

4 MR. KELLY: Objection, form.

5 THE WITNESS: There -- there can be, and
6 that entirely depends on where the nerve is located, so
7 what nerve you are trying to ablate and what nerves in
8 particular you are trying to not oblate.

9 "Perpendicular" means that you are taking
10 the -- you're taking the surface of the bone as the
11 reference surface, and then a needle is coming towards
12 the bone at 90 degrees. If the nerve traverses the
13 bone, then you can have a flat surface to do a lesion.
14 And if your lesion produces a flattened out burn, then
15 that can be useful.

16 If the lesion is not flattened out to
17 occupy the surface of the bone, then you will fail to
18 produce any useful lesion of the nerve. And if the
19 nerve is, for example, on the side of the lumbar spine,
20 for example, and you could still approach on the side of
21 the lumbar spine, you could still approach from a
22 relatively perpendicular level -- you have to come very
23 much from the side, but one could -- then your lesion
24 would risk being too close to the spinal nerve root and
25 would produce complications; hence, the need to do a

1 parallel lesion and maintaining a safe distance in the
2 parallel approach between the tip of the needle and the
3 spinal nerve root.

4 BY MR. PHILLIPS:

5 Q In your opinion, Dr. Russo, is the NIMBUS
6 device superior to the use of cooled RF with the
7 perpendicular approach?

8 MR. KELLY: Objection, form.

9 THE WITNESS: With the perpendicular
10 approach, the NIMBUS -- yes, it is, because there are
11 times when you wish to do a perpendicular approach, but
12 the anatomy dictates that you need to switch your plan
13 in that individual and go to a parallel approach. And
14 in that scenario, you would not be able to proceed with
15 the operation solely with a cooled RF device at hand.

16 BY MR. PHILLIPS:

17 Q As between the NIMBUS device and a cooled RF
18 device, do you have a preference which one you would
19 prefer to use?

20 MR. KELLY: Objection, form.

21 THE WITNESS: Very much so. That's based
22 on variety of factors. The first is cost. Most of the
23 hospitals in which I work would, in fact, have a
24 negative profit outcome from using the cooled RF device.
25 That is to say, the amount of money that the hospital

1 bills the health fund for would be eroded into
2 the -- into the red by the use -- the disposable cost of
3 the cooled RF. So the hospital would inform me that I
4 cannot use it from a cost basis.

5 Secondly, the -- secondly, the cooled RF
6 mandates that you use the entire system from -- from the
7 particular company that makes the cooled RF. You cannot
8 mix or match.

9 So, for example, many of the hospitals
10 have a legacy supply of radiofrequency probes. They
11 might have 20, 30, 40. My principal hospital has 60 RF
12 probes. And we're able to intersperse the probes into
13 radiofrequency cannula at will. So we can use a NIMBUS
14 needle or -- or other needle. So that whole legacy
15 product of purchase becomes pointless and a -- and a
16 burden to the hospital, because they've been purchased
17 but now can't be used. So principally, for those
18 reasons, and one more, principally for those reasons, I
19 favor the NIMBUS.

20 The "one more" is related to the fact
21 that I have a subtle ability to determine the exact
22 position and -- and not -- not shape, but the position
23 of the lesion with a NIMBUS, of which I have no control
24 with the cooled RF. So the cooled RF will make a
25 globular spherical lesion. If pushed up against bone,

1 of course it's not a true sphere, because it can't
2 dissolve the bone. So it -- it is -- it is a sphere
3 with a truncated cutoff base, but nevertheless
4 it's -- it's spherical, and I cannot prevent it from
5 being spherical. However, because of the tines related
6 to the NIMBUS, I can choose to be exactly perpendicular,
7 and I know the pyramidal globular shape I'll create.

8 But the anatomy may mean that I actually
9 want to be a little bit off perpendicular so that I will
10 then have the globular shape at a slight angle. So I
11 can adapt the globular shape of my lesion to the anatomy
12 I see in front of me. Whereas if I move the cooled RF
13 off exactly perpendicular, it's still a sphere. It's a
14 sphere, it doesn't matter where I do it, it will remain
15 a sphere, because the sphere is what it produces.

16 So I -- I lose the specificity of choice,
17 which is not present necessarily in all patients, but
18 it's certainly present in a good 30 percent of patients
19 that I actually want to turn the tines that way or turn
20 the tines that way, because there's an osteophyte
21 growing off the side blocking what I want to do.

22 BY MR. PHILLIPS:

23 Q Okay. For my next question, I want you to
24 assume that clinicians in the art were aware of the
25 teachings of the Godara patent publication. That's

1 Exhibit 1015. And my question is -- well, first of all,
2 you say in your declaration that you believe the NIMBUS
3 device was a game changer that brought the RF neurotomy
4 field out of the Ice Age.

5 A Yes.

6 Q Do you remember that?

7 A Yes, yes.

8 Q Okay. So is that still your opinion, even if
9 you assume that those clinicians like yourself, pain
10 specialist physicians, were well aware of the teachings
11 in Godara about the use of -- alleged use of an RF, a
12 cooled RF device, that can be used in a perpendicular
13 approach?

14 MR. KELLY: Objection, form.

15 THE WITNESS: Yes, it is. And the reason
16 being is that the original presentation of clinical use
17 of cooled RF was for the sacroiliac joint.

18 Now, generally when you get a new device
19 come along, it is purporting to provide some improvement
20 over existing devices. It is a new device, is designed
21 to solve something that existing devices cannot solve,
22 or improve safety or faster time or cheaper costs. So
23 there has to be some advantage. The strange thing about
24 cooled RF, which is why so many people did not take it
25 up, separate from the cost, was that it wasn't

1 incrementally achieving anything over the current state
2 of play of how to perform radiofrequency neurotomy of
3 the sacroiliac joint.

4 So in standard radiofrequency neurotomy,
5 we used what's called the "palisade technique." Do you
6 want -- suppose I need to explain that.

7 BY MR. PHILLIPS:

8 Q Please, go ahead.

9 A So you put one needle down perpendicular to
10 the sacrum. As outlined, that would not make a decent
11 lesion, because it's a simple 16 gauge. You'd put
12 another needle down approximately 10 millimeters away
13 from the first, also perpendicular, and you would use
14 bipolar setting. So what you do is select bipolar on
15 the machine, and then what would happen is all the
16 electrical energy generated by the generator would flow
17 from this electrode to this electrode, and you would
18 burn across the gap, as long as that gap was
19 10 millimeters or less. The gap was greater, it was two
20 separate burns, and in that case it's not going through
21 the return -- return pad or earthing pad.

22 So we would make a burn and then put one here
23 and make a burn, put one here and make a burn, and we
24 would walk our way up the sacroiliac joint. That's
25 called the "palisade technique." So we comprehensively

1 burnt longitudinally by a perpendicular technique, not
2 reliant on the point at the end, and it worked well, and
3 it continues to work well today. And, in fact, it
4 remains the commonest way to perform sacroiliac joint
5 radiofrequency neurotomy.

6 So cooled RF in the sacroiliac joint
7 application gave us no actual advantage at all, which
8 was a bit disappointing. And I suspect that in many of
9 these things where a patent says that something can be
10 done some way novel that's never been done before, most
11 clinicians, including myself, will wait until that one
12 person does it, which can be years later, to do a
13 perpendicular lesion in the lumbar, thoracic, or
14 cervical spine. So we didn't really see it as something
15 that we should apply in the spine other than the
16 sacroiliac joint. And it was a number of years before
17 the first person eventually decided to do that, and case
18 reports were written.

19 Q Dr. Russo, what percentage of RF neurotomy
20 procedures are performed on spinal nerves?

21 MR. KELLY: Objection, form.

22 THE WITNESS: Somewhere between 92 to
23 98 percent, depending upon the clinical practice of the
24 individual. There'll be some variation.

25 //

1 BY MR. PHILLIPS:

2 Q You say in paragraph 239 of your declaration
3 that you estimate that more than 99.5 percent of all RF
4 neurotomy procedures are performed on spinal nerves. Is
5 that your testimony?

6 MR. KELLY: Objection, scope, form.

7 THE WITNESS: Yes. That's certainly
8 for -- for my practice and most people's practice. The
9 amount that we do for knees, hips, and so forth is -- is
10 minimal, because in that setting, we're doing pulsed
11 radiofrequency neurotomy, not thermal.

12 BY MR. PHILLIPS:

13 Q In the vernacular of pain specialist
14 physicians such as yourself, when you just say "RF
15 neurotomy" without specifying where the neurotomy
16 procedure is taking place, what does that mean to pain
17 specialist physicians like yourself?

18 A In general terms, it means thermal RF
19 neurotomy.

20 Q Does it imply that it is on a spinal nerve?

21 MR. KELLY: Objection, form.

22 THE WITNESS: No.

23 BY MR. PHILLIPS:

24 Q Okay. Now, I want to ask you about the
25 Australian case that you were asked about earlier this

1 morning.

2 A Yes.

3 Q So you provided written testimony in that
4 case; correct?

5 A Yes.

6 Q Okay. So documents like declarations or --

7 A A declaration, yes.

8 Q Okay. Do you remember the content, any
9 content of those declarations in the Australian case?

10 A Different contents. So there was content
11 around the NIMBUS needle. There was some content around
12 the Racz needle. It covered quite a lot of ground.

13 Q Do you recognize any of your written testimony
14 in your declaration, Exhibit 2001, as having been copied
15 or substantially similar to your written testimony in
16 the Australian case?

17 A No. I didn't copy anything. I didn't refer
18 to the original Australian declaration. Some of the
19 commentary might be common, but nothing was copied and
20 nothing was referred to from the -- from that original
21 2019.

22 Q So to your knowledge, there's no overlap
23 between what is written in Exhibit 2,001 and what was
24 written in your declarations in the Australian case?

25 A Correct. I mean, I'm sure there's a picture

1 of a spine -- there is a picture of a spine in here, I'm
2 sure there's a picture of the spine in 2019, but that's
3 for illustrative purposes.

4 Q Is section Roman numeral 6-A of your
5 declaration, Exhibit 2001, regarding an overview of RF
6 neurotomy, is that based on any content in your
7 Australian case declarations?

8 A That was based on an extraction from my paper
9 published in -- I think 2017 was when that was
10 published. So some -- some historical component might
11 be an overlap, but essentially, no.

12 MR. PHILLIPS: Okay. That's all I have.
13 Thank you, Dr. Russo.

14 EXAMINATION

15 BY MR. KELLY:

16 Q Okay, Dr. Russo, we just have a few recross
17 questions for you. I think you testified in response to
18 a question that Mr. Phillips asked that cardiac ablation
19 is not performed with needles; is that right?

20 A Correct.

21 Q Are you aware that the Stratus patents
22 expressly teach embodiments of the needles disclosed in
23 the patent that can be used for cardiac ablation?

24 A I would have to reference that.

25 Q I think I handed you earlier a copy of

1 Exhibit 1,001.

2 A Yeah, I think I'm just going to find it.
3 Peter Crosby, Cody Jorgensen, Rob Wright.

4 Do you wish to refer me to the relevant bit
5 that you wish me to examine?

6 Q Well, let's start with -- refer to column 19.

7 A Yes. I'm struggling to find any cardiac
8 reference.

9 Q If you refer down to line 36, column 19, and
10 here the 782 patent states, "In some embodiments, the
11 elongate member is insulated; for example, constructed
12 from insulated material and/or having an insulated
13 coating, except for a proximal part. Figure 3-I
14 illustrates an example embodiment of a needle 309,
15 comprising an insulating coating 330, covering a distal
16 portion of the tip 321, and coatings 332-A, 332-B,
17 covering a distal portion of the filaments 319-A, 319-
18 B." Do you see that?

19 A No, I don't. You're just going to have to
20 help me out here. So this is --

21 Q I'm reading -- sorry.

22 A -- this is on 19 where it says the "hub 231"?

23 Q I'm in column 19 at line 36, paragraph
24 beginning "In some embodiments."

25 A Oh, I don't think we are on the same page.

1 Q Are you in Exhibit 1,001?

2 A 1,002.

3 Q Let's look at 1,001.

4 A Yes, right. Okay. This might be more
5 helpful. Right, 1936. Right, "In some embodiments, the
6 elongate member."

7 Yes. So I've just read that paragraph.

8 Q Okay. And do you see at the end of that
9 paragraph, the 782 patent states, "For example, when
10 ablating endocardial lesions in which the device
11 accesses the target through a cardiac chamber,
12 insulating the distal portion of the tip 321, which
13 stays in the chamber, can make the biophysics of the
14 lesion; for example, impedance power heat, more precise
15 because the insulated distal portion of the tip 321 that
16 is surrounded by blood in the chamber will not be part
17 of the field."

18 A Correct.

19 Q So this is disclosing a needle that can be
20 used for ablating endocardial lesions.

21 MR. PHILLIPS: Objection, form.

22 BY MR. KELLY:

23 Q Is that correct?

24 A Just one moment, please. I'm just
25 going -- going back and reading up above. Yes.

1 Q So this is a needle for performing cardiac
2 ablations; right?

3 A Yeah. It refers to an example embodiment of a
4 needle with an insulated coating with a distal portion
5 of filaments, which can be used, for example, for
6 ablating tissue in the lumen of a structure such as an
7 endocardial lesion. "Endocardial" means the -- going
8 from the blood surface to the inside of the heart.
9 "Endo" means inside the heart. So that's what it's
10 describing.

11 Q All right. Let's turn to column 48, line 35.

12 A Line 35. Yes.

13 Q There's the sentence beginning, "For another
14 example."

15 A Yes.

16 Q Do you see that?

17 And here, the 782 patent states, "For another
18 example, embodiments of the needles described herein
19 could be adapted for use in procedures such as cardiac
20 ablation, in which cardiac tissue is destroyed in an
21 effort to restore normal electrical rhythm in the
22 heart."

23 A Yes.

24 Q Do you see that?

25 A I do.

1 Q So this is another statement confirming that
2 needles can be used for cardiac ablation; correct?

3 A Yes.

4 Q Okay. And this is an example of the 782
5 patent suggesting that its needles can be used for
6 cardiac ablation in addition to RF neurotomy?

7 MR. PHILLIPS: Objection, form.

8 THE WITNESS: Yes.

9 BY MR. KELLY:

10 Q Okay. Earlier Mr. Phillips asked you about
11 your testimony regarding an Ice Age --

12 A Yes.

13 Q -- in RF neurotomy development. And in your
14 response you described a palisade technique --

15 A Yes.

16 Q -- that was used with standard RF needles;
17 right?

18 So when you say "standard RF," can you
19 describe what you mean?

20 A I mean a 16-gauge, 18-gauge radiofrequency
21 cannula with an uninsulated tip.

22 Q Okay. So not a cooled probe?

23 A Correct.

24 Q And not a probe with deployable tines?

25 A Correct.

1 Q Okay. And these probes were known in the art
2 even before cooled RF technology?

3 A Correct.

4 Q Okay. And my recollection is that you
5 described in the palisade approach that these standard
6 RF needles are inserted perpendicularly into the patient
7 about 10 millimeters apart from one another; is that
8 right?

9 A Correct.

10 Q Okay. So even before cooled RF technology, a
11 perpendicular approach was being used in neurotomy; is
12 that right?

13 MR. PHILLIPS: Objection, form and
14 foundation.

15 THE WITNESS: For sacroiliac joint
16 denervation, yes.

17 BY MR. KELLY:

18 Q Okay. Could you refer to Exhibit 1051?

19 A Now, which one is that?

20 Q Page ...

21 A Oh, no, sorry. It's just on the front covers.

22 Q This one.

23 A Yes. The -- the book. I've got my own
24 language to describe these. Yes, which section?

25 Q Let's look at page 8.

1 A Yes.

2 Q And if you look at the -- well, when you were
3 explaining the palisade approach earlier in response to
4 your question from Mr. Phillips, you described multiple
5 needles being positioned next to each other; right?

6 A Typically two, 'cause then one comes out and
7 leapfrogs over the other one.

8 Q Okay. And if you look here in the last
9 sentence of the third paragraph on page 8 of
10 Exhibit 1051, there's a sentence that begins "Finally."

11 A Yes.

12 Q And here the Stratus book says, "Finally, the
13 expanded tine surface area produces large, continuous
14 bipolar lesions between adjacent devices spaced up to
15 20 millimeters apart at 85 degrees C for 150 seconds,
16 resulting in 28-millimeter by 10-millimeter by 13-
17 millimeter lesion volume." Do you see that?

18 A Yes.

19 MR. PHILLIPS: Objection, form.

20 BY MR. KELLY:

21 Q So the Stratus book is saying that the NIMBUS
22 device can also be used with multiple needles next to
23 each other; is that right?

24 MR. PHILLIPS: Objection, form.

25 THE WITNESS: It is. So bipolar is

1 achievable -- yes.

2 BY MR. KELLY:

3 Q Okay. And so how is this different from the
4 palisade approach?

5 A The palisade approach fails at more than a 10-
6 millimeter gap between the two needles. Because of the
7 larger surface area achieved with the tines, you can now
8 go up to 20 millimeters apart, which means you are
9 halving the number of actual lesions you need to make.
10 So you are halving the tine compared to a traditional
11 palisade technique.

12 Q And you would do this when you wanted a lesion
13 size that was bigger than the size that just one NIMBUS
14 device would provide; is that right?

15 A Correct.

16 Q So --

17 A Or you wished to have -- to only -- to have a
18 20-millimeter gap and still have an effective lesion.

19 Q So in what scenarios would a 28-millimeter by
20 10-millimeter by 13-millimeter lesion volume be
21 appropriate for RF neurotomy?

22 A For that, that would typically be something
23 like the sacroiliac joint, or it would be the
24 articular -- the sensory articular branches of a
25 shoulder joint or a hip joint.

1 Q I want to just revisit briefly your testimony
2 on cardiac ablation. When you originally testified in
3 response to Mr. Phillips's question that needles were
4 not used for cardiac ablation, was that because you were
5 unaware that the Stratus patents disclosed this?

6 A No. That is because no one sticks a needle
7 through the skin into the heart.

8 Q But the Stratus patents say you can; is that
9 right?

10 A No. The Stratus patent does not say that. It
11 says that if you are endoluminal, you could then insert
12 the active tip into the cardiac tissue wall.

13 Q So when Mr. Phillips asked his question, you
14 understood him to mean sticking a needle into the heart
15 percutaneously?

16 MR. PHILLIPS: Objection, form.

17 THE WITNESS: Yes.

18 BY MR. KELLY:

19 Q When Mr. Phillips asked you about your
20 preference for the NIMBUS device as compared to cooled
21 RF, you indicated that the NIMBUS device provides a
22 flattened out lesion. Do you recall saying that?

23 A Yes.

24 Q Okay. If we look back at the image of the
25 NIMBUS lesion, and let's say in page 1 of the Stratus

1 book, Exhibit 1051, where in this image on the left-hand
2 side is the flattened part of the lesion?

3 A The right-hand side.

4 MR. PHILLIPS: Objection, form.

5 BY MR. KELLY:

6 Q And this is proximate to where the three and a
7 half millimeter measurement is indicated?

8 A Yes.

9 Q Okay. If the filaments were not both deployed
10 the same length, would the lesion be flat?

11 A If one --

12 MR. PHILLIPS: Objection, scope.

13 THE WITNESS: -- if one filament was
14 shorter than the other, the base would be angled.

15 BY MR. KELLY:

16 Q Okay. And if -- earlier in our conversation,
17 I recall you discussing what the lesion would look like
18 if the filaments were angled out, say, 45 degrees, and I
19 think you described that the lesion shape would be more
20 rounded at the bottom; is that right?

21 A No. That was specifically that if the tines
22 were partially retracted, in order to have a flat base,
23 you would then have a wider angle on the tines, is what
24 I said.

25 Q Okay. So in order to achieve the flat base

1 that's shown here in Exhibit 1051, there are still a set
2 of parameters that the filaments must be configured
3 within in order to achieve that base; right?

4 A Yes.

5 Q Okay.

6 A As well as the tissue interface, of course,
7 which also has a role to play.

8 Q Earlier, Mr. Phillips asked you about whether
9 portions of your declaration in Exhibit 2,001 were
10 copied from your Australia affidavit. Do you recall
11 that?

12 A Yes.

13 MR. PHILLIPS: Objection,
14 mischaracterizes.

15 BY MR. KELLY:

16 Q And your testimony under oath is that no
17 portion of your Exhibit 2,001 was copied from your
18 Australia affidavit; is that right?

19 A Correct.

20 Q So if I were to run a document comparison of
21 Exhibit 2,001 and your Australia affidavit, I would find
22 no overlap; is that right?

23 A I don't think there would be significant
24 overlap, except in discussion of history or mechanism of
25 action, use of radiofrequency in neurotomy. There's

1 certain baseline things that were obviously going to be
2 discussed in -- in both presentations.

3 Q So you're saying some of it may have been
4 copied.

5 A "Copied" suggests that somebody -- that me
6 actively went and opened one document, looked at it, and
7 transposed into another document. I did no such thing.

8 Q Okay. So portions of the documents may be the
9 same --

10 A May be similar without being copied.

11 Q Okay. So you're saying that you personally
12 did not copy any portion of --

13 A Correct.

14 Q -- your Australia affidavit into
15 Exhibit 2,001?

16 A Correct.

17 MR. KELLY: Okay. All right. Thank you
18 for your time, Dr. Russo. No further questions.

19 THE OFFICER: Okay. So we haven't
20 formally discussed this yet, but will there be a read
21 and sign, Counsel?

22 MR. PHILLIPS: Yes. I would prefer we do
23 that.

24 THE OFFICER: Okay. And where would you
25 like me to send the original for him to read and sign?

1 MR. PHILLIPS: You can send that to me.

2 THE OFFICER: Understood. Okay. Just so
3 I can get that e-mail on the record, that's going to
4 mphillips@lpiplaw.com?

5 MR. PHILLIPS: Correct.

6 THE OFFICER: Okay. Would anyone like to
7 order a copy of the transcript for today?

8 MR. KELLY: Well, we --

9 THE OFFICER: You have one coming to you,
10 Counsel. I just meant --

11 MR. KELLY: Okay. Okay.

12 MR. PHILLIPS: We do not need an
13 additional copy.

14 THE OFFICER: Okay. That all being taken
15 care of, the time is 2:31 p.m., and we are off the
16 record.

17 (Off the record.)

18 THE OFFICER: The time is 2:39 p.m.
19 We're back on the record.

20 Mr. Kelly, I just want to confirm with
21 you that you've ordered an expedited copy of today's
22 transcript for delivery on August 27th?

23 MR. KELLY: That's correct.

24 THE OFFICER: Okay. With that all being
25 taken care of, the time is 2:39 p.m., and we are back

off the record.

(Signature reserved.)

(Whereupon, at 2:39 p.m., the proceeding
was concluded.)

CERTIFICATE OF DEPOSITION OFFICER

I, JOHN CANFIELD, the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



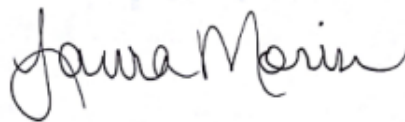
JOHN CANFIELD

Notary Public in and for the
State of California

☒ Review of the transcript was requested.

CERTIFICATE OF TRANSCRIBER

I, LAURA MORIN, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

A handwritten signature in cursive script that reads "Laura Morin". The ink is dark and the signature is centered on the page.

LAURA MORIN

Marc A. Russo c/o
MATTHEW C. PHILLIPS, ESQUIRE
mphillips@lpiplaw.com

August 27, 2025

RE: Avanos Medical Inc. v. Stratus Medical LLC
8/22/2025, Marc A. Russo (#7562975)

The above-referenced transcript is available for
review.

Within the applicable timeframe, the witness should
read the testimony to verify its accuracy. If there are
any changes, the witness should note those with the
reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of
Deponent and Errata and return to the deposing attorney.
Copies should be sent to all counsel, and to Veritext at
litsup-ga@veritext.com

Return completed errata within 30 days from
receipt of testimony.

If the witness fails to do so within the time
allotted, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

Avanos Medical Inc. v. Stratus Medical LLC

Marc A. Russo (#7562975)

E R R A T A S H E E T

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REASON_____

Marc A. Russo

Date

Avanos Medical Inc. v. Stratus Medical LLC

Marc A. Russo (#7562975)

ACKNOWLEDGEMENT OF DEPONENT

I, Marc A. Russo, do hereby declare that I
have read the foregoing transcript, I have made any
corrections, additions, or changes I deemed necessary as
noted above to be appended hereto, and that the same is
a true, correct and complete transcript of the testimony
given by me.

Marc A. Russo

Date

*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS

_____ DAY OF _____, 20____.

NOTARY PUBLIC

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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