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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,
Petitioner
v.
STRATUS MEDICAL, LLC,
Patent Owner.

IPR2024-01209 (Patent 10,966,782 B2)
IPR2024-01210 (Patent 10,736,688 B2)
IPR2024-01211 (Patent 10,736,688 B2)
IPR2024-01212 (Patent 10,925,664 B2)[1]

Record of Oral Hearing
Held: November 6, 2025

Before MICHAEL J. FITZPATRICK, SUSAN L. C. MITCHELL, and ARTHUR M. PESLAK, Administrative Patent Judges.

IPR2024-01209 (Patent 10,966,782 B2)
IPR2024-01210 (Patent 10,736,688 B2)
IPR2024-01211 (Patent 10,736,688 B2)
IPR2024-01212 (Patent 10,925,664 B2)[1]

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The above-entitled matter came on for hearing Thursday, November 6, 2025, commencing at 1:00 p.m. EST, at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

1 P-R-O-C-E-E-D-I-N-G-S

2 (1:00 PM)

3 JUDGE MITCHELL: Thank you. You may be seated. So
4 good afternoon, everyone. We have a final hearing this afternoon in four
5 inter partes reviews, IPR2024-01209, -01210, -01211, and -01212. I am
6 Judge Mitchell and with me by video conference are Judges Fitzpatrick and
7 Peslak. I would like to start with getting appearances on the record, if I
8 could. So who do I have for Petitioner?
9 MR. KELLY: Hi, Judge Mitchell. This is Chris Kelly of Meunier
10 Carlin and Curfman for Petitioner. Also with me is Warren Thomas, also
11 Meunier Carlin and Curfman. We'll both be arguing on different issues
12 tonight. And also we have with us Mr. Clark Wilson, in-house counsel at
13 Avanos. And I just want to note Mr. Wilson's not on the protective order. So
14 to the extent we talk about protective order material, we'll ask Mr. Wilson to
15 leave the room during that time.
16 JUDGE MITCHELL: Okay. I was going to ask you because I know
17 Petitioner put in demonstratives that have confidential information. It
18 looked to me like maybe we didn't necessarily need to go to that level of --
19 but I don't -- are you planning on maybe talking about confidential
20 information in your presentation? Or you're just worried that we may ask,
21 and you may answer with it.
22 MR. KELLY: Well, yes, Judge Mitchell. So the confidential
23 information is narrowly on the commercial success issue. So I doubt it will
24 bleed over into any of the other issues. And as you may have seen, that's

1 addressed at the very end of our presentation, so we may not get to it on
2 opening remarks.
3 JUDGE MITCHELL: Okay.
4 MR. KELLY: But if we happen to address it on rebuttal, then we'll --
5 I imagine it won't take very long, and we'll just ask Mr. Wilson to leave
6 during that time.
7 JUDGE MITCHELL: Okay, great. Yes. As long as you can police
8 and make sure that, you know, we only have people in the room. Now, we
9 do have a line. So to the extent and maybe we save commercial success, if
10 we get to that, towards the end just so if we need to shut the public line, I
11 can just do it once, and the people that may be on the line, you know, can
12 leave. I hate to shut it and then reopen it if I can avoid that. So, I'll ask you
13 all to help me. If you think we're going to go into that, maybe say you'll
14 reserve it, and let's do that at the very end if we're getting into confidential
15 information if that's doable.
16 MR. KELLY: No problem for Petitioner, Your Honor.
17 JUDGE MITCHELL: Okay, great. And who do I have for Patent
18 Owner?
19 MR. PHILLIPS: Thank you. Good afternoon, Judge Mitchell.
20 Matthew Phillips, for Patent Owner Stratus with the law firm of Laurence
21 and Phillips IP Law. With me today is Dan Higgs who will be doing part of
22 the argument. Kevin Laurence, from our firm, is also with us as well, as
23 well as our legal assistant Alex Phillips -- Alex Phillips.

1 JUDGE MITCHELL: Great, great. And thank you. We always
2 welcome to our LEAP attorney. So appreciate you being here to do part of
3 the argument.
4 So as set forth in our oral hearing order, each side has 60 minutes to
5 present its case with an additional 15 minutes for Patent Owner for the
6 LEAP practitioner. Just a reminder to assist us in following along with your
7 argument, and certainly for clarity of the record when we look back to go
8 through the record, it's very important that if you're referring to an exhibit,
9 you say it on the record so we know exactly what you're referring to. And
10 that you state the page number to which you are referring.
11 And I know we have, you know, all the demonstratives or -- for all the
12 cases, but if you are going to talk about a particular case and there's an issue
13 that's not common to the others, if you just give us the case number too that
14 would be great. So Petitioner will present its arguments first because the
15 Petitioner bears the burden of showing unpatentability of the challenged
16 claims. So let me ask Petitioner, do you want to reserve any of your time for
17 rebuttal?
18 MR. KELLY: Yes, Your Honor. We'd like to reserve 15 minutes --
19 JUDGE MITCHELL: Okay.
20 MR. KELLY: -- of our 60 minute total.
21 JUDGE MITCHELL: Okay great. And Patent Owner, you get the
22 last word. Would you like to reserve some time for -- for certain rebuttal?
23 MR. PHILLIPS: Like five minutes.
24 JUDGE MITCHELL: Okay.
25 MR. PHILLIPS: Please.

1 JUDGE MITCHELL: So as soon as I get the clock, whenever you are
2 ready, Mr. Kelly, that'll be great.
3 MR. KELLY: Okay. We're ready when you are, Your Honor.
4 JUDGE MITCHELL: Yes.
5 MR. KELLY: Thank you. And it's -- it's good to see you, Judge
6 Mitchell and Judge Fitzpatrick, Judge Peslak. It's a pleasure to be here today
7 in Alexandria. I'd like to start at slide two, and we've provided an overview
8 on slide two of the topics we intend to cover today. We'll touch briefly on
9 the Stratus Patents, the general teachings of the prior art, field of the
10 invention, and the level of skill in the art. We'll spend substantially more
11 time discussing the motivation to combine and a reasonable expectation of
12 success issues.
13 And if we have time at the end of our opening, we'll address some of
14 the Stratus' secondary considerations arguments, or perhaps we'll reserve
15 some of that for our rebuttal time. My priority today is to make sure that
16 everyone on the panel has their questions answered. So if we need to
17 deviate from this order to address a particular question you have, please let
18 me know. We're happy to do that. No problem at all.
19 Moving on to slide three. We provided a general overview of the
20 three patents at issue in these IPRs. There's obviously four IPRs and three
21 patents. The issues presented by these patents are substantially the same. As
22 you'll see the 782 and the 688 patents are directed to systems. The core
23 features of those patents are essentially the same. The only differences
24 relate to a fitting that is included in the 688 patent claims. There don't
25 appear to be any disputes about that limitation.

1 With respect to the 664 patent, this includes method claims, but those
2 method claims are directed to essentially a use of the same product that is
3 covered by the 782 and the 688 patents. So there aren't really any
4 substantially different questions presented across the four IPRs. For the
5 purposes of our presentation today, we'll focus on the 782 Patent IPR just as
6 a matter of efficiency.
7 At slide four, I'd like to touch briefly on some figures from the Stratus
8 Patents, and the point I'd like to emphasize is that we've color coded these
9 figures in the Stratus Patents, figures 2D and 3D, and we've carried that
10 color coding throughout both the petition and today's demonstrative
11 presentation. So you'll see at Figure 3D of the '782 Patent, the tip of the
12 needle is shaded red. That red tip is secured to the end of an elongate
13 cannula, 203. There are deployable filaments that extend outwardly from
14 that cannula, which are shaded blue.
15 If you look ahead to slide five, there's a tip on the left hand side of
16 slide five, and you see that's entirely shaded red because the only thing
17 illustrated there is the tip. And you can also see the lumens that are formed
18 to carry the filaments. On the right side of slide five, you'll see Figure 16F
19 from the '782 Patent, and this shows the red tip connected to the end of the
20 elongate member. The Removable RF Probe is shaded green, and, again, the
21 Deployable Filaments are shaded blue. So both in the -- in the Stratus
22 Patents and in the prior art, whenever you see green, that's the removable
23 probe. Whenever you see blue, that's the Deployable Filaments. Whenever
24 you see red, that's the tip of the device.
25 JUDGE PESLAK: Mr. Kelly?

1 MR. KELLY: Yes, Your Honor?
2 JUDGE PESLAK: In terms of the challenged patent, so are there any
3 dimensions disclosed for the filament size, the needle size, or the filament
4 lumen?
5 MR. KELLY: So there are -- there is no limitation in the claims
6 themselves with respect to the size of the filaments. In the -- in the
7 specification, there are disclosed sizes for the filaments in terms of ranges
8 with respect to the disclosure, but those ranges are not claimed. Does that
9 answer your question?
10 JUDGE PESLAK: How about the needle size itself?
11 MR. KELLY: There's no in the -- in the claims, the claims are not
12 limited to a particular needle size. So, you'll find nowhere in any of the
13 three patents that the needle is limited to a particular size. In the
14 specification, the patent discloses that in some embodiments, the needle can
15 be 16 gauge, or it can be smaller than that, but there's no limitation about the
16 size. And Patent Owner has not argued at any point in this proceeding that
17 the claims are limited to a particular size of needle.
18 JUDGE PESLAK: Okay. Thank you.
19 MR. KELLY: As you know, all of the grounds in the four IPRs are
20 rooted in the combination of the Racz, Fitz, and Lee references. Either just
21 those references in isolation or, in some cases, combined with other prior art.
22 And at this stage of the case, there's some things that are in dispute, and
23 there's some things that aren't. We summarize these in slide seven. There's
24 no dispute between the parties that if the prior art is combined as proposed in

1 the petition, that combination discloses every limitation in the challenged
2 claims. There's no dispute about that. Stratus argues for --
3 JUDGE FITZPATRICK: Mr. Kelly?
4 MR. KELLY: Yes?
5 JUDGE FITZPATRICK: What about -- there was a dispute about
6 electrically charged, you know -- you know, filaments that are, you know,
7 that are electrically charged by the probe at the distal end of the instrument.
8 There's an argument by Patent Owner that that's not shown in the prior art.
9 That they -- either that the prior art that uses a probe doesn't have filaments,
10 or the prior art that uses filaments doesn't have the probe. Instead, those are
11 energized somewhere near the proximal end.
12 MR. KELLY: Yeah. That's correct, Your Honor. Patent Owner
13 advances that argument. I would characterize that argument as attacking the
14 references individually as opposed to attacking the combination of the
15 references. And what we've explained in the petition and what I'll elaborate
16 on in detail today is that the combination of those references clearly
17 discloses energizing the filaments by physical contact, both through the
18 probe and the tip.
19 JUDGE FITZPATRICK: I think what Patent Owner might say to that
20 is well, not exactly, because the filaments from the prior art are not of the
21 configuration that you would need them to be. Instead, they are they run
22 the entire length of the device and are in electrical connections somewhere
23 near the proximal end. So I think there's a little bit of overlap between
24 whether this is attacking the references individually or -- or if each of these
25 limitations truly is taught by the prior art. I wonder if you can address that

1 point that they make. I don't know if I'm paraphrasing it well enough, but I
2 think, you know, the argument I'm referring to.
3 MR. KELLY: Yes, I do, Judge Fitzpatrick, and maybe this is the -- a
4 good opportunity to just skip ahead to a portion of our presentation where
5 we -- we address this issue.
6 So as you -- if you, I'm turning -- I'm skipping ahead to slide 27. And
7 as you can see here on the left side of slide 27, we have the device of Lee as
8 disclosed, and there are perimeter filaments arranged in Lee's device that
9 extend outwardly around the tip. Okay. And what Lee teaches is that those
10 perimeter filaments are guided outwardly from the tip by physical contact
11 with the tip. So those filaments are being guided outwardly because they
12 physically engage the tip of the needle.
13 Now, in Lee's device, those perimeter filaments are connected at their
14 proximal end to some energy source. But in Racz's device, the RF energy is
15 transmitted by the RF probe, which contacts the tip of the needle. So you
16 have a teaching in Racz that physical contact between the probe and the tip
17 of the needle is how the RF energy emanates from the tip.
18 So, as we'll explain today, a person of ordinary skill would have been
19 motivated to add filaments to the tip of a single -- single tip needle, like that
20 in Racz. And if you do that and you use channels to guide those filaments
21 outwardly, you're going to provide -- a person of ordinary skill would
22 provide those channels at the tip, just like Lee has done. And if you do that
23 in a device like Racz, you are necessarily going to get contact, and that's
24 what's shown in slide 28 where we -- we have detail on this.

1 So you've got basically two teachings of physical contact, one in Lee,
2 for guiding the filaments, and one in Racz, for emanating RF energy
3 throughout the device. And as you can see here, if the green probe is
4 energized and is conducting that RF energy to the tip by physical contact,
5 and then the filaments are also being guided out by physical contact with
6 that same tip, the RF energy is going to be transmitted through all three
7 elements.
8 And that is the natural consequence of combining the teachings of the
9 prior art. And you won't find it individually in the references, which I think
10 is what Patent Owner's argument is. But when you combine them together
11 and you consider the multiple teachings of physical contact and what a
12 POSA would understand would be obvious in view of Racz teaching that RF
13 energy can be transmitted in that way, then the combination is obvious.
14 JUDGE FITZPATRICK: Thank you, and that makes sense. I fully
15 understand and appreciate that there's going to be contact there and
16 therefore, you know, they're going to get charged. They're going to get
17 energized when -- when -- when the energy sources turn on the probe. But
18 in this modification where the filaments, even though they don't need to be
19 connected at the proximal end because they're not being energized there, do
20 they extend there? What is the nature of the proposal? Is it -- are these
21 filaments only at the distal end, or do they run the length of the device?
22 MR. KELLY: Yeah. Thanks. That's a great question, Judge
23 Fitzpatrick. So I think the key thing that the -- the petition articulates is
24 what's happening at the opposite ends of the filaments. Okay. So at the
25 distal end of the filament, they are engaging the tip in these channels at the

1 tip, and that's what's guiding them outward. And at the proximal end of the
2 filament, they are connected to an actuator.
3 Now that actuator doesn't have to be all the way at the proximal end of
4 the needle. It could be in the middle of the needle. Excuse me. But the
5 filaments have to be connected at their proximal end to an actuator so that
6 they are being deployed inwardly and outwardly from the needle. That's in
7 the prior art. So the petition clearly articulates the connection at the
8 proximal end of the filaments and the distal end of the filaments.
9 What is happening between those two spaces? The only thing that
10 matters is that they are arranged so that there's space for the probe to go
11 down the middle. And you'll see throughout the petition we explain that
12 those filaments are arranged around the inner perimeter of the cannula.
13 They don't have to be in the sidewall. They just have to be in the inner
14 perimeter so that there's space for that green probe to be inserted down the
15 center of the cannula. So I think you've got a clear definition of what's
16 happening at the distal end of the filaments, a clear definition of what's
17 happening at the proximal end, and also definition of how that RF energy is
18 being transmitted.
19 JUDGE FITZPATRICK: Thank you.
20 JUDGE PESLAK: Counsel, I have one follow up question. I'm
21 looking at where I see the right hand figure here. So are your filaments in
22 the channel in the tip? So they're they would be surrounded by material.
23 Is that how this combination is going to work?
24 MR. KELLY: Yes. So thank you, Judge Peslak. The teaching from
25 Lee is that channels at the tip of the needle are what are used to guide the

1 filaments in and out of the -- in and out of the needle. And so that's what
2 this combination reflects is if you -- if you define those channels at the tip of
3 the needle then they will guide the filaments out. There's no need for the
4 channels to extend along the entire length of the needle because the
5 filaments aren't being guided in or out of the cannula at that point.
6 And in fact, if you look on the left side of slide 27, you can see that
7 the filaments in Lee, they're engaging those channels at the tip portion,
8 which is shaded red. Once they get proximal from the tip, they're no longer
9 in channels. They're just sitting in the middle of the cannula which is shaded
10 yellow. So the teaching we're relying on is channels at the tip, and that's
11 where the channels are provided.
12 And this is also why on the right side of slide 27, Your Honor, the
13 entire portion of the needle that we're showing here is shaded red because
14 what we're illustrating is the tip. We're not illustrating the rest of the needle.
15 And I think that might be something that Patent Owner has confused in its
16 analysis.
17 JUDGE PESLAK: Okay. Thank you.
18 MR. KELLY: Okay. I'd like to move back to slide 14 and address the
19 field of the invention, which is one of the disputed issues. From the outset
20 of this case, Petitioner has maintained that the correct field of the invention
21 is exactly what the Stratus Patents say, thermal ablation systems and
22 methods. Certainly the patents discuss RF neurotomy throughout the
23 specification, but they're not limited to RF neurotomy, and that is actually
24 explicit in the patents. The patents say that the delivery of RF energy tissue
25 in the anatomy can be practiced for a multitude of reasons and the

1 embodiments described herein can be adapted for use in other medical
2 procedures. And elsewhere in the patent they give examples of cardiac
3 ablation. So the patents are very clear that they're not limited to RF
4 neurotomy.
5 Stratus argues that RF neurotomy is an isolated field, and to make that
6 argument, they rely on the testimony of their expert, Dr. Russo, who said in
7 his declaration that there's historically been little to no crosstalk or cross
8 pollination between various areas of RF ablation. And what Dr. Russo is
9 really saying in his direct testimony is that when technology materializes in
10 one area of RF ablation, such as tumor ablation or cardiac ablation, it doesn't
11 migrate to other areas of RF ablation. That's his testimony in his direct
12 declaration.
13 As it turns out, that's not true, and Dr. Russo's testimony and his
14 declaration was not credible. Stratus submitted an article by Dr. Russo,
15 which is Exhibit 2004. You see this on slide 14. He wrote an article entitled
16 The History of RF Neurotomy. And in that article he describes how cooled
17 tip ablation technology was first developed in the cardiac field. It then
18 found application in tumor ablation and then it cross pollinated into RF
19 neurotomy. And in fact, this isn't an obscure technology. This is the
20 technology that's at the core of this Avanos's COOLIEF product today, which
21 sells in large numbers.
22 At slide 15 in the same article, Dr. Russo explained that the lead
23 inventor of the Stratus Patents was actually working on cooled tip
24 technology at the time he developed the claimed invention. So even the lead
25 inventor of the Stratus Patents would have been well aware that technology

1 cross pollinates between different areas of RF ablation. RF neurotomy is not
2 an isolated field. And at slide 16, we asked Dr. Russo about this in his
3 testimony, and he confirmed there is cross pollination between different
4 areas of RF ablation. And so the testimony that he gave that Stratus relies on
5 to support its isolated field argument is not credible, and it would be an error
6 to rely on it.
7 Turning to the level of skill at slide 17, Petitioner's expert Dr. Tucker
8 articulated a level of skill that is tethered to the correct definition of the field.
9 He explains that you'd have a bachelor's degree in biomedical engineering, a
10 few years of experience with thermal ablation systems and methods. Stratus
11 argues for a different definition that unnecessarily requires experience as an
12 interventional pain specialist physician. Essentially, what they're saying is a
13 person of ordinary skill has to be a practicing doctor.
14 Perhaps the fact that defeats this most clearly is the testimony of
15 Stratus's own experts. Mr. Crosby, who is an engineer, not a doctor, testified
16 about nearly every issue in this IPR, and he did so without seeking the
17 expertise of Mr. Russo or without seeking the expertise of any other
18 interventional pain specialist physician. So it makes no sense that Stratus's
19 own experts could testify in this case without following their own definition
20 of the level of skill. The Board should reject that narrow definition and
21 adopt Petitioner's definition of the level of skill.
22 A related issue is at slide 18 where we address Stratus's argument that
23 Lee is not analogous art. If the Board adopts Petitioner's definition of the
24 field then Lee is clearly in the same field as an analogous art. But even if
25 the Board were to adopt Stratus's narrow definition, Lee clearly addresses

1 the same problem that was faced by the Stratus inventors. How do you
2 expand and control the ablation volume? This is exactly what Lee
3 addresses, and even Patent Owner's expert, Mr. Crosby, agreed that Lee's
4 purpose is to increase the volume of ablated tissue. So there should be no
5 question that Lee is analogous art and shouldn't be excluded from the
6 analysis.
7 At slide 19, we've reproduced what I think is the fundamental legal
8 underpinning of Petitioner's motivation to combine argument. If there is a
9 known technique to address a known problem using prior art elements
10 according to their established functions, the law says there's a motivation to
11 combine. That is exactly the case here. In Racz, there was disclosed a
12 single tip RF neurotomy needle, no Deployable Filaments. And this was in -
13 - this type of needle was common in the 1990s. I think Racz was filed in
14 maybe 1998. And Fitz, which published in 2005, identified a problem with
15 these needles, which you see at slide 20.
16 Fitz explains a problem with current designs is that they do not allow
17 for adequate coverage of the target area. Fitz even shows in figure one here
18 the limited ablation area that is produced by a needle with no Deployable
19 Filaments and a single tip. And Petitioner's expert, Dr. Tucker, opined that
20 Fitz would have taught a POSA that this limited coverage problem would
21 have been present in Racz's device. So a person of ordinary skill having the
22 benefit of Fitz's teaching is going to know that Racz's device has a limited
23 coverage problem.
24 At slide 21, Fitz also identifies a known solution to this problem. Fitz
25 proposes an improved coverage RF neurotomy device and proposes using

1 deployable electrodes which deploy outwardly from the tip of the needle in
2 order to enhance the energy coverage of a single tip needle. So Fitz is
3 disclosing not just a known problem but also a known solution, and this is
4 specific for RF neurotomy. Fitz is an RF neurotomy reference. Petitioner's
5 expert explains that this solves the problem of inadequate coverage that
6 would be present in single tip devices, and Patent Owner's expert agreed that
7 Fitz discloses the general idea of deployable electrodes to increase the
8 ablation volume.
9 So how would a person of ordinary skill have implemented these
10 deployable electrodes in Racz's device? Well, in slide 22, Dr. Tucker
11 explained that Deployable Filaments were actually well known in the art at
12 the time of the invention. And all of these Dr. Tucker discussed in his
13 background. And as you can see, there's many different types of Deployable
14 Filaments available. Some are straight, some are curved, some deploy from
15 the side of the cannula, some deploy from the tip. These types of
16 Deployable Filaments were widely adopted in different types of RF ablation
17 devices. The petition relies on the Lee reference, which are the figures you
18 see on the right, and they do so for good reason.
19 At slide 23, we explain that Lee provides more motivation, a detailed
20 solution for how to implement those filaments, and the established functions
21 of the filaments. So Lee discloses that Deployable Filaments can be used to
22 both expand and control the ablation volume. So not just make the ablation
23 volume bigger but also control where the ablation volume is and what size it
24 is.

1 Lee explains that filaments defined ablation volume in the target
2 tissue. Lee explains that variations in that ablation volume can be achieved
3 by controlling the number of filaments, the length, the direction, the
4 arrangement, and as a result, the arrangement of the filaments can form any
5 desired pattern. So what Lee is teaching to a person of ordinary skill is that
6 if you want to expand the ablation volume for an RF ablation needle, and
7 you want to control where that volume occurs in the human body,
8 Deployable Filaments is the answer. At slide --
9 JUDGE PESLAK: Counsel?
10 MR. KELLY: Yes, Your Honor.
11 JUDGE PESLAK: Does Lee disclose either what size the filaments
12 are or the gauge of the device?
13 MR. KELLY: No, Your Honor. Lee is not specific about the specific
14 size of the device. My understanding of Patent Owner's argument is because
15 Lee discusses using the device to ablate uterine fibroids, they argue that
16 necessarily, Lee's device is orders of magnitude bigger than an RF
17 neurotomy needle. And as we discuss on later slides, that's actually not
18 correct, and I'm happy to address that now, if you'd like.
19 JUDGE PESLAK: No, you can go on with your argument, Counsel.
20 MR. KELLY: Okay. Thank you. At slide 24, an important
21 consideration that Dr. Tucker highlighted is that a person of ordinary skill,
22 considering the teachings of Racz, Fitz, and Lee, also would have been
23 motivated to preserve the functionality of Racz's probe. So Racz teaches
24 that his probe does two things.

1 Number one, the probe transmits RF energy by physical contact down
2 the central lumen of the needle. So the probe is responsible for transmitting
3 that RF energy to the needle's tip. But the probe does a second function too.
4 The probe is removable, and that allows fluid to be injected down the center
5 of the cannula. So when a doctor has the needle in place, that doctor can
6 remove the probe from the lumen and inject anesthesia or other fluid down
7 the center of the lumen without moving the needle. So the presence of
8 Racz's probe in the center of the device is one that a person of ordinary skill
9 would want to keep.
10 So the result of this is that the combined teachings of the reference
11 would leave a person of ordinary skill wanting to do two things. Number
12 one, they'd want to add filaments to the end of Racz's device to expand the
13 ablation volume, which is the problem that Fitz identified. And number two,
14 they would want to keep the removable probe and the central lumen to
15 preserve that functionality. So you've got two motivations that are very clear
16 in the teachings of the prior art.
17 So how would a person of ordinary skill achieve both of those express
18 goals? Well, Lee discloses that filaments can be added using channels at the
19 tip of the cannula, that those -- those filaments can include perimeter
20 filaments where arranged around the inner -- the inner perimeter of the
21 cannula, and they leave space for a central element.
22 At slide 25, you can see that Lee has a central stylet that is exiting out
23 the center of the needle, and the remaining filaments are arranged around
24 that central element so there's space for it. So what Lee is teaching is that if
25 you need to add perimeter filaments to a device, and you need to arrange

1 those filaments to keep space for a central element, this is how you do it.
2 You have channels that are at the tip, and the filaments are arranged to leave
3 that central space. That's the teaching of Lee.
4 JUDGE FITZPATRICK: Does in Lee, that element that's labeled 24,
5 the central one, does that -- is that just an electrically charged filament like
6 the others that just happens to be right in the middle?
7 MR. KELLY: Yes, Your Honor. And so our argument is that if you
8 combine -- if a person of ordinary skill were combining the references, there
9 would be no need to retain that central filament because the distal tip of
10 Racz is already energized by the RF probe. So you already have RF energy
11 emitting from the distal tip of the needle. What you want to do is spread that
12 RF energy further away around the tip, and that's what the perimeter
13 filaments do. So if you were implementing perimeter filaments on Racz to
14 expand the ablation volume, you wouldn't need the central filament. And the
15 benefit of that is that you get to preserve space for the RF probe. So this is
16 the solution to how do we achieve those two goals that a person of ordinary
17 skill would have, adding filaments and preserving the probe functionality.
18 JUDGE FITZPATRICK: In Lee, this -- this central film at 24, does
19 that -- is that like a master filament that provides the electricity that it
20 touches the rest of this trocar or the tip and then transmits to the other
21 filaments? Or they are all -- all are -- or each filament is electrically charged
22 in somewhere near the proximal end, right?
23 MR. KELLY: Yep. My understanding --
24 JUDGE FITZPATRICK: It's the latter, right?

1 MR. KELLY: Yes, Your Honor. So the filaments that are employed
2 from Lee are essentially all the same. The difference is -- is the position. So
3 when you see here on slide 25 you have a central filament and perimeter
4 filaments, there's not really any difference between those filaments.
5 JUDGE FITZPATRICK: So does Lee talk about -- does Lee itself talk
6 about hey you can get rid of this 24, retract it all the way, and then you can
7 use that to administer medicine down the middle or anything else?
8 MR. KELLY: I'm sorry?
9 JUDGE FITZPATRICK: Or is that just something that you -- that that
10 person -- that you're saying a person of ordinary skill in here would know
11 they could do?
12 MR. KELLY: That -- that -- that feature is disclosed in Racz, Your
13 Honor. So Racz -- Racz --
14 JUDGE FITZPATRICK: Understood.
15 MR. KELLY: Yeah.
16 JUDGE FITZPATRICK: But it's a different -- yeah, it's -- it's a
17 different reference though. Okay.
18 MR. KELLY: Yeah. That's right.
19 JUDGE FITZPATRICK: I think I can answer. Thank you.
20 MR. KELLY: Considering all these teachings together brings us back
21 to the fundamental KSR tenet. If a technique has been used to improve one
22 device -- and I'm at slide 26. If a technique has been used to improve one
23 device and a POSA would recognize that it would improve similar devices in
24 the same way, the technique is obvious unless its actual application is
25 beyond his or her skill.

1 And this brings us back to slide 27, which we discussed before. If a
2 person of ordinary skill takes Racz's known single tip device with a
3 removable probe and an active tip and adds perimeter filaments, just like as
4 disclosed in Lee, and uses channels at the tip, just like as disclosed in Lee,
5 the result is the combination that you see here, and this has every single
6 feature of the challenged claims.
7 And as we explain at, slide 28, the other consequence of this is that
8 the Deployable Filaments would naturally be energized by the physical
9 contact. Because again, you have physical contact, a transmitting RF
10 energy, as disclosed in Racz, and you have physical contact with the tip
11 guiding those filaments, as disclosed in Lee. When you put those things
12 together, the only thing that can happen is that the filaments, the tip, and the
13 RF probe are all energized because they're all conductive.
14 JUDGE MITCHELL: So -- so for that, do we have to do an inherency
15 analysis? Like you would say oh, if we put this together, it's inherently
16 going to have. So it necessarily will have power to everything.
17 MR. KELLY: I think it's true that it will necessarily transmit power to
18 everything, but I wouldn't consider it inherency argument. What I would
19 consider it is how a person of ordinary skill would apply the teaching of
20 Racz. So what Racz is teaching is that when you want to energize a
21 conductive element on the end of an RF ablation needle, you can do it by
22 transmitting RF energy with physical contact.
23 And in Racz, the way that happens is that the probe contacts the tip
24 itself. So you have contact between the provider of the RF energy and the
25 distributor of the RF energy. And so adding filaments and energizing the

1 filaments by physical contact is an obvious expansion of that teaching. So
2 the core teaching of transmitting RF energy by physical contact is already in
3 Racz. And a person of ordinary skill motivated to add the filaments, which
4 again are deployed outwardly by physical contact with the tip, you're -- it
5 would be impossible for the filaments not to be energized unless they were
6 made of a non- conductive material, which of course they're not because the
7 purpose of the filaments is to transmit RF energy and expand the ablation
8 volume.
9 JUDGE MITCHELL: Okay. Thank you.
10 JUDGE FITZPATRICK: Mr. Kelly, let me ask another question on
11 this topic with the filaments. We keep -- you -- you keep referring to person
12 of ordinary skill here adding the filaments of Lee to Racz. What would I --
13 and I -- and I appreciate that more than one thing can be obvious at the same
14 time, including inferior apparatuses. Why wouldn't a person of ordinary
15 skill in the art, if they just were aware of Lee, why wouldn't they just say,
16 hey, problem solved, let's just use Lee?
17 MR. KELLY: Because if you just use Lee, Your Honor, then you lose
18 the functionality that is -- that is in Racz -- what's disclosed in Racz. So
19 what Racz discloses is that the benefit of having that Removable RF Probe is
20 that you can have the combination of transmitting RF energy using the probe
21 and also injecting fluid down the center of the lumen. Because when the
22 probe is removed, you have that open space to transmit anesthetic fluid to
23 the patient. So the teaching in Racz is that you don't want to get rid of that
24 functionality. You want the removable probe, and you want the lumen down
25 the center of the needle. So if you just use the device in Lee, you're going to

1 lose that functionality. So the obvious combination is putting those two
2 things together.
3 JUDGE FITZPATRICK: It seems like if you have Lee though – I'll
4 push back a little bit on that one. It seems like if you have Lee, you don't
5 need a probe. And so it's not that you need a removable probe, you need the
6 removed probe it is the benefit. Not, you know, because you don't need a
7 probe to charge it if you have the filaments, you know, unmodified. If you --
8 if you leave Lee's filaments just the way they -- they are in the native
9 refence, they're going to -- they're energized at the proximal end somewhere.
10 So what about just getting rid of 24, this central filament, and then
11 using that to send -- because I think you talked about earlier that that would
12 be a benefit a person of ordinary skill in the art would recognize that. It
13 seems a little bit inconsistent with a person of ordinary skill in the art saying
14 ah-ha, Lee -- excuse me, yeah, Lee doesn't have a central lumen that's
15 available. So we're going to go -- we're going to add the filaments to Racz
16 because we need that central lumen to be open, at least at times.
17 MR. KELLY: It do I understand your question, Judge Fitzpatrick?
18 Is the question why wouldn't we modify Lee to include Racz's probe instead
19 of the other way around?
20 JUDGE FITZPATRICK: It definitely -- it definitely hints at that.
21 There's a lot of kind of circular things going on. And this is another way,
22 actually, of looking at my first question about Patent Owner's argument that
23 not all the limitations are taught. And when they -- when they slice and dice
24 this thing down to small enough, they get to the point where they can say
25 hey, this is not taught in the prior art. This is filaments that are -- that are --

1 it's the idea of having these filaments that are -- that matter -- yeah, that are
2 charged, I guess, at the proximal end. And you have them in Lee. You --
3 you can already create that ablation value.
4 So what's missing from Lee is this central -- removable central probe.
5 Why would that be valuable when you already have Lee? Because you
6 would want some sort of lumen, right, so you can administer medicine ahead
7 of time. For example, anesthetic. But what -- yeah, why -- why wouldn't
8 you just remove this might be a total detour, I'm sorry, but why wouldn't
9 we just remove that central filament in 24 -- in Lee and take advantage of
10 that space?
11 MR. KELLY: Well, I think -- I think what you're suggesting, Your
12 Honor, is the same combination. Because, really, Petitioner's argument is
13 that you are combining different concepts from the prior art. You're
14 combining the concept that Deployable Filaments expand the ablation
15 volume. We all agree about that. You're combining the concept of having a
16 central lumen down the middle of the probe allows for the delivery of fluid
17 down the center, and you're putting those two things together. Now, if
18 you've got to have the lumen down the center of the -- the cannula then you
19 might as well energize the tip with an RF probe.
20 And in the real world, these RF probes are fungible products that are
21 sold by companies, right? So these are -- it's -- you've got one device with
22 one point of contact energizing all the filaments and the tip as opposed to
23 having to individually electrically connect each of the individual filaments.
24 So if you can energize them all with one probe, I don't see why person of
25 ordinary skill wouldn't choose to do that.

1 JUDGE FITZPATRICK: Thank you.
2 MR. KELLY: I'd like to address some of Stratus's arguments
3 beginning at slide 29. Stratus argues that the combination is just a paper
4 design and rooted in hindsight. And as we've indicated here at slide 29,
5 nothing could be further from the truth. In Dr. Tucker's cross examination,
6 he was asked is it fair to say this is a paper design? He said no, you're taking
7 components that have been in the literature, and you're using them for the
8 same purpose and the same fashion as they were used in the patents. Any
9 one of ordinary still could make this.
10 At slide 30, Stratus argues that the obviousness combination is a
11 particular modification that is too vague. First, the petition is anything but
12 vague, but Stratus's demand that the petition -- the petition articulate
13 unclaimed features has no support in the law. And I think later today you'll
14 see at slide 32 of Patent Owner's demonstrative. They have a laundry list of
15 complaints about the petition of things that aren't shown or described in the
16 petition, none of them are claimed. The petition was crystal clear about the
17 combination and the things that are claimed.
18 JUDGE MITCHELL: Can I pause you right there? I'm sorry. I think
19 I've --
20 MR. KELLY: Yes, Judge Mitchell.
21 JUDGE MITCHELL: -- lost Judge Fitzpatrick. There's no -- do you
22 know if we have Judge Fitzpatrick?
23 UNIDENTIFIED MALE SPEAKER: It doesn’t sound like it.
24 JUDGE MITCHELL: There. Do we have him back? We might have
25 just --

1 JUDGE FITZPATRICK: Everyone, I'm sorry. I don't know what
2 happened.
3 JUDGE MITCHELL: Oh, there we go.
4 JUDGE FITZPATRICK: Can you -- can you hear me now?
5 JUDGE MITCHELL: I have -- I have you, but I don't have Judge
6 Peslak I don't think.
7 JUDGE FITZPATRICK: Something happened with the -- with the
8 internet. It's just -- just cut off while we're waiting for. I can tell you, Mr.
9 Kelly, exactly where you were. You were talking about slide 29, and you
10 were just about to talk about his response, the witness's response, to the
11 paper designing accusation.
12 MR. KELLY: Thank you, judge.
13 JUDGE MITCHELL: I think I have everybody. So go ahead.
14 MR. KELLY: Okay. I think we're back. You're right, Judge
15 Fitzpatrick. So we -- we asked Dr. Tucker about this in his cross -- or he --
16 Dr. Tucker was asked by Patent Owner in his cross examination is it fair to
17 say the combination is a paper design? And he explained, no, you're taking
18 components that have been in the literature, you're using them for the same
19 purpose and the same fashion as they were used in the patents, and any one
20 of ordinary skill can make this.
21 At slide 30, Stratus argues that the obviousness is based on -- in the
22 petition is based on a particular modification, and it's too vague. And
23 nothing could be further from the truth. The petition was very, very clear
24 about its combination, and you'll hear from Stratus a laundry list of
25 complaints. I think it's slide 32 of their demonstrative about things that are

1 not in the patents. These are all unclaimed features. The question is whether
2 or not the claimed invention is obvious, not whether it was obvious to add
3 various unclaimed features to the product. So Stratus's arguments about the
4 combination being too vague have no support in the law. The petition was
5 very, very clear throughout.
6 I'd like to skip ahead to some of the Stratus's teaching away
7 arguments, and I'll skip ahead to slide 34. Stratus argues that Racz teaches
8 away from deploying a flexible electrode. And, in fact, Racz doesn't teach
9 away at all. What Racz discloses is that flexible, curved tips are especially
10 useful when neurotomy is being performed in target regions that are very
11 soft or fluid filled, like the trigeminal ganglion area, which is in the face.
12 So what Racz is saying is that when the neurotomy procedure is being
13 performed in an area with soft tissue, these flexible electrodes, like what's in
14 this Radionics TEW kit shown at slide 34, these work great. And what Racz
15 says is that if the neurotomy is going to be performed in an area where the
16 tissue is tougher, you might want to select a different type of electrode. So
17 this isn't a teaching away, it's just a preference of what electrode you want in
18 what circumstance, but all of these things are examples of RF neurotomy.
19 JUDGE PESLAK: Counsel?
20 MR. KELLY: Yeah, sure.
21 JUDGE PESLAK: I think Patent Owner is also arguing that Racz
22 teaches away from a straight needle. And if you look at, you know, the
23 bottom of column one of Racz over to column two, it talks about problems
24 with straight needles. It says that they -- it could be serious medical risks to
25 the patient. And we all know the law of teaching away. That teaching away,

1 you have to show that disparaging or discouraging. It -- isn't that column of
2 -- isn't that beginning of Racz back right -- isn't that really -- wouldn't that
3 discourage a person of ordinary skill in the art from using a straight needle?
4 MR. KELLY: It wouldn't, Your Honor, and the reason is because the
5 benefit of using a bent tip is only in a specific application of RF neurotomy.
6 So Racz is talking about using the needle in a very bony area of the body.
7 So RF neurotomy involves the ablation of any nerve in the body. It could be
8 in the face, it could be in the knee, it could be in the spine. And what Racz
9 is saying is that if you have a single tip needle, and if you're performing
10 neurotomy in a very particular part of the body with bony a structure then
11 using a bent tip can be beneficial because it allows the physician to not have
12 to reinsert the needle over and over and over again.
13 And what Racz contemplates is that, in fact, to your point earlier,
14 Judge Fitzpatrick, an inferior technology, a straight tip, was -- was actually
15 perfectly useful before Racz's invention. So these procedures were already
16 being performed with straight needles. What Racz says is that if you're in
17 the particular part of the body, and you've got a single tip, that a bent tip can
18 be helpful. So Racz is not teaching away, it's just teaching a preference in
19 certain limited scenarios, which is not a teaching way.
20 The other point I would make, Judge Peslak, is that whether the --
21 whether the tip is bent or not is just a design choice that the person of
22 ordinary skill is going to make. It doesn't impact whether or not they're
23 going to add filaments or use the removable probe. So this argument about
24 whether Racz requires a bent tip is sort of -- this is an unclaimed feature.

1 None of the patents require a straight tip or a bent tip. So it's really not an
2 effective teaching away argument.
3 JUDGE PESLAK: Okay. Thank you.
4 JUDGE FITZPATRICK: Mr. Kelly, let me just ask a question. I
5 understand -- I understand that it sounds like your position is that Racz
6 teaches both straight and curved tips. Without directly addressing whether
7 or not if it's the curved tip then are Patent Owner's arguments meritorious?
8 So another way to say it is what is your proposal? Is your proposal that a
9 straight tip would have been modified and achieved the invention, or a
10 curved tip would have been modified to achieve the invention?
11 MR. KELLY: The argument, Judge Fitzpatrick, is that the claims do
12 not require a straight tip or a curved tip.
13 JUDGE FITZPATRICK: Understood. I just want to know what --
14 what is -- what is the thing that we want to map the claim against. And so if
15 I have the claim that I want to look at this hypothetical, you know, what the
16 person of ordinary skill here would have done, what does it look like? Does
17 it have a curved tip, or does it have a straight tip?
18 MR. KELLY: The answer is either, and that's what Dr. Tucker
19 testified in his cross examination. Depending on what type of
20 JUDGE FITZPATRICK: Okay. So can you speak to then -- can you
21 speak to Patent Owner's specific arguments assuming the curved design?
22 MR. KELLY: Yeah. My understanding, Your Honor, is that Patent
23 Owner's argument is that if the needle has to be curved then the reason that's
24 relevant is because it would be very, very difficult to allegedly manufacture
25 channels along the entire length of the cannula that were narrow and have a

1 curved profile. My understanding is that that's why this curved issue is
2 relevant to them. The reality is that the channels only have to be at the tip.
3 That's what Lee teaches. And so whether or not the tip itself is curved has
4 no impact on whether or not a person of ordinary skill would be able to
5 make the combination.
6 JUDGE FITZPATRICK: Well, I understand it'd be a lot easier, right,
7 because you're only -- the channels would be much shorter, but they'd still be
8 curved.
9 MR. KELLY: Not if they were just at the tip, because it's -- I mean, if
10 you look at the --
11 JUDGE FITZPATRICK: The very, very tip. Okay. Okay, I
12 understand now.
13 MR. KELLY: Yeah.
14 JUDGE FITZPATRICK: Okay. Because you're saying curved tip and
15 then I think you're using the word tip, you know, in two different ways,
16 right? One at the very end, the very distal end of the tip, and then one
17 maybe, I don't know, the last full inch.
18 MR. KELLY: Yeah. And it --
19 JUDGE FITZPATRICK: That’s what it seems to me.
20 MR. KELLY: The reality, Your Honor, is that the filaments that are
21 being used in these devices are made of nitinol, which is a well-known
22 flexible metal. So having them curve around the -- around the tip is not
23 really a problem, right? I think Patent Owner's arguments are just rooted in
24 unsupported manufacturing arguments that really have no basis in the
25 evidence.

1 Speaking of which, I'd like to turn now to reasonable expectation of
2 success. It looks like we have about four minutes left, so we'll touch on this
3 very briefly. At slide 37, we just reiterate the tenant from *In re: O'Farrell*.
4 Obviously, this does not require absolute predictability -- predictability. All
5 that is required is a reasonable expectation of success, and that's what's here.
6 At slide 38, you'll see the combination was predictable and routine.
7 Dr. Tucker testified that implementing filaments at Racz's distal tip would be
8 a routine engineering task. He explained that this is just using prior art
9 elements according to their established functions, and that putting those
10 things together would yield the expected improvement. This is -- none of --
11 there's nothing about this combination that is unpredictable.
12 And this kind of goes to the point you made, Judge Fitzpatrick, about
13 the tip of the needle and the electrical contact to the filaments. It's not
14 surprising that if you take conductive filaments and you put them through a
15 channel at a tip that is metal and is already activated with RF energy, there's
16 no surprise that they're going to be activated too. This is just basic physics.
17 So this combination is entirely predictable. There would have been nothing
18 surprising about it.
19 At slide 39, Dr. Tucker was asked about this. He explained you take
20 Lee's filament out of that central channel. All the filaments are along the
21 outside of that channel. Racz's probe is down the center. He was asked do
22 you believe this is routine engineering? He said amen. And you'll find
23 throughout this case that when Patent Owner's experts were cross examined,
24 they recanted a lot of their testimony. Dr. Tucker reiterated this.

1 At slide 40, Mr. Crosby in his declaration produced the Acessa User
2 Guide, which is Exhibit 2010. This is a user guide for the commercial
3 embodiment of Lee. And Mr. Crosby explained that a person of ordinary
4 skill would have understood that Lee's device produces the ablation volume
5 that's described in this user guide, and he argued that the ablation volume
6 would have been orders of magnitude larger than is appropriate for RF
7 neurotomy. On cross examination, he admitted that that's not the case. Mr.
8 Crosby's testimony at this point was not credible.
9 In fact, Lee would produce ablation dimensions about 19 millimeters
10 by 17 millimeters, which, as you can see on slide 42, compared to the size
11 that Stratus advertises for its device, is not that much bigger. And in fact,
12 you can see from the Acessa User Guide, which again, Mr. Crosby relies on
13 for how a person of ordinary skill would have understood Lee, it produces
14 an ablation volume that looks identical to what Stratus advertises its devices
15 produce. So again, the result of putting these things together based on what
16 a person of ordinary skill would have known would have been entirely
17 predictable, and it would have yielded exactly what's described in the Stratus
18 Patents.
19 JUDGE PESLAK: All right, Counsel?
20 MR. KELLY: Yes.
21 JUDGE PESLAK: I just want to make sure you understand what I'm
22 seeing in this figure here.
23 MR. KELLY: Yes.
24 JUDGE PESLAK: It is the -- are those egg shaped things that’s the
25 black -- that -- that's part of the nerve that would be ablated?

1 MR. KELLY: It is the area -- it is the area of the tissue that is ablated
2 when the filaments are energized. So that --
3 JUDGE PESLAK: Okay.
4 MR. KELLY: So the area outside that egg is not going to be ablated,
5 and the area inside the egg will be ablated.
6 JUDGE PESLAK: Okay. Thank you.
7 MR. KELLY: The last point I would make with our time remaining, I
8 don't want to get too much into our rebuttal time, is that all of Stratus's
9 impossible to make arguments are premised on this notion that RF
10 neurotomy needles have to be 16 gauge or smaller. The evidence does not
11 show this. Racz is very clear that it's a RF neurotomy reference, and it says
12 various sized electrodes can be made from 10 to 30 gauge, and it's referring
13 to figures one through three, embodiments without departing from the
14 invention.
15 Stratus's only evidence that after RF neurotomy needles are 16 gauge
16 or smaller is unsupported testimony from their expert. There is no evidence
17 anywhere in this case other than unsupported expert testimony, that the
18 needles have to be 16 gauge or smaller, and their experts simply aren't
19 credible. We'd like to reserve the rest of our time for rebuttal, unless the
20 panel has any further questions at this time.
21 JUDGE MITCHELL: I think we're good. Thank you.
22 MR. KELLY: Thank you, Your Honor.
23 JUDGE PESLAK: Thank you.
24 MR. PHILLIPS: Good afternoon, Your Honors. If you're ready, I will
25 proceed.

1 JUDGE MITCHELL: Go ahead. Thank you, Mr. Phillips.
2 MR. PHILLIPS: Thank you. I'm going to turn to slides two and three
3 of our agenda. We have this is color coded. I will address the issues in red,
4 and my colleague Dan Higgs will address the issues in blue. And thank you,
5 again, for the opportunity for him to do that in the LEAP program. And I'm
6 actually not going to address all of these issues. I want to focus on what I
7 think are key dispositive issues, which is the reasonable likelihood -- I'm
8 sorry, the reasonable expectation of success and the related enablement
9 issue.
10 It is the Petitioner's burden to show a reasonable expectation of
11 success for its proposed combination, Racz's modified device. They have
12 not met that burden. The filaments in Racz's modified device would be
13 about the thickness of two or three human hairs, far too thin and weak to
14 reasonably be expected to work or to even be safe. The channels for those
15 filaments, which must be in the sidewall of the needle, could not have been
16 formed with any reasonable expectation of success. That sidewall would be
17 about half the thickness of a fingernail, and the needle -- and those channels
18 must have some length, whether we're talking about just a portion near the
19 distal end or the whole length of the needle, and that's absurd, and I'll show
20 you that.
21 And the sidewall with those channels would be too weak structurally
22 to have a reasonable expectation of success to function as a neurotomy
23 needle. And these are issues that the petition and Dr. Tucker simply did not
24 address. After we pointed out these flaws and presented affirmative
25 evidence on these issues, we never heard again from Dr. Tucker on these

1 points, he ran away. And no other expert for the Petitioner testified on these
2 issues. This is a dispositive issue. It moots out every other issue in the case.
3 If Your Honor's write a decision on this issue, which is the -- is common to
4 all four cases, that's all you need to do.
5 JUDGE PESLAK: Counsel?
6 MR. PHILLIPS: Yes.
7 JUDGE PESLAK: As I understand your reasonable expectation of
8 success or argument, it's based on an RF neurotomy needle, correct?
9 MR. PHILLIPS: Correct.
10 JUDGE PESLAK: Being no more -- no larger than 16 gauge, correct?
11 MR. PHILLIPS: Correct.
12 JUDGE PESLAK: So
13 MR. PHILLIPS: I think Judge Peslak has is frozen.
14 JUDGE MITCHELL: Yes. Did we lose Judge Peskak? Sorry. I
15 apologize for our technical difficulties.
16 JUDGE FITZPATRICK: I apologize, as well. And to let you know
17 that I'm still here. I'm still on.
18 JUDGE MITCHELL: Are they able to get him back?
19 (Pause)
20 JUDGE PESLAK: Okay. Can you hear me now?
21 JUDGE MITCHELL: We can.
22 MR. PHILLIPS: Yes.
23 JUDGE PESLAK: Sorry. Sorry about that. So
24 MR. PHILLIPS: You were asking about needle size when you froze,
25 Your Honor.

1 JUDGE PESLAK: Right. And as I read the independent claims here,
2 I don't see how they're limited to RF neurotomy or any particular needle
3 size. So it seems to me that, at best, your reasonable success -- reasonable
4 expectation of success argument only applies to the dependent claims. Can
5 you address that?
6 MR. PHILLIPS: Not exactly, Your Honor. In the 782 Patent, all of
7 the claims -- every independent claim recites a neurotomy needle.
8 JUDGE PESLAK: Okay. So in the other claims, that's not -- in the
9 other cases that -- other I'm sorry about, but any other -- other patents,
10 that's not true, correct?
11 MR. PHILLIPS: In the 664 Patent, Your Honor, a dependent claims
12 10 through 19 and 26 through 29 also referred to ablating a nerve to relief --
13 relieve pain. So that's --
14 JUDGE PESLAK: Right, but the independent claims do not, correct?
15 MR. PHILLIPS: Correct. But, I think the key point, Your Honor, is
16 that that's not the relevant issue. What matters here is that the proposed
17 combination of prior art that is Racz's modified device, according to the
18 petition, must be a neurotomy needle. They've come up with one
19 combination universally applied to all claims, whether the claims are limited
20 to neurotomy or not. Maybe they were lazy. For whatever reason, they
21 chose one combination of prior art to -- as a one size fits all approach to
22 attack all claims. So Racz teaches the neurotomy needle. There's no
23 suggestion or argument to modify it to be bigger than a neurotomy needle. It
24 must be a neurotomy needle. As a result, it must be 16 gauge or smaller.
25 That is the issue.

1 JUDGE PESLAK: But still a reasonable expectation of success have
2 to apply to the claimed invention, Counsel.
3 MR. PHILLIPS: No. The reasonable expectation of success is that
4 the Petitioner has a burden to show that the -- their proposed combination of
5 prior art has a reasonable expectation of success. That's the legal
6 requirement.
7 JUDGE PESLAK: Okay. Let's just continue with your argument.
8 MR. PHILLIPS: I'm sorry. I didn't hear you.
9 JUDGE PESLAK: Continue with your argument.
10 MR. PHILLIPS: Okay. All right. Thank you. I can continue on
11 needle size and explain why Racz's modified device must be 16 gauge or
12 smaller, if you would like, or I can come back to that later.
13 JUDGE PESLAK: I don't want to disturb your arguing.
14 MR. PHILLIPS: Okay.
15 JUDGE PESLAK: Proceed the way you want.
16 MR. PHILLIPS: Okay. Well, I would like to -- before I jump into the
17 reasonable expectation of success issue, I'd like to lay a little groundwork by
18 going through what the proposed combination is according to the petition.
19 Every challenge is based upon a base combination of Racz, Fitz, and Lee.
20 I'm on slide nine, Your Honors.
21 Let's skip ahead to slide 13. This -- these are illustrations of Racz's
22 modified device in the petition. According to the petition, you start with
23 Racz's tip, it's shown in red, and you retain Racz's probe shown in green, and
24 you add Lee's filaments shown in blue. How do you do that? How do you

1 add Lee's filaments to Racz's needle? That's what the Petitioner and Dr.
2 Tucker had to figure out, and it's a really challenging problem.
3 You cannot put the filaments within the lumen of Racz's needle, as
4 done in Lee's figures one and 49. That wouldn't work if you retain Racz's
5 probe, which fits snugly within the lumen. And in fact, they emphasize that
6 there is physical contact at the end of the -- of the needle between the probe
7 and the cannula. So the filaments have to go outside the lumen. Now they
8 can't go completely outside the needle. That means they have to be within
9 the sidewall. And that was undoubtedly inspired by Lee's figure 23.
10 If I could back up to slide 12, these are figures from Lee quoted in the
11 -- cited in the petition, and you have figure one on the left, figure 49 on the
12 right. Those teach one embodiment, which is not applicable to Lee's -- I'm
13 sorry to Racz's modified device because of both of those figures, the
14 filaments are within the central lumen. That doesn't work if you retain
15 Racz's removable probe.
16 Instead, what you do is -- what is left is Lee's teaching in figure 23
17 where he has a central lumen, 909, a sidewall, 916, and then a number of
18 channels within the side wall, 922. That's the inspiration for Racz's modified
19 device. Turning to slide 14, here's a close up view of Racz's modified device
20 with a cutaway view.
21 So skipping ahead to slide 16, let's look at how the petition came up
22 with Racz's modified device. Here on pages 27 to -- 25 through 27 of the
23 petition, they tell us the development of Racz's modified device, what the
24 basic requirements of that combination must be. Not just an example, the
25 basic requirements.

First, I'm on slide 17, they tell us that they want to add Lee's filaments to Racz. Next, I'm on slide 18, they recognize that they must preserve Racz's probe. So they say, quote, filaments can be arranged around the inner perimeter of a cannula, and they cite to Lee in figure 23. Next, on slide 19, they realized that they need some deflection surfaces so that when the filaments slide down those channels, they're urged to outward radially -- radially. And then, whoops. I'm so sorry.

Okay. Slide -- I'm on slide 20. They tell us again that they're preserving the functionality of Racz's probe. They're maintaining those deflection surfaces, and then while you get Racz's modified device. And if -- and this is before they illustrate it, before they give any examples of what it looks like, they told us, in words, what it must have.

And they told us the same thing on pages 39 through 41 of the petition when they go through and they match up Lee's filaments with claim one, claim limitations 1F through 1I. And if I can go to slide 26, they say again that a POSA would have arranged the parameter -- perimeter filaments, the channels and the ramps around the internal perimeter of Racz cannula, and that's highlighted here in yellow on slide 26. These are the fundamental features that Racz's modified device must have.

Now, whether these channels in the sidewall are just in a portion of the needle or the whole length of the needle, it's unclear in the petition. But regardless, even if it's in a just a portion of the needle, they would be impossible to make. And the filaments that would fit in that sidewall, which is narrower than half a fingernail, would be so weak that they would not function. So there's not a reasonable --

1 JUDGE PESLAK: Counsel, on one of the earlier slides, I don't know
2 if it's your slide or Petitioner's slide, but it showed a figure -- showed a
3 figure 3D with -- you know, the claim device, and it has a filament coming
4 out of the side, and it looks like it's in a channel. So what -- why -- why --
5 why is it impossible to manufacture and sort of show something very similar
6 to that shape in your patent?
7 MR. PHILLIPS: Your Honor, I'm not sure which figure you're
8 referring to. I'm guessing you're referring to a figure in Lee that -- that has --
9 JUDGE PESLAK: I'm looking at your slide five.
10 MR. PHILLIPS: Okay. Okay. Slide five, Your Honor, illustrates, the
11 claimed invention -- the invention. This is a drawing from the patent under
12 review. This, all of the patents, at least the 782 patent.
13 JUDGE PESLAK: I'm asking why these channels in Petitioner's
14 proposed combination can't be manufactured, but it looks like there's
15 something pretty similar here in this figure in the claimed invention.
16 MR. PHILLIPS: Yeah. Okay, I understand. This is very, very
17 different from Racz's modified device. This is Stratus's invention. There are
18 two filaments. They go down the central lumen of the needle and then they
19 come out at the tip as shown on the left, the cutaway cross sectional view
20 that you see on the right is taken right around where this line from 304b
21 would be. If you can see my cursor, that's where that cross section is taken.
22 At that point, these filaments have come from the central lumen and gone
23 into grooves that are in this red tip piece. Okay.
24 So there's nothing like that in Racz's modified device. In Racz's
25 modified device, for at least some length of the needle, the filaments are

1 within the sidewall. What is shown here, and this is kind of to scale, but
2 what is shown here, the outer perimeter of the wall is 303. And then you can
3 see that the circle inside of that is the inner diameter of the wall. Nothing
4 comparable like that is in the invention. That's a unique feature, an
5 impossible to make feature in Racz's modified device.
6 And I would further add that in the commercial embodiment of the
7 Stratus invention, the NIMBUS device, these filaments are .356 millimeter
8 in diameter. That's about four times the size of the biggest possible
9 filaments that you would have in Racz's modified device, even assuming you
10 use a maximum sized needle, 16 gauge, and -- in which case the needle
11 sidewalls would be .229 millimeters thick. Maybe you could fit a .2
12 millimeter filament in a channel in such a sidewall.
13 JUDGE PESLAK: We're never going to --
14 JUDGE FITZPATRICK: Oh, sorry judge.
15 JUDGE PESLAK: I just want --
16 JUDGE FITZPATRICK: You go ahead, Judge Peslak.
17 JUDGE PESLAK: The -- that cross sectional drawing that you put in
18 your slide, and it's in your surreply of the modified Racz device, yeah, this
19 one. Where did all those numbers come from? Because I don't see that
20 that's in your expert's declaration.
21 MR. PHILLIPS: Yeah.
22 JUDGE PESLAK: So I was a little puzzled as to where all those
23 numbers came from that are in that -- that are on this figure.
24 MR. PHILLIPS: Yeah. Understandable, Your Honor. First of all, this
25 isn't drawn to scale. It's not drawn to scale. Secondly, I -- I made a

1 typographical error in this slide. What is labeled here is 220 microns is
2 actually 229 microns. There is support for that in Dr. Peter Crosby's
3 declaration. That's what he said -- that is the -- the thickness of a standard
4 16 gauge needle wall. Okay.
5 JUDGE FITZPATRICK: And just so we're -- the record's clear, that --
6 that term appears twice in this figure, and you're talking about the red, the
7 sidewall, that should be 229. The blue is correct. It should be 220.
8 MR. PHILLIPS: Correct, Your Honor. And --
9 JUDGE FITZPATRICK: Thank you.
10 MR. PHILLIPS: And so you subtract a little bit, two times X. X is
11 the margin because the channel here cannot be as wide as the sidewall,
12 obviously, and then the filaments themselves cannot fit so tightly within the
13 channels that they don't move. You need a little margin. So Z, the diameter
14 of the filament, is .22 millimeters minus 2X minus 2Y. That's where the
15 scale comes from. I'm sorry .229 millimeters minus 2X minus 2Y. Okay.
16 And I would like to explain that this is fantasy. This is science fiction.
17 This cannot be made. Whether you're talking about a small length of the
18 needle, near the distal end, or the entire length of the needle, whether you're
19 talking about a straight needle or certainly a bent needle, this cannot be
20 made. And let me explain why. So I'm on slide 47. First in the petition, this
21 is everything the petition says about a reasonable expectation of success.
22 The petition says see Dr. Tucker's declaration. Dr. Tucker says without any
23 explanation, any support, there would have been a reasonable expectation of
24 success, and he relies very heavily on this notion of routine engineering. He
25 says it over and over again.

1 On slide 48, here some examples of where he recites routine
2 engineering. He also likes to say that it would be easily implemented, easily
3 formed, easily accommodated. But Peter Crosby, our engineering expert,
4 explained how that is not true. And once we filed that evidence, we never
5 heard from Dr. Tucker again or any other expert for the Petitioner.
6 In fact, Dr. Tucker, during his deposition, when asked how to make
7 Racz's modified device, in particular those channels for the filaments, he
8 disavowed all responsibility for having to know that. He said I'm not that
9 type of engineer. I don't know. I'm not a manufacturing engineer. I'm not
10 an industrial engineer. He didn't consult an engineer that would know.
11 And he did say, oh, I think a person of ordinary skill in the art that's a
12 manufacturing guy would know how to do that, but his own definition of a
13 person of ordinary skill in the art does not include a manufacturing guy. He
14 obviously did not attempt to build this. And according to him, he didn't have
15 to. Because according to him, this is not a manufacturing patent. That's a
16 phrase he used over and over. I don't know what that means, but that's I
17 don't know what a manufacturing patent is, but that's what he said. And --
18 but yet he admitted that it is not always possible to take a paper design and --
19 and make it. It's not always physically realizable.
20 Now, Peter Crosby explained that one of ordinary skill in the art at the
21 time of the invention would have considered a number of ways to possibly
22 make Racz's modified device, all of the -- all of the possible techniques he
23 could imagine, he explained, can -- would not work. Not possible at the
24 length of a neurotomy needle, even a portion of it, certainly not possible in a
25 needle with a bent tip. And he said that the needles would be too weak.

1 Structurally it wouldn't work. And there's crickets on the other side after this
2 evidence was put in. Nothing to refute it with it contrary expert testimony.
3 Instead --
4 JUDGE FITZPATRICK: Hey, can I interrupt you there and just ask
5 about Lee and Fitz.
6 MR. PHILLIPS: Yeah.
7 JUDGE FITZPATRICK: They obviously have filaments. And is it
8 Fitz? And Fitz is a -- is a neurotomy. Is it your position that -- that whatever
9 is used to make those filaments work in Lee and Fitz, that -- that it's fantasy
10 there too? That those patents don't enable their own descriptions? They're
11 all in presumably the wrong claims dimensions. Or are you saying that in
12 Lee and Fitz, the filaments are much bigger, and so the math is different?
13 MR. PHILLIPS: It's hard to say about Fitz. Fitz is a very, very thin
14 patent. It has about one page, of specification, one page of drawings.
15 There's very little description. I don't know that it is enabled at all. And at
16 what scale is completely unclear based on Fitz. With Lee, Lee is a very
17 different device. Lee is a needle for ablating uterine fibroids, which range in
18 size from about -- at the smallest when they're treated about the size of a
19 blueberry to -- they can be as large as a grapefruit. There are documented
20 cases of uterine fibroids that weigh more than I do. They can be huge. So
21 it's a very, very different scale.
22 And I do want to clarify one thing. Acessa, the commercial
23 embodiment of Lee, does generate an ablation volume at least an order of
24 magnitude greater than the Stratus invention. In fact, if we could take a look
25 at the Petitioner's slide 40, I want to point out three mistakes that the

1 Petitioner has made assessing the ablation volume of the Acessa device
2 compared to that of Stratus.
3 Now, on Page 40 on the left, you have, different ablation volumes for
4 Acessa based upon how far the filaments are deployed from zero to 5
5 centimeters. Okay. And then on slide 42, this is where they compare Lee's
6 ablation shape to the Stratus ablation shape, and they make three mistakes.
7 Number one, the picture here for Lee's ablation shape is the picture that
8 corresponds to 1.5 centimeter deployed filaments even though they -- what
9 they mean and what they say is that it's for .5 centimeters. So they're using
10 the wrong illustration. Number one.
11 Number two, the -- the only way you get a comparable ablation
12 volume with Acessa is if the filaments are not deployed at all. And let me
13 explain that by going to Exhibit 2010, which is the Acessa User Guide, and
14 I'm looking at Page 22. Okay? And then --
15 JUDGE FITZPATRICK: I'm going to pull that up.
16 MR. PHILLIPS: Yeah.
17 JUDGE FITZPATRICK: I'm going to pull that up because it's not in
18 the slides. Just give me one second. In Exhibit 2010?
19 MR. PHILLIPS: 2010, Page 22.
20 MR. KELLY: And, Your Honor, we just -- we just -- for the record,
21 we'd like to object to this as a new argument. It wasn't presented in the
22 surreply, and just for the record. Thank you.
23 MR. PHILLIPS: Okay. Let me know when you're ready, Judge
24 Fitzpatrick.

1 JUDGE FITZPATRICK: You know what, I I'm ready, but I want to
2 say something. I just want to -- when you come back up, why don't you
3 make that objection so it's clear because the microphone didn't really work
4 that well.
5 MR. KELLY: Thank you.
6 JUDGE FITZPATRICK: Okay. Yep.
7 MR. PHILLIPS: Did you want to do that now?
8 MR. KELLY: No.
9 MR. PHILLIPS: No? Okay. Okay. So the Stratus ablation volume is
10 11 millimeters downward and 10 millimeters across. That shown on Slide
11 42. The only thing that is comparable in size is shown in the first line of the
12 first table on page -- I believe this is Page 22 of Exhibit 10 -- 2010, where
13 the -- it's 10 millimeters by 8 millimeters. That's close. The next one is
14 bigger, but this is with 0 centimeters deployment. If you have 0 centimeter
15 deployment, you have a spherical or prolate spherical ablation volume. It
16 doesn't have that teardrop shaped shape. Okay. So -- so that is another
17 mistake that Petitioner has made here.
18 When you instead have deployment of 0.5 centimeters, this is the first
19 row of the next table, the downward dimension is 1.9 millimeters -- or I'm
20 sorry, 19 millimeters, 1.9 centimeters, and across its 17 millimeters. And
21 that's in both directions because this is cylindrical symmetrical. So that's
22 approximately twice as big in the downward direction, twice as big in both
23 lateral directions. That's two times two times two. That's a factor of eight
24 bigger. And that does not even account for the fact that with the Stratus,

1 with only two filaments, is not a symmetrical ablation volume. It expands
2 laterally in one direction, but not in the other.
3 And by the time you have full deployment of this -- the filaments in
4 the Acessa device, that ablation volume is 150 times bigger than that of the
5 Stratus NIMBUS device. So we're really talking about devices that are on a
6 much different scale. And so, no, we're not saying that Lee's device would
7 be impossible to make. What would be impossible to make is if you try to
8 incorporate the idea of putting Lee's filaments in the sidewall of a 16 gauge
9 needle, that's Racz's modified device as big as it could possibly be, that is
10 impossible to make.
11 JUDGE MITCHELL: And your --
12 JUDGE FITZPATRICK: What if
13 JUDGE MITCHELL: Oh.
14 JUDGE FITZPATRICK: And what if each --
15 I'm sorry, Judge.
16 What if the -- the person of ordinary skill in the art just puts the
17 filaments in Racz in the exact same manner that they are in Lee?
18 MR. PHILLIPS: That's not what the petition is proposing, Your
19 Honor.
20 JUDGE FITZPATRICK: Okay.
21 MR. PHILLIPS: Let's take a look.
22 JUDGE FITZPATRICK: Let me ask -- let me ask you another
23 question and you can address both when you're -- this -- these are going to
24 be retractable, right? In the -- in the modified device, you agree that you
25 understand that they would be retractable.

1 MR. PHILLIPS: Yes.
2 JUDGE FITZPATRICK: I didn't understand that whole volume
3 argument. I understood what you meant by it, but I didn't understand why
4 that the premise that it would be controlling since the operator could extend
5 those filaments less or more as desired.
6 MR. PHILLIPS: The problem with reasonable expectations of
7 success does not depend on upon how far the filaments are deployed. The
8 fact that you have filaments at all that must fit inside channels that are
9 formed entirely within the sidewall of a needle makes it impossible to make,
10 no reasonable expectation of success. And such filaments would be so thin
11 that there would be -- even if you could make the channels for those
12 filaments, the filaments would not have a reasonable expectation of success
13 in use. They would deflect. They would break. I'll get to that.
14 JUDGE FITZPATRICK: Could I just ask you to go to the slide, let's
15 see, 35? This figure is in a lot of stuff, but it's the one that I have handy. It's
16 Petitioner's slide 35 because it reproduces --
17 MR. PHILLIPS: Sure.
18 JUDGE FITZPATRICK: -- Lee figure 48.
19 MR. PHILLIPS: Sure.
20 JUDGE FITZPATRICK: And what they have labeled the tip. Let me
21 -- I'll wait. Let me know when you're there.
22 MR. PHILLIPS: Is this the one, Your Honor?
23 JUDGE FITZPATRICK: It's slide 35. Oh you had -- you're showing
24 me too. Gotcha. I was looking at my own version. Yes. So. Their
25 filaments -- Lee -- Lee's filaments are extending through red structure, which

1 is labeled 1614 by the Patent and labeled tip by an annotation. I can read
2 that's obviously the tip, but is that a portion of the needle, which I mean, is
3 that -- would you agree that that's a portion of the needle or no? Because it -
4 - then my next question is, well, how does Lee do it? How does Lee have
5 these filaments going through there -- there through?
6 MR. PHILLIPS: Yeah. I don't know if it's a portion of the needle or
7 not. It's obviously not the cannula, but it is part of the overall device. What
8 I do know is that the way Lee does it here is, first of all, not the way it's done
9 in Racz's modified device. The way it is done here, it's hard to see because
10 this is a poor quality image, but the filaments to the left of the red tip are
11 within the central lumen of the cannula, which cannot happen in Racz's
12 modified device because that is where the RF probe goes.
13 And in fact, if we go to slide 27, they tell us, -- slide 28, sorry. They
14 tell us and they show us that it is important that there be physical contact
15 between Racz's probe and Racz's active tip. And they also tell us that this is
16 routine engineering, which, according to Dr. Tucker, is you just follow a
17 recipe, you take something from Racz, something from Lee. You don't
18 change them. You just mash them together. So they are not modifying the --
19 the probe of Racz, the needle of Racz, they're just adding filaments to Racz.
20 And they can't do it with a tip that's like the trocar .14 or 1614 in Lee. It has
21 to be as shown here in their drawings -- their illustrations of Racz's modified
22 device, like this on slide 33.
23 And that's the problem. Once you do it like this, you have to have
24 channels in the sidewall of the needle to accommodate these filaments. And
25 the evidence in this case shows that that could not have been done -- couldn't

1 have been done at all, but certainly not with a reasonable expectation of
2 success. And that is dispositive.
3 JUDGE MITCHELL: So is your argument that if I take these
4 filaments and I put them in the sidewall, I can't they're not -- they're too
5 big to go in the sidewall. And if I make the filaments small enough to be in
6 the sidewall of Racz, the sidewalls are going to collapse. Like you're just --
7 it's not going to physically work to use the device for what it's intended to do
8 with ablation. Is that the argument?
9 MR. PHILLIPS: Correct. And it's not only that, Your Honor, but
10 everything you said is correct, but it's also that you couldn't there's no
11 reasonable expectation of success to make the channels in the sidewall to
12 accommodate these filaments, and the filaments themselves would be so
13 weak that they would not protrude straight out, as shown here. They would
14 be about the thickness of two or three human hairs. And even if they're
15 nitinol or some other biocompatible metal, that would be too thin to reliably
16 go where they're supposed to go to enlarge the ablation volume and they
17 might get bent, deformed permanently, and not be able to be retracted out, or
18 they might break off. And so Dr. Russo testified that there's no way he
19 would ever use a device like Racz's modified device. It would be
20 irresponsible and unsafe.
21 JUDGE MITCHELL: So is your -- is your argument depended on the
22 fact that it's a 16 gauge needle that we're starting with?
23 MR. PHILLIPS: Our argument is at its most persuasive if you start
24 with a 16 gauge needle, and that is the largest neurotomy needle possible.
25 But even starting from the starting point that the Petitioner proposes, which

1 is a 10 gauge needle, it still wouldn't work. It's their burden, and they have
2 not put in evidence that a -- that you could make channels like this in the
3 sidewall of a 10 gauge needle. They could have. In their reply, they could
4 have come back with that evidence. They didn't, and that speaks volumes.
5 A 10 gauge needle has a sidewall which is about twice as thick as that
6 of a 16 gauge needle sidewall. So we're talking about the full thickness of a
7 fingernail rather than half a fingernail. So imagine the challenge of
8 somehow manufacturing channels that go down something that thin for
9 some appreciable distance, maybe not the whole length of the needle, but
10 some appreciable distance, having them lined up and smooth enough that
11 you can send a filament down there. It's -- it's just pure fantasy, Your Honor.
12 This is a paper design that cannot be made. And that's not even the standard.
13 Of course, the standard is could one of ordinary skill in the art at the time of
14 invention have had a reasonable expectation of success in making it? And
15 the answer is no.
16 There are three counterarguments that the Petitioner makes in regards
17 to this. One is they challenge the premise about the needle size. Second,
18 they rely on the Kalpakjian reference as allegedly teaching techniques to
19 make such small diameter holes. And third, they talk about how Lee
20 allegedly teaches a way to make similarly sized ablation volumes, which I've
21 addressed. That's -- that's the Acessa document that we've talked about.
22 So let me address the needle size issue and Kalpakjian and then, I'll
23 probably yield my time to Mr. Higgs. Okay. On needle size, the only
24 support for the Petitioner's position that the needle could be larger than 16
25 gauge is one passage of Racz. It is replicated here on the left side of slide

1 51, and it does say 10 to 30 gauge, okay, but it's talking about variations of
2 Racz's needle. And on the very next column, as quoted on the right side,
3 Racz explains that there are other clinical applications for his invention other
4 than neurotomy.
5 So how would one of ordinary skill in the art read this reference of 10
6 to 30 gauge? Well, they have to wonder is that really talking about
7 neurotomy or something more? What did Dr. Tucker say about this, their
8 expert? He said, oh, that's a starting point. But first of all, Dr. Tucker had
9 no idea what the size of a neurotomy needle is. He said I'm not that type of
10 doctor. He's a pathologist, a non practicing pathologist. So he said I would
11 ask the doctors who actually use these devices and see what they say, and
12 that is on Page 142 of his deposition transcript, Line 17 through 21.
13 So let's see what the doctors who actually do this say. Turning to slide
14 52, here's testimony from Dr. Russo. He's a world renowned pain specialist
15 physician. He does RF neurotomies a dozen times a day, every day. He's
16 the only witness in this case who has held a neurotomy needle in his hands,
17 who has inserted it into a live patient, who has energized it, looked at it
18 under an X ray to make sure it's in the right position, energized it, and then
19 have follow up consultations with the patient. He knows from experience
20 what size needles are used and commercially available, and he said that
21 anything bigger than 16 gauge is too stiff and would cause too much tissue
22 damage. And so you don't see neurotomy needles bigger than 16 gauge.
23 And he also said if it's smaller than 22 gauge, it's not stiff enough to get to
24 the right place.

1 When he says this, he knows what he's talking about based upon
2 experience, and there's no contrary expert testimony in this case. And he
3 cites documents. He cites Tullis and Cosman for support. If I turn to slide
4 53, Tullis teaches that a neurotomy needle is 16 gauge or more, that means
5 or smaller. The bigger the gauge number, the smaller the needle. More
6 preferably 18 gauge or more. Cosman says 16 to -- to 23 gauge. So very
7 nearly exactly the same thing as Dr. Russo said.
8 Now, the Petitioner cites a couple documents to try to dispute this.
9 One is Godara. Let's look at Godara on slide 54. Godara mentions 12
10 gauge. He does, but he's talking about a number of different applications.
11 Not just neurotomy. And he says that that very needle could be up to 40
12 centimeters long. This is an RF neurotomy needle, Your Honors. This is the
13 NIMBUS device. This needle is 15 centimeters long. I double that to 30,
14 add 10 more, 40. That's not a neurotomy needle.
15 Slide 55, Shealy. Shealy refers to a 12 gauge needle, but it's an
16 introducer. The way an introducer works is just as described in this passage.
17 First of all, a stylet is put down the lumen. It is put roughly into position in
18 the patient's body. The stylet is removed, an electrode is put down the
19 lumen, and then the needle is retracted all the way. It is out of the body, out
20 of the picture, and then the electrode is put into its final position. So
21 introducer needle is not an neurotomy needle. It is not involved in the
22 delivery of RF energy to the tissue. And finally, the 782 Patent, Stratus's
23 Patent, corroborates what Dr. Russo said. He says 16 gauge to 20 gauge.
24 Okay.

1 Let me address Kalpakjian in the reply the Petitioners cite to the
2 Kalpakjian textbook as Exhibit 1063 to say it discloses two techniques that
3 could have been used to make very narrow holes. Let's look at what
4 Kalpakjian says. I'm on slide 58. EDM, electrical-discharge machining.
5 Sure enough, it says you can make holes as small as .005 inches or .1
6 millimeters. And then laser beam machining, LBM, says .005 millimeters,
7 but only to a -- with a depth to diameter ratio of 50 to one. At the diameter
8 of the channels we're talking about, that depth would be less than .4 inches.
9 So not long enough.
10 But this is only part of what Kalpakjian says. They did not include in
11 Exhibit 1063 material from a couple pages later in the same book, in the
12 same chapter. That's reproduced on slide 59, where Kalpakjian gives
13 important design considerations and basically says with EBM and LBM,
14 deep slots and narrow openings should be avoided. That's exactly what
15 these channels in Racz's modified device would be.
16 And in the next edition of Kalpakjian, shown in the lower right, it
17 elaborates even more and says, you shouldn't use this with a reflective
18 workpiece, which would be a metal needle. So the fact is, maybe these two
19 techniques are useful if you've got a flat, thin material, and you want to
20 make a little teeny hole, but they don't make -- they cannot reasonably
21 expect it to make a deep hole in a very narrow, thick wall, as would be
22 necessary in Racz's modified device. So Kalpakjian does not support the
23 Petitioner's position on needle size.
24 JUDGE PESLAK: And Counsel?
25 MR. PHILLIPS: Yes.

1 JUDGE PESLAK: I want to make sure the record's cleaner. So
2 what's shown on 59 -- on slide 59 is what you submitted with your surreply,
3 correct?
4 MR. PHILLIPS: Yes. Exhibits 2044 and 045, Your Honor.
5 JUDGE PESLAK: Okay. And whether it's this material or the earlier
6 material from this reference that Petitioner submitted, there's no expert
7 testimony on either side addressing any of this. Everybody's just asking us
8 to -- and both sides are making attorney arguments about this, correct? Is
9 that really what's going on here?
10 MR. PHILLIPS: I would say you're 90 percent correct, Your Honor.
11 Doc -- I'm sorry, Peter Crosby did testify about laser drilling, which is laser
12 beam machining, and he said it would not work. You couldn't make deep
13 cuts. So Kalpakjian corroborates what Peter Crosby says about laser beam
14 machining. But when it comes to EDM, electric discharge machining,
15 you're correct. No expert on either side has testified about this.
16 And I do want to emphasize that the Petitioners put in this partial copy
17 of Kalpakjian without any expert testimony to explain it whatsoever. Had
18 they done so, we could have cross examined that expert, pointed out these
19 inconsistent passages, and we wouldn't have a dispute about whether we
20 could supplement the record with the -- these additional pages. But they
21 didn't do that. I don't know why, but they didn't do that.
22 JUDGE PESLAK: Okay. Thank you.
23 MR. PHILLIPS: The last point I'd make before I yield a rest of our
24 time to Mr. Higgs is that there's also an enablement issue here. And -- and
25 for the same reasons, based upon the same evidence, it would have taken

1 undue experimentation to make or use Racz's modified device. So the prior
2 art is not enabling.
3 You know, when I taught a law school class -- taught patent law, the
4 way I would describe the enablement requirement for the prior art to my
5 students is that if you one day have a client who has invented a lightsaber,
6 Star Wars is not prior art. It's science fiction. The Star Wars movie does not
7 teach one of skill in the art how to actually make a lightsaber. That's what
8 we have here. Racz's modified device is science fiction. It's a fantasy. It's a
9 paper design that cannot be realized.
10 JUDGE FITZPATRICK: And I wanted to say -- let you know my
11 opinion legally on this issue, if you can change it, and that is that this is an
12 erroneous position. There is no such requirement as enablement of a
13 modified device. It's a reasonable expectation of success. And the cases that
14 you cite talk about prior art references enabling the disclosures that are
15 relied upon to build the obviousness in this case.
16 So to me, the enablement issue is that there are -- the issues here are:
17 does Lee enable what the Petitioner is relying on it for? And I think there's
18 some case law that says it also has to enable a claim, whether or not they're
19 relying on it. But the issue is whether the individual references enable their
20 own disclosures. And then when it comes to the combination, the issue is
21 whether a person of ordinary skill in the art would have had a reasonable
22 expectation of success. So if -- and you can respond to that, let me know
23 what you think, and maybe the only way to deal with this will have to be
24 have you submit like your best case on this afterwards.

1 MR. PHILLIPS: Well, I don't think we need to resolve the -- that
2 possible disagreement of regarding enablement. I think you're absolutely
3 right, Your Honor, about reasonable expectation of success. And it's actually
4 a better issue to resolve the issue the -- this case because with reasonable
5 expectation of success, there's no question the burden is on the Petitioner,
6 and they have not met it. With enablement, whether you're right or I'm right,
7 there's like a shifting burden of at least production, which makes it messy.
8 But this is a very simple case under reasonable expectation of success.
9 JUDGE FITZPATRICK: Gotcha. And I just -- that I want to go back
10 to something that is figure, sorry -- your slide five.
11 MR. PHILLIPS: Sure.
12 JUDGE FITZPATRICK: Which goes, you know, the Stratus, it's an
13 embodiment of the patent, and it's figure 3D and then an unlabeled figure
14 next to it, which is a cross section of it. In -- on figure 3D on the left, 210 is
15 showing a lumen, right? An opening to a lumen. It -- that's a void, correct,
16 where it's pointing?
17 MR. PHILLIPS: Yes.
18 JUDGE FITZPATRICK: Okay. Where is -- and then when the cross
19 section, you said it's taken somewhere in the vicinity of where line 304b is.
20 MR. PHILLIPS: Correct.
21 JUDGE FITZPATRICK: And -- and in that cross section, it looks like
22 the central area is physically blocked. And so --
23 MR. PHILLIPS: Yeah, this central area, which --
24 JUDGE FITZPATRICK: -- am I interpreting this correctly?

MR. PHILLIPS: Yeah, I think so. This central area where I'm moving my cursor, which has kind of three wings that come out, one on the top, one a little down to the left, one a little down to the right.

JUDGE FITZPATRICK: Oh you have to give me one second. I was looking at my own view.

MR. PHILLIPS: Sure.

JUDGE FITZPATRICK: I think I'm looking at what you are displaying now. Can you do that again with the mouse?

MR. PHILLIPS: Yeah, yeah.

JUDGE FITZPATRICK: What you were doing.

MR. PHILLIPS: This central area.

JUDGE FITZPATRICK: Ah, it doesn't show up.

MR. PHILLIPS: Oh, I'm sorry.

JUDGE FITZPATRICK: That’s okay.

MR. PHILLIPS: The central area is -- it has a funny shape, but there's, like, a wing going up to the top and then a wing going down to the right and down to the left. That would be colored red. That's part of this conductive tip to 11. Before the tip, so if you go further proximally down the lumen --

JUDGE FITZPATRICK: Yeah, yeah.

MR. PHILLIPS: At some point there is no tip. And at that point the filaments shown in blue are just in the central lumen.

JUDGE FITZPATRICK: Okay.

MR. PHILLIPS: That's how they get down to the distal end of the needle. And then it's only the tip at the very end that has grooves, kind of

1 like Lee, to push them out. And I just want to reiterate that this is very, very
2 different from the way Racz's modified device must work. They told us over
3 and over again that at the distal end, the filaments are outside the inner
4 perimeter of the cannula, and they are within and fully enclosed within the
5 sidewall of the needle. And that's what's problematic in terms of a
6 reasonable expectation of success to make those channels.
7 JUDGE FITZPATRICK: Okay. Does anything come out of 210 when
8 a doctor uses this? Is this like liquid anesthetic come out of there?
9 MR. PHILLIPS: It could be. Yes.
10 JUDGE FITZPATRICK: Okay. And then does anything like that's
11 solid come out like -- like --like an RF probe. Does it ever get that far
12 distally, or does it get blocked before it gets to that point?
13 UNIDENTIFIED MALE SPEAKER: No, it doesn't get do those
14 things.
15 MR. PHILLIPS: I'm not sure, and you can't tell from these drawings.
16 JUDGE FITZPATRICK: Okay. I just didn't understand the
17 relationship of that central -- and also is like a dam, right, blocking the
18 central lumen. And so how does -- how does anything get down the middle?
19 It seems like an obstacle to me. And it might not be ultimately relevant to
20 this case, but it helps me understand the arguments better, I think.
21 MR. PHILLIPS: Sure.
22 JUDGE FITZPATRICK: About what was going on here.
23 MR. PHILLIPS: Okay if there are no other questions, I will yield the
24 rest of the time to Mr. Higgs.
25 JUDGE MITCHELL: Can I ask one quick question?

1 MR. PHILLIPS: Yes.
2 JUDGE MITCHELL: And this is probably self evident, but you're --
3 you're getting to the size of the needle in your claim language from the claim
4 requiring a neurotomy needle. Is that how you're -- you're --
5 MR. PHILLIPS: Those claims inherently have a size limitation, that
6 is correct, but even the claims that are not limited inherently to a neurotomy
7 needle, the same enablement argument applies to those claims because
8 Racz's modified device is a neurotomy needle. That's the way the petition
9 presented it. As such, it must have a reasonable expectation of success. As
10 such, it must be 16 gauge or smaller. As such, there's -- there's no way to
11 make those channels for the filaments in the sidewall.
12 JUDGE MITCHELL: Okay. And one last question. I believe the
13 Petitioner's Counsel said you're not disagreeing that all the limitations are
14 met somewhere in the different prior art references. It's just there wouldn't
15 be any reasonable expectation of success in bringing them together the way
16 the Petitioner is bringing them together to get to the claimed invention?
17 MR. PHILLIPS: That's right. We're not disputing the presence of any
18 particular claim limitation in the prior art collectively.
19 JUDGE MITCHELL: Okay.
20 MR. PHILLIPS: We are disputing reasonable expectation of success,
21 and, as Mr. Higgs will address, motivation to combine through teaching
22 away.
23 JUDGE MITCHELL: Okay, great. Thank you.
24 JUDGE FITZPATRICK: I'm sorry to make you stay. I just have one
25 more question.

1 MR. PHILLIPS: Of course.
2 JUDGE FITZPATRICK: It's column A, and it's just so then then we
3 can hear the rebuttal, you know, so I can ask, you know. The column A of
4 Lee has been referenced before, it's this is the 10 to 30 gauge disclosure.
5 MR. PHILLIPS: Yeah.
6 JUDGE FITZPATRICK: I think it's your -- you know, Petitioner has
7 said, hey, there is -- you know, that goes bigger than 16 because it goes
8 down to 10, right? So reverse. And your response to that, I believe, was,
9 yeah, that's talk that's not talking about our neurotomy needles, right?
10 MR. PHILLIPS: Correct.
11 JUDGE FITZPATRICK: Okay. But it is talking about whatever else
12 is talking about. So if it's not about, you know, neurotomy needles, it's
13 talking about something it's described --
14 MR. PHILLIPS: Yeah. I mean it's like most patents, it describes a
15 broad range for all of the possible applications of -- of what he disclosed.
16 And he explicitly says even though it's primarily about a neurotomy needle,
17 that there could be other clinical applications. That's why --
18 JUDGE FITZPATRICK: Got you.
19 MR. PHILLIPS: Dr. Tucker said that passage 10 to 30 gauge is just a
20 starting point for understanding the size of a neurotomy needle, and that he
21 would talk to doctors like Dr. Russo.
22 JUDGE FITZPATRICK: What's let me just propose something and
23 see what your response is. What if you take Racz -- the 10 gauge, and it
24 doesn't have to be -- and let's -- and let's -- and we'll credit your side and say
25 that cannot be an RF neurotomy needle, that application, because it wouldn't

1 work, right. It's too big. But we're going to take that 10 gauge because it
2 does teach it. And then we're going to modify it as proposed by Petitioner
3 and then we're going to map the claims to it. A lot of the claims aren't
4 limited to RF neurotomy ablation devices. And so what will be the response
5 to that -- to that to defend those claims?
6 MR. PHILLIPS: My response
7 JUDGE FITZPATRICK: I mean, I know a lot of arguments apply to
8 everything, right?
9 MR. PHILLIPS: Yeah.
10 JUDGE FITZPATRICK: But how do you deal with the size issue
11 with respect to those claims?
12 MR. PHILLIPS: My response is it is still the Petitioner's burden to
13 show a reasonable expectation of success. They have not done it for even a
14 10 gauge needle, right. You read the petition, it just baldly says, quoting Dr.
15 Tucker, reasonable expectation of success. We came back, and we said no.
16 Here are the reasons why. Here's eight techniques that one would consider.
17 None of them worked. They didn't come back with any evidence to say, oh
18 yes, it could work, at least even for 10 gauge. There's no evidence that it
19 could -- that those channels could be made. They haven't met their burden,
20 Your Honor.
21 JUDGE FITZPATRICK: Thank you. I'm sorry to keep your
22 colleague waiting.
23 MR. PHILLIPS: No need to apologize.
24 MR. HIGGS: Thank you, Your Honor. I appreciate the opportunity to
25 -- to be here under the LEAP program. So, yes. I will first -- first of all,

1 Judge Fitzpatrick. Is your question answered on -- on this slide that's up
2 presently? Okay. Okay. So I would -- I would like to address the teachings
3 --
4 JUDGE FITZPATRICK: Oh, excuse me, I was on mute. I was just
5 going to -- and that I -- you didn't hear me. I don't know that it is. So if
6 there's a -- like if you can explain to me how does something get down the
7 middle --
8 MR. HIGGS: Sure
9 JUDGE FITZPATRICK: -- through that cross section and then out the
10 hole.
11 MR. HIGGS: Sure.
12 JUDGE FITZPATRICK: You know, at the end.
13 MR. HIGGS: Sure.
14 JUDGE FITZPATRICK: Yeah.
15 MR. HIGGS: So -- so the way it is in in the commercial embodiment
16 at the proximal end of the inserted piece, which is the central sort of star
17 shaped thing in the middle, there is a ramp that when the probe is pushed
18 down through the tube, goes into the -- push -- directs that probe into the top
19 right channel.
20 (off mic comments)
21 MR. HIGGS: No, probe. The probe -- when the probe is inserted in,
22 it goes into the top right channel, 306C. So when fluid is being delivered,
23 the fluid isn't delivered at the same time as the probe is inserted.
24 JUDGE FITZPATRICK: Got you. Okay.
25 MR. HIGGS: So the fluid would go down first.

1 JUDGE FITZPATRICK: So there's only two filaments.
2 MR. HIGGS: There are only two filaments. Yes.
3 JUDGE FITZPATRICK: The third hole --
4 MR. HIGGS: Top left, bottom center.
5 JUDGE FITZPATRICK: The third hole is the way it gets there.
6 MR. HIGGS: The third hole is where the probe goes in and then
7 contacts and makes -- and energizes.
8 JUDGE FITZPATRICK: So then it must be redirected a little bit
9 centrally, right, by the time it gets to very distal tip?
10 MR. HIGGS: It -- so yeah. It's -- it -- because the filaments are in
11 there as well, the probe goes down sort of alongside the filaments that are
12 already up through extending through the channel, all the way through the
13 lumen of the cannula. And it comes down to the right. The probe, as it's
14 being inserted, gets pushed upward to the right so that there's nice intimate
15 contact to provide that electrical contact connection.
16 JUDGE FITZPATRICK: Okay. Thank you.
17 MR. HIGGS: Certainly. With that, if we could turn to slide 39. Oh, I
18 apologize, I'm not on the presentation mode. Okay. So I will start with the
19 teachings away -- teaching away arguments at slide 39, of which there are
20 three in this case. And as I was listening to the Petitioner go through their
21 motivations to combine, their slides 19 to 25, it really struck me that they did
22 a good job of taking bits and pieces of the three elements of prior art that
23 they've combined, and really, they're only taking components from Racz and
24 from Lee. Fitz is just there for motivation, but they're just combining things
25 from two references.

1 The only problem is they took the good parts, they ignored the bad
2 parts, and that's really a problem for them. Okay? Especially on the side of
3 teaching away. Okay. So, Matt Phillips has talked very much about why it
4 is, and I encourage Your Honors to please review our slides as well as our
5 arguments as to why it is that in the petition, they truly are saying that the
6 channels, the filaments, everything is going through the sidewall. At some
7 point, everything has to go through the sidewall, which is just in reality, not -
8 - it's just a fiction. It can't be done, which we have prevented -- presented,
9 so much evidence on that's completely rebutted, okay?
10 But -- but why is that important? It's because the filaments become so
11 small in a 16 gauge needle to be able to go -- if we could actually go to slide
12 41, there's an image showing Racz's modified device on the right where
13 there are the channels in the sidewall, and you see the filaments that they are
14 going through the sidewall, and coming out -- being deployed from the distal
15 end of the cannula.
16 Now, this is the Petitioner's cartoon. What happens at that size? What
17 happens to the filaments? Physically, their physical properties are such that
18 they deflect easily. They bend, they curve as they're going through the
19 tissue, as they're being deployed from the cannula. And that's just the
20 natural way things happen when you shrink something down to that size.
21 We're talking about filaments that are no thicker than three human hairs in
22 width.
23 So what happens with something like that? What did Racz say about
24 this? The Petitioner said well, Racz talks about how these devices. Let's
25 look at the center, these devices Radionics TEW Kit. They say well well

1 clearly those are usable in RF procedures, and that -- maybe that may well
2 be, but is that an RF neurotomy needle? No, Racz is an RF neurotomy
3 needle. That's the starting point of Racz's modified device, an RF
4 neurotomy needle, and needles are used in different ways than these prior art
5 devices. Okay.
6 And so what do they say? What does Racz say? It was -- Racz was
7 aware of this, RF device, RF neurotomy device, but it says I don't want to do
8 that with my needle. Why not? Because circled in the bottom right, such
9 flexible off axis electrodes have a limitation that their tips cannot penetrate
10 tough tissue or encounter hard bone without being damaged or diverted. It
11 specifically says I don't want to do this. I'm going to use this type of a
12 system where you have Deployable Filaments in this space because I don't
13 want things to be damaged, diverted. That's not good in RF neurotomy
14 where you're dealing with nerves. So what am I going to do instead? I'm
15 going to make a rigid bent tip to achieve such curvature. So that's what Racz
16 says.
17 What does the Petitioner say in response? Look at their slide 35. And
18 they focus on how Lee describes rigid filaments. That's the response to this.
19 Oh yeah. Well, that's what Lee says. Lee teaches rigid filaments. The
20 problem is Lee, again, is on a much, much bigger skill scale where you can
21 have those filaments. And incidentally, Lee's device, the commercial
22 embodiment, doesn't use filaments going down the side wall. It uses
23 filaments going through the central lumen, okay, where it is possible to get
24 larger, stiffer filaments.

1 So, in reality, Lee, when you shrink Lee's filaments down to this size,
2 they're no longer acting like Lee's filaments. They're no longer stiff and
3 rigid. They act instead like the very, very, thing -- the very electrodes that
4 Racz teaches away from. Okay, so on this point, Racz's modified device is
5 antithetical to both Racz's and Lee's express teachings. And both of
6 JUDGE PESLAK: Counsel?
7 MR. HIGGS: Yes.
8 JUDGE PESLAK: Is there any disclosure in any of the challenged
9 patents as to what size the filaments are?
10 MR. HIGGS: There is.
11 JUDGE PESLAK: And what size are the filaments?
12 MR. HIGGS: What's -- this the ranges that are from .06 millimeters, I
13 believe, over, is it 1.5 millimeters, somewhere in that range. And then there
14 are several -- there are several ranges that are cited, and each of them
15 becoming narrower and narrower until they focus in on the actual size of the
16 filaments used, .35 millimeters.
17 JUDGE PESLAK: And so what -- so then what size would the
18 filaments have to be to go through those -- that picture that Mr. Phillips put
19 up before that was a cross-section, what size would you assume the
20 filaments were for that?
21 MR. HIGGS: Right. In this -- in this particular example, they would
22 -- Lee states they would be .22 millimeters, which, yes, Your Honor, it does
23 fall within that range. But, at least with respect to the lower end of that
24 range, that end of the range certainly is not enabled, and not possible, but the

1 range itself is broadly recited. How that lower end of the range got in there,
2 I couldn't speak to that. I didn't draft the that patent. But --
3 JUDGE PESLAK: So for lack of a better term here, is this range of
4 filament size in the challenged patent's disclosure, are they floppy too? I
5 mean floppy -- they would be not rigid in a --
6 MR. HIGGS: Yes. At the lower end, absolutely. Because our -- our
7 expert witness, Crosby, he did the analysis of that size filament. He did the
8 calculations, and it turns out that at that lower end they do end up being
9 floppy. So they would not be -- they would not be suitable. But the range
10 itself is sound because squarely within that range are the actual commercial
11 embodiment of those filaments.
12 JUDGE PESLAK: Okay. So -- and the challenged patents say that
13 the filaments are made of nitinol, correct?
14 MR. HIGGS: Correct. And I will just say one thing. That it's only
15 the 782 Patent that recites that range. But, yes it does -- it does indicate that
16 nitinol is one possible substance.
17 JUDGE PESLAK: Okay. And that's the same type of material that's
18 disclosed in which one? Lee or Racz?
19 MR. HIGGS: In Lee I believe, yes.
20 JUDGE PESLAK: Okay. Thank you.
21 MR. HIGGS: Certainly, Your Honor. Any other questions on that?
22 Okay. Thank you. So -- so both of our -- both Dr. Russo and Mr. Crosby
23 both, analyzed the size of these filaments as well in the record and have
24 testified to all of the foregoing properties of these filaments when you shrink
25 them down to this size. Let me return to slide -- where were we? 40, 41.

1 They both testified to this and everything that I had discussed previously,
2 and you can see their discussion at paragraphs -- for the Russo declaration,
3 that's paragraphs 216 to 228. For Crosby, that's paragraphs 276 to 282
4 where they discuss these teachings away in Racz and that the size and the
5 properties of these filaments. Okay. So that's what they testified to.
6 What did Dr. Tucker say in response to this? Nothing. Not a peep.
7 What did the Petitioner's other expert witnesses say? They didn't have any.
8 So, we presented all of this evidence regarding what would happen to film
9 us this size, and nothing was -- we received no response from the Petitioner.
10 But this is not the only way in which the Petitioner has shown
11 complete disregard for the teachings of Racz and Lee. As was discussed
12 previously, Racz also is -- is directed specifically to a bent tip. On this slide
13 42, we see the first and last pages of Racz. From front to finish, from
14 beginning to end, Racz is all about a bent tip. Starting in the title, bent tip
15 abstract, all throughout the entire specification.
16 And for size constraints, we've only put the front and the end page. If
17 we put everything up here, we'd all be blinded by the yellow highlighting,
18 but I will pick up at the last bit of the written description where it says it
19 should be noted that the terms needle probe cannula, as used herein, all
20 denote all medical and surgical tools. So this is boilerplate typical in patents
21 to expand the reach of this patent. But in expanding the reach, it maintains
22 the bent tip structure disclosing --
23 JUDGE MITCHELL: Can I --
24 MR. HIGGS: -- any claim --
25 JUDGE MITCHELL: Can I pause you? I'm sorry.

1 MR. HIGGS: Yes.
2 JUDGE MITCHELL: We've lost again. We've lost Judge Peslak.
3 MR. HIGGS: Okay.
4 JUDGE MITCHELL: I'm so sorry.
5 MR. HIGGS: No, it's understandable.
6 MR. PHILLIPS: The timer's still running.
7 JUDGE MITCHELL: I'm so sorry.
8 MR. PHILLIPS: Okay. Thank you.
9 MR. HIGGS: Thanks.
10 JUDGE PESLAK: Okay. I'm back. Sorry about that.
11 MR. HIGGS: No problem. Welcome back. So -- so I was just saying
12 from start to finish, bent tip. It's the focus. It's the -- it's the drumbeat of this
13 patent and -- and is absolutely required by every claim, as well, a rigidly
14 bent tip. So, what did -- what did our experts say was the -- that one of
15 ordinary skill in the art would take from these references? Let me go to the
16 next slide. There are two slides. This is, slide 44. On the left is Mr. Crosby,
17 who says the bend at the tip is the raison d'etre of the invention. It's its
18 essence. Its core. Its purpose in being. And on the right --
19 MR. PHILLIPS: I think we may have lost Peslak again.
20 JUDGE MITCHELL: I'm sorry. Are we able to get Judge Peslak
21 back again? Nothing like trial by fire for your first LEAP argument. I'm
22 sorry.
23 MR. HIGGS: No problem.
24 JUDGE PESLAK: Okay. I'm back again. Hopefully, I'll stay here
25 this time. Thank you.

1 MR. HIGGS: Okay.
2 JUDGE MITCHELL: All right.
3 MR. HIGGS: Okay. So I was just saying that both of our expert
4 witnesses have testified to what one of ordinary skill in the art would take
5 from -- from Racz. And then on the right is what Dr. Russo testified to is
6 that one of ordinary skill in the art, quite logically, would take from Racz
7 that the permanently bent tip must have some degree of curvature. It cannot
8 be straight. Bent does not mean straight. And what did the -- what did --
9 MR. PHILLIPS: Tucker.
10 MR. HIGGS: -- Dr. Tucker say? Surprisingly, to me, the Petitioner
11 wished to highlight this. They -- on their slide 36 -- not that one. It's slide
12 36. Perfect. Thank you. Slide 36, the Petitioner highlights exactly what
13 their expert witness thinks of this disclosure. I think that one skilled in the
14 art would see that the degree of curvature can be varied. So yes, it could
15 include zero. So their expert witness says that curved means straight, which
16 to me is nonsensical. And I think it shows the level of credibility that Dr.
17 Tucker's testimonies should be given.
18 And then finally, moving to slide -- I apologize, slide 42. No. It's --
19 now it's my turn for technical difficulties. Slide -- I think I just passed it.
20 Okay. Slide 45. Well, I have 15 seconds left. So what I will say is that
21 there's also some teachings regarding anchors. I do wish I had more time to
22 discuss it, but.
23 JUDGE MITCHELL: If you would like some more time, and I'll add
24 on to Petitioner's.

1 MR. HIGGS: You know, that's -- that's okay. I appreciate it. Thank
2 you very much, Your Honors. I apologize for not leaving you sufficient time
3 to ask questions, but thank you for this opportunity.
4 JUDGE MITCHELL: Thank you.
5 MR. KELLY: I'm ready --
6 JUDGE MITCHELL: Okay.
7 MR. KELLY: -- Your Honor. I'd like to first just object to Mr.
8 Phillips's arguments with respect to the Acessa User Guide. Those are new
9 arguments that weren't presented in their Sur-reply. I'd also like to object to
10 his use of physical examples that were not in evidence. I'd like to begin
11 earlier your Patent Owner's counsel affirm that their reasonable expectation
12 of success arguments are indeed premised on RF neurotomy needles being
13 16 gauge or smaller.
14 The only way Patent Owner's reasonable expectation of success
15 arguments survive is if the Board finds that all RF neurotomy needles are
16 large are 16 gauge or smaller. It would be an error to conclude that. There
17 is no credible evidence of it. The only evidence that is credible shows the
18 opposite. The only evidence they have that all RF neurotomy needles are 16
19 gauge or smaller is the testimony of Dr. Russo, and he -- and he cites no
20 evidence on which his testimony is based. They are essentially just asking
21 you to trust him, and they are asking you to do that despite the fact that he
22 has not been a credible witness on other issues. He said there was no cross
23 pollination of technology between different areas of RF ablation, and there
24 was.

1 JUDGE FITZPATRICK: Before you -- one second. Before you just
2 move to another issue. On this size, has Petitioner taken a firm position as to
3 what the maximum gauge size is for an RF neurotomy needle?
4 MR. KELLY: Our position is that Racz discloses that 10 gauge RF
5 neurotomy needles are well within the -- the knowledge and skill.
6 JUDGE FITZPATRICK: So but your -- so relying just on that, you
7 don't have your own position? It could be bigger and so --
8 MR. KELLY: Bigger than 10 gauge, no.
9 JUDGE FITZPATRICK: -- on gauge?
10 MR. KELLY: What the evidence that's in the record shows that
11 anything between 10 and 30 is appropriate for RF neurotomy.
12 JUDGE FITZPATRICK: Actually, they have competing evidence. It's
13 in the form of opinion testimony, but it's -- it's also there.
14 MR. KELLY: Yeah. Our position is that that testimony is entitled to
15 no weight.
16 JUDGE FITZPATRICK: Understood.
17 MR. KELLY: The other point I'd like to make, Your Honor, is that
18 even if the Board considers all of the claims limited to neurotomy, even
19 though they're not, even if the Board will regard all the claims as limited to
20 neurotomy, and even if the Board were to conclude that all RF neurotomy
21 needles are 16 gauge or smaller, there is still a reasonable expectation of
22 success. And I would direct you to slide 44 of our oral hearing
23 demonstrative.
24 Stratus essentially demands more than it discloses in its own patent.
25 The specification is silent as to how to manufacture the claimed invention.

1 And the Federal Circuit has been clear where a Patent Owner did not provide
2 the type of detail in his specification that he now argues is necessary in prior
3 art references, that supports a finding that one skilled in the art would have
4 known how to implement the features of the references.
5 At slide 45, we asked Patent Owners expert, Mr. Crosby, the
6 engineering expert. We asked him, would you agree that the 688 Patent is
7 silent on how to manufacture its needle? And, he agreed, gives no details of
8 manufacturing techniques. At slide 46, we asked him, despite that a person
9 of ordinary skill would have been able to make the needle? And he said yes.
10 At slide 47, we then pointed out to Mr. Crosby that the 688 Patent doesn't
11 even include the cutaway views and detail on how the probe and the filament
12 interact together.
13 So the figures that you see on the right side of slide 47 and the 782
14 Patent, these don't appear anywhere in the 688 Patent, nor does any detail of
15 manufacturing techniques. And still, Mr. Crosby agreed that a person of
16 ordinary skill would have the level of skill necessary to make that needle
17 without any information on manufacturing, and without any detail on how
18 the probe and the filament connect together at the tip. So the testimony of
19 Patent Owner's own expert as to what the level of skill is includes, by
20 considerable margin, how to manufacture these inventions.
21 JUDGE FITZPATRICK: Mr. Kelly, then -- since you're making this
22 comparison, is it fair for us to assume, correct us if it's not, then in your
23 proposed modification, the filaments would extend down the central lumen
24 in the same manner as they do in -- in the disclosed -- in the disclosures of

1 the patents? Because they've characterized your position as that not being
2 the case. That instead they travel down the sidewalls.
3 And so if they're different, it's -- it's reasonable -- I could understand
4 how there could be different opinions about whether the seemed -- like, you
5 know, you need different instructions for people to do two different -- to
6 build two different apparatuses. So if your proposed apparatus is different
7 than theirs, that could account for the lack of instructions in the patent versus
8 for your proposed device.
9 MR. KELLY: Yeah. I think the point I would make, Judge
10 Fitzpatrick, is that the petition and Petitioner's arguments are focused on the
11 claimed invention. The claimed invention requires Deployable Filaments.
12 And so that's why we've explained that the tip would have these channels in
13 the tip that would guide the filaments outwardly. But the claimed invention
14 doesn't require that the -- that the filaments have to be in a sidewall. It just
15 requires that they're somewhere in the cannula.
16 And so we -- either case could work. We're not saying that they have
17 to be in the sidewall. We're not saying that they have to be in the cannula.
18 The fact is the filaments are actuated by the actuator, and they're deployed
19 outwardly through -- through channels in the tip. But there's absolutely
20 nothing anywhere in the petition that requires those filaments to be in
21 sidewalls along the entire length of the cannula. This is a -- this is a detail
22 that's just a design choice for a person of ordinary skill. The other point I'd
23 like to emphasize is --
24 JUDGE PESLAK: Hold on. Counsel?
25 MR. KELLY: Yes.

1 JUDGE PESLAK: Maybe I'm wrong, but I think Patent Owner's
2 argument is that because you're going to run the filaments through some
3 channels and arranged at the tip that you can't do because of the size, okay.
4 And the claims do require that filaments have to be -- can come out of the tip
5 or be, you know, withdrawn. So I think the focus is there's no reason -- I
6 think they're claiming there's no reasonable expectation of success in your
7 combination. And that's how you're missing a claim limitation because they
8 say it's impossible to make because of the sizes. Can you address that?
9 MR. KELLY: Yes. And I think if you review the testimony of Mr.
10 Crosby on this issue, which is the testimony they rely on, what he is saying
11 is that, number one, the needle has to be 16 gauge or smaller. That's his
12 starting point. So if you don't find that, none of his testimony applies.
13 Number two, he explains that the channels have to go along the entire length
14 of the cannula, and his testimony about the inability to manufacture those
15 channels is completely rooted in this idea that the channels have to go the
16 entire length of the needle, and they simply don't. The petition does not
17 require that in order to find the claims obvious.
18 So even Mr. Crosby's testimony about the ability to make these
19 channels has no bearing on the petition's combination of the prior art. Lee
20 doesn't have channels that go all the way down the sidewall, and the
21 petition's combination of the references doesn't require that. It's only at the
22 tip. And his testimony is not that you can't just make channels at the tip --
23 MR. PHILLIPS: We lost Judge Peslak again.
24 JUDGE MITCHELL: Oh my gosh. I am so sorry.

1 JUDGE PESLAK: Counsel, I'm back. I just got the brush beginning
2 of what -- how you were responding. So you -- I apologize. So if you can
3 just start again, I appreciate it.
4 MR. KELLY: Of course, Your Honor. The point I was making is that
5 the petition's combination requires channels at the tip of the needle. It
6 doesn't require channels that run all the way down the length of the cannula.
7 And if you review Mr. Crosby's testimony on this issue, all of his arguments
8 are addressing the inability to manufacture channels that run the entire
9 length of the cannula. Our arguments are not premised on that. So there's
10 no evidence in the record that you can't make channels just at the tip of the
11 size that is addressed in the patents.
12 And I think also Mr. Crosby's testimony with respect to the 688
13 patent, where he confirmed a person of ordinary skill could make this needle
14 without any detail on manufacturing techniques or any detail on the cutaway
15 views of the tip, I think that further reinforces that this is well within the
16 level of skill in the art.
17 I'd also like to reinforce, if you look at slide 47, you'll see at the top of
18 slide 47, figure 16A from the 782 Patent. This is the red tip that fits in the
19 end of Stratus's cannula, and it has these little grooves, and that's how the
20 channels are guided. This is the exact same thing that is disclosed in Lee. If
21 you refer back to slide 39, for example -- or excuse me, refer back to slide
22 27. This is the same thing that is disclosed in Lee. There is no difference
23 between Stratus's 782 Patent figure 16A and the red tip that is shown in
24 figure 48 of Lee. They function the exact same way.

1 To the extent there's any difference at all, it is simply a matter of size.
2 And Dr. Tucker testified that adjusting the size would be well within the
3 level of ordinary skill of the art. So, I mean, essentially Stratus's argument is
4 it wouldn't have been obvious to make this smaller, and I think that just can't
5 hold water.
6 I'd also refer and Mr. Tucker testified to this at Exhibit 1031,
7 Paragraph 146, about how it would have been obvious to adjust the size of
8 these elements to make them operable with one another. And in fact, the
9 patent -- as you pointed out, Judge Peslak, the patent itself, Stratus's patent
10 says that .06 millimeter diameter filaments work. And they are telling you
11 that .2 millimeter filaments, in their oral demonstrative, would not work. So
12 the patent is saying that filaments that are way smaller than what they're
13 telling you in this proceeding don't work, actually do. And the inconsistency
14 between the -- the disclosure in their patent and what they are telling you, is
15 impossible cannot be reconciled.
16 And even Mr. Higgs earlier agreed that the Stratus patent works kind
17 of like Lee. He's absolutely right because the tips are the same. To the
18 extent there's any difference, it's simply a matter of size.
19 And with respect to size, I would just go back to slide 42. There was
20 some discussion earlier with respect to the Acessa User Guide, and I believe
21 Stratus's counsel explained that the Acessa User Guide shows that Lee's
22 ablation volume is orders of magnitude too large, and that the numbers here
23 are inaccurate. They are exactly correct. What this slide shows at slide 42 is
24 that Lee's ablation dimension is 19 millimeters by 17 millimeters, and that is
25 exactly what it shows in the chart when the filaments are deployed by 5

1 millimeters. So this is -- that is an ablation volume with the filaments
2 deployed. And so this notion that Lee's device is some -- you know, is
3 massively larger than what is being claimed is a fiction, and it's supported by
4 Crosby's testimony and what's shown in the Acessa User Guide.
5 The final point I'd -- I'd like to make, Your Honor, is that Stratus
6 excuse me, Stratus's counsel keeps referring to the inability to make Racz's
7 modified device, and that is simply not the question in this case. The
8 question is would a person of ordinary skill, with the benefit of all of the
9 teachings of Racz, Fitz, and Lee, have been able to make the claimed
10 invention, and Stratus's arguments about the minutia of Racz's modified
11 device, which is one example provided in Dr. Tucker's declaration and one
12 example that's provided in the petition, is not the same thing as addressing
13 whether the claimed invention is obvious.
14 And I would strongly advocate to you to keep that in mind as you
15 evaluate Patent Owner's arguments. We yield the remaining portion of our
16 time, unless there's any questions from the panel.
17 JUDGE MITCHELL: Thank you.
18 JUDGE FITZPATRICK: I have one question. It's kind of ties in to
19 that last point of kind of it's not in any specific place. It's -- it -- look at --
20 look at the teachings and what are they -- what do they -- what do they teach
21 a person of ordinary skill in the art. And I just want to get -- I just want to
22 go back to one of the teachings that -- that they're pointing to. It's in Racz.
23 It's in column 2, let's see lines -- basically column two, lines 35 to 38. I'm
24 going to read it.

1 Quote, such flexible off axis electrodes have a limitation that their tips
2 cannot penetrate tough tissues or in hard bone without being damaged or
3 diverted, unquote. And -- and they're pointing to that as a teaching way.
4 And I think in your opening, you had said well, that there are multiple
5 applications of RF neurotomy needles. Even taking that at face value, if
6 that's a teaching away, it's only a teaching away to those applications, tough
7 tissue or hard bone.
8 What -- you know, I think maybe the most -- the most difficult, I
9 think, part of your case is starting with this curved tip that Racz teaches, and
10 it teaches us, I think, because -- in part because of what I just read to you. It
11 opts for that. And so if you can -- if you can address that issue just one more
12 time, this curved tip issue.
13 MR. KELLY: Well, I would -- I would just say two things, Judge
14 Fitzpatrick. First, the flexible curved tip that Racz is discussing in the
15 portion of column two that you refer to. If you look at slide 35 of our
16 demonstrative, the curved -- the flexible curved tip that you -- you see
17 extending out of this Radionics TEW kit, this is what they're talking about.
18 And what they're saying is this type of flexible tip, this works well in very
19 soft fluid, very soft tissue. And what Lee teaches is that if you've got to
20 penetrate very tough tissue, Lee's filaments work great. So Racz is not
21 teaching away from the filaments of Lee. Racz is teaching away from the
22 filament that you see in this green Radionics kit right here, and they bear
23 absolutely no resemblance to one another.
24 And the other point I would make is that Petitioner's combination of
25 the prior art has nothing to do with Racz's bent tip. Racz is disclosing that a

1 single tip RF neurotomy needle can -- the end of it can be bent if you need it
2 to be, but straight tip needles are bent -- or sorry, straight tip needles were
3 well known in the art. Racz even discusses that in its background, and it
4 doesn't say that those needles are inoperable. It just says you might have to
5 reinsert them a few more times. So, it's not a teaching away. There's
6 nothing in Petitioner's combination that requires the tip of Racz's needle to
7 be bent. This is just a design choice.
8 Now, I think this is a classic bodily incorporation error. This is Patent
9 Owner trying to incorporate features of the reference that are not claimed
10 into the obviousness combination, and that's legally impermissible.
11 I would also point to column eight, Line 15 in Racz. If you read here,
12 Racz says the shape of the tip and the extent of insulation versus exposed
13 electrode can be variable depending on the application. And that is because
14 the tip is only bent for certain applications, certain subsets of neurotomy.
15 The claims, which many of them aren't limited to neurotomy at all,
16 they are certainly not limited to the specific type of neurotomy that Racz is
17 directed to. And even -- and even the ones that are, it would be obvious to
18 have a bent tip or a straight tip with the filaments combined. So the --
19 regardless of whether the tip is bent or straight, the obvious -- obviousness
20 combination holds up. I know I'm over my time. So I'm happy to answer
21 any other questions or yield.
22 JUDGE FITZPATRICK: Thank you.
23 JUDGE MITCHELL: Yeah, I think we're good.
24 MR. KELLY: Thank you all.

1 JUDGE MITCHELL: Thank you. And I will add time to Patent
2 Owner's rebuttal.
3 MR. PHILLIPS: Thank you, Your Honors. I'll take a just a minute.
4 JUDGE MITCHELL: Sure.
5 MR. PHILLIPS: I do want to address what Mr. Kelly said about -- I
6 think he said that the filaments could be in the central lumen of Racz's
7 modified device. That is not stated anywhere in the petition. Please look at
8 slide -- our slide 26, which quotes from the petition that says a POSA would
9 have arranged the perimeter filaments, channels, and ramps around the
10 internal perimeter of Racz's cannula. The same thing is quoted on slide 18
11 from the petition.
12 Second, I believe Mr. Kelly said that Mr. Crosby's analysis of the
13 infeasibility of making the channels in Racz's modified device assumes that
14 those channels extend the entire length of the needle. First of all, I think that
15 is the right reading of the petition because if you do not if the you can't
16 have the filaments in the lumen while accommodating Racz's probe. Racz's
17 probe fits snugly in the lumen. But secondly, what Crosby was really saying
18 is that if the channels have any appreciable length along the needle, even if
19 it's just a portion near the tip, there would not be a reasonable expectation of
20 success to make them. It has -- his analysis was not strictly limited to
21 channels that are only as long as the needle.
22 The third point I want to address is Mr. Kelly mentioned that the
23 Stratus Patents mention a .06 millimeters filament, and that is correct. But
24 the Stratus Patents also refer to embodiments in which multiple filament
25 wires are braided together to make a bigger filament. And so I think one

1 skilled in the art reading this number in the Stratus patent would realize that
2 is not the dimension of a filament by itself but just one filament element in a
3 braided filament that is much larger.
4 And the fourth point, and this is my final point, is there is a suggestion
5 that Mr. that Dr. Russo's testimony about needle size is not credible
6 because, according to the Petitioner, he was wrong when he said there was
7 little to no cross pollination between RF neurotomy and other forms of RF
8 ablation. He said little to no cross-pollination. The only concrete instance
9 of cross pollination that the Petitioner has been able to identify across
10 decades of RF ablation is that there was one instance of inspiration from a
11 cooled tip of ablation being applied from other fields into RF neurotomy.
12 That's it. It's entirely consistent with what Dr. Russo testified. There is no
13 reason to -- to conclude that he has no credibility. He does. And unless
14 there are questions, we rest our case.
15 JUDGE MITCHELL: I think we're good.
16 JUDGE FITZPATRICK: No questions. Thank you.
17 JUDGE MITCHELL: Yeah. Thank you so much. I want to thank
18 you all for your arguments. We love oral argument because it lets us really
19 kind of, you know, explore your cases.
20 And certainly thank you, Mr. Higgs, for coming and arguing as a
21 LEAP practitioner. We will take the cases under advisement, and we are
22 adjourned. Thank you so much.
23 (OFF THE RECORD AT 3:30 PM)

IPR2024-01209 (Patent 10,966,782 B2)
IPR2024-01210 (Patent 10,736,688 B2)
IPR2024-01211 (Patent 10,736,688 B2)
IPR2024-01212 (Patent 10,925,664 B2)

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