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Paper No. 41
Entered: June 17, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.
Petitioner,

v.

THE FOUNDRY, LLC,
Patent Owner.

IPR2024-00279 (Patent 10,610,675 B2)
IPR2024-00280 (Patent 10,894,011 B2)
IPR2024-00669 (Patent 11,679,077 B2)

Record of Oral Hearing
Held: April 29, 2025

Before SHERIDAN K. SNEDDEN, SUSAN L. C. MITCHELL, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

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The above-entitled matter came on for hearing Tuesday, April 29, 2025, commencing at 9:00 a.m. EDT, 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

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3 JUDGE MITCHELL: Good morning, everyone. You may be
4 seated. And I will turn the hearing over to Judge Majors to have him do our
5 preliminaries and then get started.
6 JUDGE MAJORS: Good morning, everyone. Can everyone hear
7 me?
8 MR. CAVANAUGH: Yes, Your Honor.
9 JUDGE MAJORS: All right. This is Judge Tim Majors. And
10 with me here today on the panel are Judges Mitchell and Snedden. This is a
11 final oral hearing in three related IPR proceedings. And those proceedings
12 are IPR2024-00279; that concerns Patent number 10,610,675. And we also
13 have IPR2024-00280, and that is Patent number 10,894,011, and lastly,
14 IPR2024-00669. The patent in that case is 11,679,077. For record's
15 purposes as is conventional, I will refer to the patents in the -- throughout
16 today's oral hearing based on the last three numbers.
17 The Petitioners here are Neurent Medical Inc. and Neurent Medical
18 Ltd. and the Patent Owner is The Foundry, LLC. Our court reporter is
19 present and the Board will issue a single transcript for these cases which will
20 be made part of the record when it's available. Counsel for Petitioner, would
21 you identify who is present and who will be doing the speaking today?
22 MR. CAVANAUGH: Good morning, Your Honor. Dave
23 Cavanaugh for Neurent with Wilmer Hale. And with me is Josh Stern and
24 he will also be presenting part of the argument. I also have some colleagues
25 from Wilmer Hale, Greg Lantier, Alexis Cohen, Alex Nemtzow, and Gilbert

1 Smolenski, and our chief technology officer is listening online.
2 JUDGE MAJORS: Okay. Thank you, Mr. Cavanaugh and the rest
3 of your team. Counsel for Patent Owner, would you please identify yourself
4 and similarly identify who's going to be doing the presentations today?
5 MR. BRIGGS: Yes, good morning, Your Honor. This is Heath
6 Briggs from the law firm of Greenberg Traurig. With me is my cocounsel,
7 Elana Araj. Also in the room with us is client representative Irina Ridley,
8 Chief Legal Officer of Aerin Medical, who is the exclusive licensee of The
9 Foundry patents. I will be doing all the arguing today, Your Honor.
10 JUDGE MAJORS: Okay. Welcome Mr. Briggs and the rest of
11 your team. Okay. So, as set forth in our March 13th, 2025, order, each side
12 has a total of 75 minutes to present its argument for these three cases. The
13 panel will do our best to keep track of time, but I would encourage each side
14 to do likewise.
15 We'll also try and give you -- you can see the clock behind Judge
16 Mitchell there, but we may or may not try to give you a warning when you're
17 getting close. But as I said, if you could keep track of time yourself, that's
18 always helpful. Petitioner, you have the burden of proof in these
19 proceedings and you will present your arguments first. Would you like to
20 reserve any rebuttal time?
21
22 MR. CAVANAUGH: Yes, Your Honor. The Petitioner would
23 like to reserve about 25 minutes of rebuttal time.
24 JUDGE MAJORS: Okay. And Patent Owner, would you also like
25 to reserve any rebuttal time?

1 MR. BRIGGS: Yes, Your Honor. We'd like to reserve 15 minutes
2 of rebuttal time.
3 JUDGE MAJORS: Very well. The hearing is open to the public
4 and I believe there is a public line open, although I don't think there are any
5 confidential materials that were filed in this case. The panel has access to
6 the entire record, including the parties' demonstratives.
7 As you go through your presentations today, and I assume you're
8 going to be referring the demonstratives, if you could identify the
9 demonstrative by its page number and just give us a brief moment to catch
10 up to you, that's always helpful. Our expectation today is that unless it's
11 absolutely necessary, counsel for the opposing party will not interrupt the
12 other party's presentations.
13 And one of the things is that three different proceedings in this
14 case, it would be helpful as the parties go through their arguments if there is
15 an argument that's being made that's specific to one of the proceedings or
16 one of the patents, if you could just do your best to point that out to us.
17 And then, lastly, if you notice anything, since two of the Judges are
18 appearing by video today, if you notice any issues with the technology there
19 in the hearing room or otherwise that is impacting your presentation, just
20 please try to let us know. We can let the other panel members know and the
21 staff there in the room and we'll do our best to try to address it. All right.
22 Petitioner, we put 75 minutes on the clock and whenever you're ready, you
23 can begin.
24 JUDGE MITCHELL: Well, let me make sure, 50 right now,
25 (INDISCERNIBLE) your rebuttal.

1 MR. CAVANAUGH: Good morning, Your Honors, may it please
2 the Board. My name is Dave Cavanaugh and again, together with my
3 partner Josh Stern, we represent Neurent Medical, the Petitioners in these
4 three IPR proceedings. Mr. Stern and I will divide the arguments and I'll
5 identify who will address which issues when I cover those in a moment.
6 The patents challenged in these proceedings describe in their
7 specifications a method in the device for increasing the uptake of a
8 neurotoxin using electroporation, which as the name sounds, uses energy to
9 make the cells more receptive to the neurotoxin to address rhinitis.
10 This application was filed in 2006. The first application and for
11 seven subsequent applications, the Patent Owner described using a
12 neurotoxin to treat bronchial tubes for repairing the cells using
13 electroporation.
14 In 2019, the Patent Owner recast the invention as treating rhinitis
15 using energy. What changed between 2006 and 2019 is that Neurent was
16 developing a product that addressed rhinitis and other nasal conditions.
17 Neurent was developing a product and filing applications on the device that
18 did not use a neurotoxin or even electroporation, but did use energy to ablate
19 nerve tissue.
20 And what the Patent Owner did was to insert new matter from
21 another provisional into the specification, mark it as a continuation, and
22 pursue claims with an entirely different subject matter directed to treating
23 nasal conditions using energy as opposed to the use of a neurotoxin for
24 bronchial tube treatment. Thus, the claims which removed the neurotoxin in
25 electroporation from the claims, and the claims were allowed by the

1 examiner and the Patent Owner has sued Neurent upon these claims. These
2 three claims, now challenged in these IPRs, are not patentable and they're
3 not patentable for several reasons.
4 First, because the claims were brand new in 2019, and were not
5 described in any proper priority application, the applications claimed are
6 only entitled to a priority on the date they were filed, October 22nd, 2019.
7 However, by 2019, using energy to treat nasal conditions was well known
8 and taught by, for example, a reference to Saadat. And if you agree that the
9 claims are only entitled to the 2019 filing date, then the Patent Owner
10 concedes in the POR that all the challenged claims should be cancelled.
11 And second, even if you find that the proper priority date goes
12 back to 2006 and there is written description for the claims that are at issue,
13 they are still unpatentable over the prior art available before 2006. And in
14 fact, there's a reason why the claims using energy to treat rhinitis were not
15 pursued earlier. The idea was already well known by those skilled in the art
16 by 2006. So, the issues are narrow and let's get to them.
17 So, in Slide 2, I have a brief agenda. We've divided the
18 presentation into four general topics. First, I'll discuss the grounds in the
19 challenged claims. Next, I'll address the priority issues of The Foundry
20 patents. Then my partner, Josh Stern, will present the particular obviousness
21 grounds.
22 And finally, we've allocated some time to discuss the definition of
23 a POSITA and answer any questions that you might have. Of course, ask
24 any questions at any time. If we don't address something in our argument
25 today, we're resting on the papers, which is fully briefed in this case.

1 So, turning to Slide 4, you know, we have an overview of the
2 grounds, and Judge Majors, this is hopefully helpful to identifying which
3 grounds are particular to which particular arguments, you know. If the 2019
4 priority date is what Your Honors decide, we've identified on the left-hand
5 side the IPRs, the particular grounds, and the claims that are impacted by
6 those particular grounds. And so, as we note at the bottom of the slides, the
7 POR, the Patent Owner response, did not context the patentability of the
8 claims.
9 But even if you disagree with the petition on both the written
10 description and the priority, and if we go to Slide 5, we address the 2006
11 priority with substantive grounds on, you know, Makower and Fang, and
12 other references. And that, Your Honors, is clearly presented. Mr. Stern
13 will be discussing that in a moment.
14 So, we turn to Slide 6. And this is just -- the next three slides, we'll
15 talk a little bit about the claims that are at issue here, just to kind of frame
16 the -- kind of the issues regarding using energy to treat rhinitis. Here we
17 have Claim 1 of the '675 Patent. We've highlighted in some different colors
18 for Your Honors to kind of see how the various limitations are related.
19 There's administering therapy to a target tissue and the therapy comprises at
20 least one of delivering energy to the target tissue. And that is administering
21 therapy so that the mucus secretion is reduced.
22 And on Slide 7, we do the same thing for the '011 Patent, again
23 same color scheme. There's delivering energy to a target tissue for a
24 particular treatment. And finally, on the '077 Patent, similarly there's a little
25 bit more detail about the radiofrequency electrodes.

1 There's a radiofrequency generator, and if I say radiofrequency or
2 just the two letters, R and F, they're the same thing. I hope that the court
3 reporter will be able to kind of transcribe those. And then we get to treating
4 the target tissue in the nasal cavity and thus treat rhinitis.
5 The other two things that I'll talk about with regard to the claims,
6 and Mr. Stern is going to address these, but on this next slide, Slide 9, there
7 are some limitations and dependent claims about concentrating the energy
8 laterally. And on Slide 10, there is more details about the electrodes, that
9 there are multiple pairs of bipolar electrodes, which are also addressed in the
10 substantive grounds by Mr. Stern.
11 So, let's turn to Slide 12. And so I'm going to kind of pause at this
12 slide or move from this slide to Slide 13. But what I want to kind of start
13 with is there's a priority issue that we are going to address. What I will
14 address is the written description first. And then I'll address any questions
15 Your Honors have about the priority, but we're mindful that, you know, our
16 time is limited and I want to make sure that I get to the written description.
17 So, we go to the next slide, in Slide 13. You know, I think both
18 parties agree that Ariad is the leading case with regard to written description.
19 It provides a good framework for discussion on the sufficiency of the
20 disclosure for written description.
21 And, you know, I'm going to read the quote, "For priority, you
22 must show written description that reasonably conveys to a POSITA that an
23 inventor had possession of the claimed subject matter." So, that's the
24 objective, that's what we have to answer in whether or not the specification
25 supports those claims. And this in the Petitioner's argument the Patent

1 Owner cannot do.

2 And then let's look at the particular portions of the claim on Slide
3 14. And as I briefly went through the claims, I'm not going to spend too
4 much time here. What we've done for Your Honors is to identify the
5 particular limitations which are administering therapy by delivering energy
6 or delivering energy to administer therapy.

7 And as the Patent Owner has framed the issue in the POR on pages
8 24 and 25 of the '675 Patent IPR, the sole issue is whether the patent
9 specification has a description to allow energy to disrupt neural activity such
10 that the treatment of rhinitis is reduced.

11 Now, let's look at the specification, because we need to find like
12 that sole issue in the specification and if we turn to Slide 15, I'm going to
13 start with what is actually in the specification. And on the top left is the
14 title, "Systems and Methods for Delivery of a Therapeutic Agent." And then
15 you go to the Field of the Invention, and I've highlighted it on the bottom.

16 Their present invention relates to "methods and systems for
17 delivering toxins such as botulism -- botulinum and light chain fragments
18 that target cells in a nasal cavity." On the right-hand side there's kind of a
19 description of the context of what they were doing.

20 Recently, longer-term therapy for rhinitis which relies on Botox for
21 blocking mucus production has been found. And then they talk about
22 increasing the uptake of the neurotoxin by the use of energy.

23 And we see that improved methods for delivering the toxins on
24 column 3 and then the toxin is delivered may comprise any neurotoxin
25 capable of disabling mucus secretion. So, at least on this slide, and we have

1 two others that we can go through, they're framing their invention as again
2 use of a neurotoxin to interrupt the mucus secretion and the energy is to
3 facilitate that uptake of the neurotoxin.
4 So, let's go to the next slide, on Slide 16. You know, the how do
5 they do that? What is this energy? Well, they're talking about the use of
6 energy to kind of create a porosity in the slide (sic), permeabilization to
7 enable translocation of the Botox across the cell membrane. That's in the
8 abstract.
9 On the right-hand side, they also talk about the use of energy to
10 enhance the delivery of toxin to the cells. I'll return to this segment in a
11 moment, but I'd like to go to the next slide and, you know, the specification
12 is clear that the applying energy is to enhance the delivery of the toxins.
13 And here we see on Slide 17, you know, in the top left, enhance
14 the delivery of the toxins. The present invention -- according to the present
15 invention, the delivery of the Botox or the substance is mediated and
16 enhanced by selective application of energy.
17 And that is consistent with what we have on the right-hand side of
18 Slide 17, also in the present invention if allows the kind of the delivery of
19 botulinum and other toxins to be preferentially delivered.
20 So, in turning now to Slide 18, you know, when the neurotoxin
21 claims as I mentioned in my opening has been a part of this specification for
22 its entire length until 2019. And, you know, this is just how they have used
23 that particular kind of framing of it, delivering toxins, applying energy to
24 enhance the delivery of the neurotoxin.
25 And if we turn to Slide 19, the Patent Owner, you know, argues

1 that there's a two-step treatment, the first step delivering energy and the
2 second being delivery of the neurotoxin. And, you know, it's the toxin that's
3 delivering the therapy and not energy alone. And I think that we said that in
4 our reply at page 4. I think it's an important framing for what the Patent
5 Owner has in their argument.
6 Because the specification, and this is on Slide 20, the specification
7 doesn't provide a description of energy-only treatment. And what I'd like to
8 do is to go through the Slide 20. And on this first piece, the Patent Owner
9 has kind of identified five words of the specification in a parenthetical
10 related to the use of non-reversible poration. And somehow -- and argue
11 somehow that conveys the energy-only treatment and that's simply not the
12 case.
13 Even if we were to take -- and this is on Slide 20 about six lines
14 down, or the parenthetical is identified, "(or in some instances) non-
15 reversible poration." And now let's look at the context of that limitation.
16 And what happens here, if we look at the context of this parenthetical that
17 they highlight, that they are relying on, it talks about neurotoxins, you know,
18 while applying energy to target cells, which cause a reversible poration of
19 the cell membranes.
20 And what's happening is, you know, this parenthetical is directly in
21 context is, you know, saying, well, you know, sometimes we want reversible
22 but sometimes there might be non-reversible and it doesn't really further
23 address that. That's the only time non-reversible is mentioned.
24 JUDGE MITCHELL: Mr. Cavanaugh, can I interrupt you?
25 MR. CAVANAUGH: Yes.

1 JUDGE MITCHELL: When it says non-reversible there, what
2 does that mean? Does that mean you have ultimate cell death or does it
3 means it's just kind of, you know, the cells are open? Like, does that have a
4 particular meaning to one of skill in the art?
5 MR. CAVANAUGH: I think non-reversible has been the subject
6 of a number of different discussions in depositions. And I think that I'm
7 going to say that two things, Your Honor. First, you know, the key issue is
8 whether or not -- whether it is reversible or irreversible poration, that there
9 needs to be some kind of treatment associated with either of those. It's
10 delivering energy for non poration, or for non-reversible, is not associated
11 with any treatment.
12 Now, in terms of a definition of what non-reversible would be, it is
13 largely as I think Dr. Bikson indicated, it's largely dependent on a variety of
14 factors. One, like what is the device, what is the treatment modality, what is
15 it you want?
16 I think the range of -- and to answer your question directly, Your
17 Honor, I think the range of non-reversible can be that the poration of the
18 cells, it doesn't snap back to where it was, and where it could be the cells
19 ultimately die. And it could be a few cells, it could be a lot more cells. But
20 there's no one definition of non-reversible poration that applies in this
21 context.
22 JUDGE MITCHELL: So, in your reading of this with that
23 parenthetical, were there any instances of non-reversible poration, you
24 would still read that to say that would enhance the delivery of toxins to the
25 cells?

1 MR. CAVANAUGH: I think it's possible that it would, yes, Your
2 Honor. And I think it's really, you know, clearly if the cells are all dead,
3 they're not going to be uptaking anything. So, but if the cell membrane is
4 damaged to a point where it's still able to uptake the neurotoxin but is not
5 going to close off the way that kind of reversible poration would be, you
6 would still get some treatment in there, but it just that it's the neurotoxin
7 that's doing the treating.
8 JUDGE MITCHELL: Thank you.
9 MR. CAVANAUGH: And so what I think is that -- so with the
10 non-reversible poration, the Patent Owner has two other examples in their
11 view of the use of use of, you know, two other points on this irreversible
12 poration.
13 There is, you know, Bickson in these transcripts and at 57 kind of
14 recognizes the risk of getting some non-reversible lack of poration in the
15 context of reversible poration. And so, you know, we have that in our reply
16 in the '675 Patent at 6.
17 And then, kind of the other piece of this, though, is the Patent
18 Owner's expert admits that there's no data presented in the specification on
19 the non-reversible electroporation. And that is, I think that, I think a key
20 part of what is absent from the specification. And the Patent Owner would
21 argue that, well, it's not really required to have data. And, you know, while
22 that is probably technically accurate that you could do it without data, but
23 not having data and just doing it in a five word parenthetical, just seems to
24 be unsupported for the written description that they seek.
25 And then if we go to Slide 21, and I'd like to start, they want to

1 somehow interpret the specification where there are two regions that
2 partially overlap. So you have one -- I'm holding my hands up, Your Honor,
3 to one area that gets treated with energy and another that overlap that get
4 treated with energy.
5 And what the context of this language is saying, you know, when
6 you deliver the neurotoxin in that circumstance, you're going to get a better
7 uptake in the overlap section, which, you know, is what we put, and this is in
8 context kind of clear. And so like, here, the delivery of the toxin is
9 enhanced, principally within the regions of overlap, where my fingers
10 overlap. And, you know, the energy applicator is identified. And this is on
11 the -- on column 9 -- actually it's column 9, line 41 to 57 of the '675 Patent,
12 the energy applicator is further provided to enhance delivery.
13 And then when we talk about the energy applicator and the
14 overlapping regions which is what the Patent Owner is identifying, then, you
15 know, it's clear that the energy is increasing uptake and not necessarily
16 doing anything with regard to treatment.
17 And that's clear, and I don't want to kind of look at the Patent
18 Owner's argument, but it seems what they're trying to say is that somehow in
19 those non-overlapping areas, there's something going on that the patent
20 specification is not describing. And in that absence of disclosure, they see
21 to -- they perceive that there's some significance of treatment.
22 The last thing I would say, Your Honor, on the energy-only
23 treatment is on Slide 22. And here, we talk about the energy being -- oh,
24 sorry, Your Honor, did you have a question?
25 JUDGE SNEDDEN: Yes, I had a question.

1 MR. CAVANAUGH: Oh, sure.

2 JUDGE SNEDDEN: All right. So, when you look at the claims
3 and in particular, the independent claims of the '675 Patent Claims 1 and 17,
4 they, I guess, the question here is with regards to written description is
5 whether or not the claims require energy-only.

6 They got -- each of these claims, both refer to administering
7 therapy. But at the same time, they're very careful to suggest that therapy
8 merely comprises delivery of energy. And so I wonder if you could speak to
9 that, whether or not the claims actually encompass energy-only, versus, you
10 know, both the administration of toxin and energy.

11 Whereas the, you know, when I look at this, in these last wherein
12 clauses of these independent claims, it fairly says comprises, which to me
13 indicates that perhaps there's more than just energy component to just an
14 energy component to the therapy.

15 MR. CAVANAUGH: Right. I think the way that the Patent
16 Owner has framed the issue is that it's energy-only as what the critical
17 specification requirement is. And, you know, the claims themselves, the
18 Patent Owner has said, well, you know, it hasn't argued that the position that
19 you're asking about, but to the extent that they would, I do think that it's
20 clear based on presentation in the specification.

21 And the way the Patent Owner has argued the sufficiency of the
22 specification, that in their view it's an energy-only and that it can't -- it
23 doesn't have a neurotoxin because they would have argued it differently.
24 They would have said, you know, we do all kinds of things with the
25 neurotoxin electroporation.

1 I mean, if you look at the difference between their PO -- the POPR,
2 where they were basically saying look, it would be a single device that is
3 doing the electroporation and the delivering of the toxic agent.
4 And on the POR, they backed away from that and then they
5 focused on the irreversible electroporation. But if they felt that it was
6 sufficient because the claims are broader than because of the use of
7 comprising or like none of that is in their briefing, Your Honor. But if they
8 felt that, then they would be arguing the electroporation differently.
9 And then they backed away from electroporation and they really
10 focused on the irreversible electroporation and so, you know, they've done a
11 kind of a four-step process to establish the sufficiency of the written
12 description, which I can talk about in a moment.
13 But then -- so two points, Your Honor, just to summarize. One is,
14 it's not really a part of their argument that it's comprised in the claim and it
15 could do other things. And the second piece is, they would have argued it
16 very differently if they felt that. They would have the irreversible
17 electroporation in the context of the reversible electroporation and they
18 would be saying, look, it's this and, it's, you know, it can be something else.
19 So, do you have any further questions, Your Honor, on that?
20 JUDGE SNEDDEN: No. Thank you, that's all.
21 MR. CAVANAUGH: So, I think that in the interest of time, and I
22 want to make sure that I'm respectful to my colleague so he has some time,
23 in looking at the, you know, I'm going to stop briefly on Slide 25, you know,
24 the Patent Owner's argument.
25 I think there's some indication that in the surreply that somehow

1 we were misidentifying their argument as one of obviousness and not
2 applying the correct case law. I think that that's manifestly not the case, that
3 we've applied the case.
4 And, you know, to the extent that they were using terms that fairly
5 conveyed obviousness, like we tried to identify that for Your Honors and for
6 the record so that we were kind of just making sure that things were cabined
7 in the right area.
8 So, I think that we're applying the appropriate standard, you know,
9 and so like I think it said whether a POSITA kind of would have understood
10 and is not sufficient, but, you know, understood and appreciated if they see
11 some difference in that, then that's, you know, what they can argue.
12 And so in the interest of time, I'm going to go Slide 27. And I
13 touched on it briefly, Your Honors, you know, and this gets to your
14 question, Judge Mitchell, on what the irreversible electroporation is.
15 And you know, so you have a device that's intended to porate and
16 that it's throughout the specification, it's only one time in a parenthetical that
17 there's non-reversible electroporation. And then, you say, okay, well, what
18 is the intent? The intent is electroporation and you might have sometimes
19 that it's non-reversible electroporation, like how do you know? But you do
20 you -- and, you know, we asked Dr. Bikson, the Patent Owner's declarant,
21 about that on the lower part of this Slide 27.
22 If you design a device that's intended to preferentially cause
23 reversible electroporation, how do you know how many cells would undergo
24 irreversible electroporation? And he said, "I think it would very much
25 depend on the device and the use case to even start the answer to that

1 question."

2 So, what the expert is saying there for Your Honors and for us is
3 that, you know, the idea that there's some electroporation absent any other
4 context, what the device is, what the use case is, it's really difficult to discern
5 meaningful treatment implications on that.

6 And so, I'd like to go to Slide 28. And, you know, we asked Dr.
7 Levine, the other declarant, does it have any data, does the specification
8 have any data using irreversible electroporation without the use of
9 neurotoxins? No.

10 And, you know, importantly, this is the second part of Slide 28,
11 you know, "If you haven't identified any examples of using irreversible
12 electroporation alone to destroy tissue to achieve a therapeutic result before
13 The Foundry patents, have you?" And he said, "No, "I have not."

14 So even using the term that's in the specification, they look at, you
15 know, you have not identified any time that irreversible electroporation has
16 been used to achieve a therapeutic result.

17 And turning to Slide 29, you know, in some ways, you don't have
18 to just believe us, you can believe the exclusive licensee, Aerin Medical,
19 because when they were prosecuting the application, another application, in
20 a related chain, you know, they were faced with a rejection using the Deem
21 reference, which is what's here.

22 And the applicant traversed the rejection, not unusual. But they
23 describe what the Deem application talks about. In fact the sole purpose of
24 applying energy to Deem is to porate target cells to enhance the uptake of
25 nerve toxin.

1 And, you know, the Patent Owner says in the surreply that, you
2 know, somehow is it binding, is it not binding. In some ways, that's beside
3 the point. We think that it is, but, you know, we don't want you to rest your
4 decision on that.
5 What we would like you to consider the context of what the
6 exclusive licensee was saying about the technology to the Patent Office at a
7 time before this litigation. And that's consistent with what we talked about,
8 what our position is, and not consistent with what the Patent Owner's
9 position is.
10 JUDGE MAJORS: Mr. Cavanaugh, can I interrupt you for just a
11 moment?
12 MR. CAVANAUGH: Yes, Your Honor.
13 JUDGE MAJORS: This panel was not on those other related IPR
14 petitions that -- I think it's Aerin Medical was the Patent Owner in those
15 cases. I just want -- there's no priority dispute, or it's not the same priority
16 dispute as is involved here, in those other cases, is there? Meaning no issue
17 of energy plus toxin or lack of description thereof?
18 MR. CAVANAUGH: Yes, Your Honor, there's no issue of
19 toxin -- lack of energy used to porate tissue to increase the uptake of toxin.
20 There's no priority issue, there's no issue of continuity.
21 JUDGE MAJORS: Okay.
22 MR. CAVANAUGH: There's one overlapping issue which is the
23 Stern reference for the multiple pairs of bipolar electrodes. And Mr. Stern,
24 appropriately named, will address that particular issue.
25 JUDGE MAJORS: Okay. Thank you.

1 JUDGE MITCHELL: Mr. Cavanaugh, just another quick
2 question. So, would you say that the statements by Aerin would be an
3 admission? Would it rise to that level of an admission?
4 MR. CAVANAUGH: You know, it is a -- it's tricky, Your Honor.
5 I think it is an admission. And so, but I want to kind of encourage you not to
6 rely on the fact that it's an admission or not, because I think it's persuasive.
7 And for all the other reasons, you know, that is kind of -- I think it's the gut
8 check, it's the kind of a like is this -- are we on the right path here?
9 And if the licensee, the exclusive licensee is saying that, then I
10 think it's persuasive. Whether it's an admission against interest, I mean
11 clearly it's against their interest because they're not (INDISCERNIBLE).
12 But the question I have is whether a real party in interest should -- has the
13 same status as a party because they have the same interest.
14 And so, and I don't think that that has been fully explored by the
15 Board in any circumstance, and certainly hasn't been explored by the Fed
16 Circuit. And so, you know, if I were to kind of hyperfocus on your question
17 with it being persuasive, we think it might be an admission because the real
18 party in interest, and they're clear that they are clearly a real party in interest.
19 They certainly have an incentive to argue whatever they want to argue. But
20 they also have to be held to what they said to the Patent Office previously in
21 a similar context of examination.
22 JUDGE MITCHELL: Okay. Thank you.
23 MR. CAVANAUGH: And so, I'm going to, you know, the second
24 part is the priority. We recognize that Your Honor has gone through the
25 issue. I will just rest on the papers for that and, you know, if Your Honors

1 have any questions, we can probably address them during rebuttal if Your
2 Honors want. But it is, you know, I think in the interest of time, in the
3 interest of getting all the positions we'd like to explore before Your Honors,
4 we'd like to kind of just rest on the papers on those. Thank you.
5 JUDGE MAJORS: Mr. Cavanaugh, before you move off of the
6 second part, the priority dispute, and you can think about this and address it
7 on rebuttal if you'd like, but I'll call the second (INDISCERNIBLE) the legal
8 issue, being the applicability of the rule and the MPEP, et cetera, is there
9 some aspect of Petitioner's argument that's been made through trial that you
10 feel was not addressed in the institution decision?
11 In other words, if the Board says, you know, we simply, you know,
12 reaffirm what we said before, is there some aspect that is not touched upon
13 in that decision? Understanding, of course, that you disagree with that and
14 probably want to preserve the issue.
15 MR. CAVANAUGH: Understood, Your Honor, and it's an
16 excellent question. And I think that, you know, the cases are a little bit all
17 over the place in terms of there is some tension between say Samsung, on
18 the one hand and other cases. I would encourage Your Honors, and I think
19 we put this in the papers clearly, but I would encourage Your Honors to start
20 with the rule because that is kind of the highest kind of controlling authority.
21 And then get to, you know, how the MPEP, of course, doesn't have
22 the force of law. It can be helpful. Often the MPEP, which as a former
23 examiner, like it can be very kind of thick and helpful. Other times it can
24 just be kind of misapplied.
25 And I would start with the rule and then go through the different

1 issues. Because it's not -- to use a case that is non-precedential in -- to this
2 panel on this case as kind of the guide, whether it's for or against, that may
3 not be as helpful as, okay, why is the rule written the way it is? And if the
4 language of the rule is clear, like what else do we need in order to make a
5 determination?
6 And so, that's what I would encourage Your Honors to do. I think
7 if you do that, you know, some of the admittedly kind of complicated 20
8 year history can become more simplified. And with that, I'll cede to my
9 colleague.
10 MR. STERN: Thank you, Your Honors. May it please the Board,
11 Joshua Stern from Wilmer Hale. I'll be addressing Petitioner's obviousness
12 grounds. These arguments apply across the three IPRs, except for one claim,
13 which is Claim 4 of the '077 Patent. In the '669 proceeding, I'll address that
14 separately.
15 Just three observations about obviousness before I dive in. The
16 first is that in briefing their case, the Patent Owner has not argued that the
17 claims reflect an invention that solved a problem in the prior art. That goes
18 to secondary considerations, they don't argue there's any unmet need, any
19 teaching away, anyone that tried and failed.
20 But they also don't argue that there was anything unexpected about
21 these claims. And the secondary considerations are just part of it. There's
22 been no argument by the Patent Owner, none, that treating a nasal condition
23 with energy delivery alone, solved any problem in the prior art.
24 Now part of that as Mr. Cavanaugh explained is that that's what
25 the -- that's not what the patent specifications are about. The patent

1 specifications are about neurotoxin delivery, addressing issues with nerves
2 and production of mucus.
3 But part of it, and this is my second point, is that with the
4 exception of a very few narrow issues, there's actually no dispute that all of
5 the elements of the claims were taught in the prior art. There's no dispute
6 that ablation treatment was known, that RF ablation treatment with bipolar
7 electrodes was known.
8 There's actually no dispute that RF ablation in the nasal cavity or
9 nasal pharynx was known. There's no dispute that the role of nerves in
10 rhinitis was known, or that there's prior art evidence for disabling nerve
11 cells, including with RF ablation, addressed rhinitis symptoms. These are
12 the fundamental elements of the challenged claims. There's no dispute that
13 all of these elements were taught in the prior art.
14 And that leads to the third point. In the context of all that was
15 known in the prior art, in the absence of anything unexpected, the disputes
16 Patent Owner has raised are based on unduly narrow views of the prior art.
17 The primary arguments that Patent Owner makes, which are
18 focused on motivation, reasonable expectation of success, are built upon a
19 very constrained interpretation of the prior art, including its physical
20 combinability as opposed to what it teaches. When the art is considered for
21 all that it teaches as it must be, then the claims would have been obvious.
22 I'll just very briefly, in the interest of time, introduce Makower as
23 our primary reference, as it's titled, it's a device for treating sinusitis and
24 other nose disorders. It has working devices for ablating in the nasal cavity
25 and nasal pharynx, which is exactly the area discussed in the claims.

1 And Figure 5H shows the primary focus of our argument. It has
2 the device with electrodes, 216. These electrodes are just described as
3 electrodes, they can be monopolar, bipolar, or any other suitable form of
4 energy. They're not specific to ring electrodes, surface electrodes or
5 otherwise.
6 What Makower says, is that the electrodes that can be used in
7 Figure 5H are well known in the art. It was well known, and there's no
8 dispute about this. It was well known that there were different types of
9 electrodes available to a person of ordinary skill, those include surface
10 electrodes, ring electrodes, or otherwise.
11 And what it says here in the sort of middle, right before the green
12 and teal, is that in operation, the device -- and this is on Slide 37, in
13 operation the device 208, that's Figure 5H, is advanced into the passageway,
14 which includes the nasal cavity, current is applied to the electrodes, and it
15 causes tissue adjacent to the struts to be cauterized or heated.
16 What it says right here is that Figure 5H, contacts tissue, delivers
17 energy into the tissue and it ablates the tissue, right here in Paragraph 187.
18 We've combined Makower with Fang. Fang is a study, it evaluated two
19 groups, a control group that just had surgery to correct a deviated septum,
20 and a second group that also received radio frequency treatment and they
21 found statistically significant results.
22 There's a question about whether Fang is conclusive or
23 inconclusive. Right here, the results, the conclusions say that there is
24 statistical significantly different results for those patients that receive the
25 multiple radiofrequency treatment and that it treated the perennial allergic

1 rhinitis.

2 And Fang continues on Slide 40 and it says why, it says how and
3 why. It discusses that there are studies that show that parasympathetic
4 nerves in the nasal cavity regulate vascular dilation, contraction of the nasal
5 mucus membrane, the radiofrequency technique was used to process parts of
6 the nasal cavity and block those nerves.

7 And the consequence, and this is on the right side of Slide 40, is
8 that the radiofrequency technique completely blocks those pathways and
9 achieves the therapeutic purposes. So, Fang is teaching a person of ordinary
10 skill right here that what happens is the radiofrequency technique blocks
11 these nerves and results in treatment.

12 And there's some again, some dispute about whether this is
13 conclusive or inconclusive, whether you can trust these results. That's a lot
14 of what the dispute between the parties is. You don't just have to take Fang's
15 word for it.

16 On Slide 62, if we can bring it up, we've identified in the petition
17 and reiterated in our reply, there are at least six references and each of these
18 is cited in our petition, the top four are cited in our reasonable expectation of
19 success section. There are at least six references that confirm Fang's
20 teachings.

21 Chen, allergic rhinitis is related to parasympathetic hyperfunction,
22 radiofrequency thermocoagulation achieves the objective of treatment.
23 Arora as cryodestruction is a different form of energy but has the same
24 result, cryodestruction treats rhinitis.

25 And Liang, radiofrequency treatment can cause various degrees of

1 damage, achieving the goal of treating allergic rhinitis, and Kong is the
2 same. The Patent Owner does not address these references which each
3 confirm independently and collectively, the reasonable expectation of
4 success, which independently confirm that Fang teaches an outcome of using
5 radiofrequency electrodes, using and performing ablation, and what that
6 outcome would be.
7 There's also no discussion and no dispute that Fang's results were
8 correct. There's no evidence that anyone, outside of litigation, criticized it's
9 results, said they were wrong, that Fang actually reached the wrong
10 conclusion.
11 In fact, all of the evidence is to the contrary. RF electrode ablation
12 was performed prior to the priority date for this treatment modality. It's
13 performed all the way to today. There's no evidence that someone said, oh,
14 actually, if you do have RF ablation, it doesn't treat in the way that they say.
15 So, let me turn back to -- there are a couple of disputes about
16 Makower I just want to briefly address.
17 JUDGE MITCHELL: Can I ask you a quick question?
18 MR. STERN: Sure.
19 JUDGE MITCHELL: This may not -- it may be something that
20 just jumped in my head, so for that irreversible poration.
21 MR. STERN: Yes.
22 JUDGE MITCHELL: Would that kind of equate to ablation or
23 ablation is basically searing everything, so you would wind up with this
24 irreversible poration as a result?
25 MR. STERN: Yes. I'm happy you asked this question, because I

1 think we should clear this up a little bit. Ablation is sort of an umbrella
2 term, it's at the highest level. And there are different forms of energy that
3 can be delivered that may have similar results but are in different forms.
4 So, what the Rubinsky reference, which we cite in our petition,
5 explains that the pulses that are used for ablation for destruction's sake, like
6 RF ablation, are different than the pulses that are used for electroporation.
7 And when Dr. Bickson testified which Mr. Cavanaugh explained,
8 is that how irreversible electroporation sort of works in practice, really
9 depends. It depends on where you are, what pulses you're using, how you're
10 using it. Irreversible electroporation as Mr. Cavanaugh explained, can result
11 in the cells dying.
12 But the question from a written description perspective, is there
13 any description that whatever cell death there might be from irreversible
14 electroporation, which is not actually stated in the specification, results in
15 treatment.
16 Are we talking about one cell incidentally getting destroyed when
17 your purpose is reversible electroporation? Or are we talking about
18 something that results in an outcome, a treatment? And for purposes of the
19 written description requirement, the inventors needed to show that they
20 possessed, that they actually have an invention where in the argument of the
21 Patent Owner, irreversible electroporation led to treatment.
22 It doesn't have to be data, it could be data, but it has to be
23 something. There's no discussion at all, that the irreversible electroporation
24 in that six word parenthetical results in anything in particular, certainly not
25 treatment.

1 So, at the highest level, is irreversible electroporation ablation? At
2 the highest level, yes. But the consequences of that are what -- is what --
3 sorry. Is what is unclear from the specification. Does that answer your
4 question, Your Honor?
5 JUDGE MITCHELL: Yes, thank you.
6 MR. STERN: So, if we turn to -- I have to find my spot here, turn
7 to Slide 52, please? There are two things I just want to quickly address on
8 Makower, and I realize I'm running short on time, we're happy to take some
9 of our rebuttal time to make sure we address the obviousness ground.
10 The first issue on Makower is the Patent Owner has argued
11 essentially Makower is about flexible catheters, ignore everything else. It's
12 directed to flexible catheters, we have this here on the top of Slide 52. And
13 they say a person of ordinary skill would not consider Makower for its
14 Figure 5H device or its RF ablation, because it's directed to flexible
15 catheters.
16 And that's just not the law. We've cited, for example, the CRFD
17 case, the Sony case, and the Netflix vs. DivX in our papers. And what
18 Netflix says is we presume a person of ordinary skill knows the teachings of
19 all the prior art in the field of his endeavor, at the time the invention was
20 made.
21 The examiner identified Makower during prosecution, found it,
22 identified it as the closest prior art. A person of ordinary skill would have
23 been aware of Makower, of its Figure 5H device. There's no dispute that
24 Figure 5H has all of the technical elements of the claim. The only dispute is
25 on the motivation and reasonable expectation of success.

1 We've also included on Slide 52, it's also just not accurate that
2 Makower is limited to flexible catheters, it expressly claims working devices
3 like those in Figure 5H, and there's nothing inconsistent with using flexible
4 catheters and working devices together.
5 If we turn to Slide 54, please. So, the second issue that Patent
6 Owner has raised is this argument, and as they described it in the Patent
7 Owner response, they say that a person of ordinary skill would not be
8 motivated to look to Makower or reasonably expect it to succeed because
9 it's, quote, "fatally defective."
10 Now, we've gone back and forth in the papers though, whether this
11 is an argument about operability or not. Obviously, they didn't use the word
12 operability, but we don't read fatally defective as amenable to another
13 interpretation. They're essentially saying a person of ordinary skill in the art
14 would look at Makower Figure 5H and say, this wouldn't work. And that's
15 just not right. That's based on two assumptions, neither of which is correct,
16 and we've established, I believe, in our papers.
17 The first is, in order to come to this conclusion that Makower is
18 inoperable or fatally defective as they use, you have to conclude that
19 Makower doesn't do what it says it does. And here on Slide 54 at the
20 bottom, it says, in operation, the device, 208, that's Figure 5H, is advanced
21 into the passageway, current is applied to the electrodes and it causes tissue
22 adjacent to the struts to be cauterized or heated.
23 It says right here, Makower says, explicitly, that this is what it
24 does, it delivers energy to tissue. Their inoperability argument is that it
25 would not delivery energy to the tissue. It's plainly inconsistent with the

1 record.

2 And if we turn to Slide 55, the argument is that it wouldn't do that
3 because it would be somehow filled with fluid when it's at the operative site.
4 I just want to clear something up because there's a little bit of imprecision
5 about the anatomy here and this argument got raised in the Patent Owner
6 response.

7 We spent a lot of time with Dr. Levine in his deposition on this and
8 Dr. Bu-Saba discusses at length exactly how these procedures work. That
9 starts at Paragraph 81 of his reply declaration.

10 What happens in these procedures, is a patient comes into the
11 office, they get anesthesia, they sit in a chair in a way that, hopefully Your
12 Honors can see me, in a way that fluid such as mucus or blood runs down
13 away from the area of the treatment, which would be in the turbinates, which
14 would be higher up in the nose.

15 So, when we asked Dr. Levine is mucus an issue in these
16 procedures, he testified, "Generally speaking, the mucus isn't an issue, it's
17 there and it's fine." And so, the imprecision comes from this. Of course,
18 there's mucus in the nose. Of course, we all know that, we have mucus
19 every day, especially this time of year, right?

20 The question is, is there mucus at the site of the procedure that
21 would be performed at the time the procedure would be performed? And the
22 record we think, fully establishes that the answer to that is no. What
23 happens in these procedures is patients are seated in a way that it falls away.
24 They receive decongestants, there is suction, there is irrigation, there's
25 forceps that take things out of the treatment site if necessary.

1 And as a result, the Makower device will go into the turbinates
2 through the nasal cavity or wherever the procedure would be performed for
3 that particular patient and there wouldn't be fluid that's in the way. Instead,
4 there would be air, and that would act as an insulator, it would allow the
5 electrodes to deliver energy to tissue.
6 And the second point is, again, I've previewed the argument about
7 inoperability as premise on Makower being limited to ring electrodes and
8 not surface electrodes. But Makower doesn't say that. Makower does not
9 say it is limited to ring electrodes. It just says electrodes. And that a person
10 of ordinary skill in the art would well understand the available electrodes.
11 As an example, it cites the Imran reference which has surface electrodes.
12 So, a person of ordinary skill in the art looking at Makower under
13 Patent Owner's view of the world, would say here's the reference, it tells me
14 I can put this in the nasal cavity, nasal pharynx, it'll apply energy to the
15 tissue. But no, it's fatally defective, it wouldn't work. It's going to deliver --
16 JUDGE MAJORS: Mr. Stern?
17 MR. STERN: Yes, go ahead, Your Honor.
18 JUDGE MAJORS: You can go ahead and finish your thought, but
19 I have a question as soon as you are done.
20 MR. STERN: Of course. And what we'd submit, Your Honor, is
21 that that's not the right way to read the reference. A person of ordinary skill
22 would read for operability, not assume inoperability, particularly when
23 there's different ways that you can approach the reference. Judge Majors,
24 I'm happy to answer your question.
25 JUDGE MAJORS: Yes. So, you briefly touch on the arguments

1 about Figure 5 of the patent itself. And as I understand the argument, it sort
2 of goes that if Makower would have a problem relative to excess blood or
3 mucus so would the Figure 5B embodiment because in terms of this ring of
4 RF energy going around it, and then this is as I understood the argument,
5 seemed to be that, well, there's so much blood and mucus and other
6 electrolytic fluid in the area that you're trying to treat, wouldn't this Figure
7 5B embodiment of the patent have the same problem?
8 MR. STERN: That's exactly right, Your Honor, and that's our
9 position. If the Makower ring electrodes would be hopelessly inoperable
10 because, I don't know if you can see my hands, but if there's tissue on this
11 side and something else on the other side, if the Makower -- they're saying
12 this side would be fluid, right.
13 And that the energy would run into the fluid as opposed to into the
14 tissue. Makower is hollow, right? Makower has the struts and so there's a
15 hollow space in between. But the Figure 5B of the patent is a ring electrode,
16 it would be pressed against the operative tissue and it would be delivering
17 energy into the tissue and then something would be on the other side.
18 So, fluid is going to be there for the hollow, it's going to be there
19 for the Figure 5B electrode as well, ring electrode as well. And the Patent
20 Owner has not explained how Figure 5B could be operable and covered by
21 the claims, which they say it is, and Makower would not.
22 Those are really inconsistent. Either there's fluid there, in which
23 case nothing works, or there's not fluid there, in which case, what Dr. Bu-
24 Saba testified is folks do this every day. He's performed 300 surgeries a
25 year in the period prior to 2006, including RF electrode procedures.

1 Dr. Bickson has testified that these procedures happen all the time,
2 Dr. Levine did the same. It wouldn't be possible to perform these
3 procedures if the anatomy was as they say it is. And that's where the
4 precision is important. The question is at the site of this operation, is there
5 fluid that would render this as being fatally defective? The answer to that,
6 we think, clearly established by Dr. Bu-Saba and Dr. Levine's testimony, is
7 no.
8 Just very quickly, Your Honors, unless you have any questions on
9 Makower, I'll just very briefly address the lateral claims and the
10 (INDISCERNIBLE) energy claims. If we turn to Slide 67. So, on the lateral
11 energy delivery, and apropos of your question, Your Honor, about Figure
12 5B, there's no dispute that Figure 5B delivers energy uniformly and laterally.
13 So, to the extent that there's this argument that Makower doesn't
14 delivery energy laterally because it has ring electrodes, that's just
15 inconsistent with Figure 5B. Dr. Levine testified that both are true in
16 Exhibit 1089, Page 194, 5 to 7. And we think that just takes care of the
17 lateral delivery claims.
18 The Patent Owner did address these claims three different ways,
19 three different petitions. They actually didn't address it in the POR for the
20 '669 at all, it's only an expert declaration. And for the other two, they sort of
21 take different views of what the reference is disclosing. In any way, the
22 devices teach delivering energy into tissue, which is lateral.
23 And if we go to Slide 66, this is Claim 4 of the '077 Patent. The
24 question is whether -- and the claims require, quote, "multiple pairs of
25 bipolar electrodes." Stern recites pairs, plural with an "s", eight independent

1 times in its disclosure. The Patent Owner's argument, and this is on the left
2 of Slide 66, appears to be that it's not enough that Stern discloses pairs of
3 electrodes utilized sequentially.
4 We don't agree that that's the only way Stern discloses using pairs.
5 It says explicitly that they could be used together. But even if taking Patent
6 Owner's assumption, they admit, they acknowledge that Stern teaches
7 sequentially.
8 Let's look at the '077 Patent specification, the only place, the only
9 place that pairs are mentioned it says multiple pairs of electrodes may be
10 activated in a sequential manner. So, Stern teaches pairs of bipolar
11 electrodes in as much detail as the challenged patent does.
12 Last thing I'll say and I won't dwell on this because I didn't see it in
13 Patent Owner's demonstratives and our papers are fulsome on this issue. In
14 terms of the person of ordinary skill in the art, we've offered testimony from
15 Dr. Bu-Saba, who is a Harvard Medical School professor and has over 25
16 years of experience as an otolaryngologist and Dr. Martin, who's an
17 accomplished engineer. We think their testimony is fully commensurate
18 with the scope of their experience.
19 And as we point out in the papers, there's no relevant dispute for
20 which they say either is unqualified. The dispute about definition of
21 POSITA seems to be outcome oriented. They are trying to disqualify our
22 experts as opposed to having a particular issue that is actually an issue.
23 We supported their testimony not just by their say so; we've
24 submitted over 100 exhibits in this proceeding, the Patent Owner submitted
25 nine. Six of those are declarations, CVs, and transcripts. We have provided

1 to the Board a fulsome factual record that demonstrates that each of the
2 challenged claims would have been obvious and we respectfully request that
3 each of the claims be cancelled. So with that, I'll reserve the rest of our time
4 for rebuttal, unless Your Honors have any questions.
5 JUDGE MITCHELL: Thank you.
6 MR. STERN: Thank you.
7 JUDGE MAJORS: You have by my count, just so you know,
8 Petitioner, you have 15 minutes left.
9 MR. STERN: Thank you, Your Honor.
10 JUDGE MAJORS: All right. Mr. Briggs, whenever you're ready,
11 you can begin.
12 MR. BRIGGS: Yes. Judge give me a second, Your Honor, to set
13 up with co-counsel.
14 JUDGE MAJORS: No problem. Do you want 15 on, or put 60 on
15 the clock and then if you need to get into your rebuttal time, that's -- you can
16 do so at your choice.
17 MR. BRIGGS: That works, Your Honor. Thank you. Okay.
18 Good morning, Your Honors. Thank you for having us at the hearing today,
19 we appreciate the opportunity to be heard. If Your Honors could please go
20 to Slide 2 of Patent Owner's demonstratives?
21 As Your Honors have already indicated, we have three different
22 patents at issue today across the three different IPRs. And just for ease, I'm
23 going to refer to those generally as "the patents" or "the IPR" with the
24 understanding that the issues are generally common across the IPRs and the
25 patents. And typically today, also in the interest of efficiency, I'll be

1 referring to the record for the '675 Patent unless I indicate expressly
2 otherwise.
3 If Your Honors could please go to Slide 6. As Petitioner pointed
4 out, there's four basic disputes between the parties and the first relates to
5 what is the correct priority date of the patents at issue. And we believe it's
6 the July 21st, 2006, priority date which encompasses a written description
7 support issue which I will address here in a minute and a priority chain issue.
8 The second dispute is whether the Petitioners have carried their
9 burden to show that the Makower and Fang references render obvious the
10 challenged claims.
11 The third dispute relates to whether Petitioners have established
12 that Makower delivers energy laterally. And finally, whether the Stern
13 reference disclosed multiple pairs of bipolar electrodes and that is for the
14 '077 Patent only as we just heard spoken from Counsel Stern.
15 So, if Your Honors could please go to Slide 11. As Your Honors
16 recognized during institution or at institution, the claims of the patents
17 require the administration of energy sufficient to achieve, in this case of
18 Claim 1, administering therapy to the target tissue such that mucus secretion
19 is reduced.
20 And that has to be achieved via the energy of the claim or in Claim
21 1 of the '675 Patent could also be via heat, but generally has to be achieved
22 by energy delivery. And Judge Snedden asked whether it's an energy-only
23 requirement and we point Your Honors to that that answer to that is yes, it is
24 an energy-only requirement.
25 And that's clearly shown by the dependent claims across all of the

1 patents which require or say where in the method, for instance in the '675
2 Patent, it says when the method further comprises delivering an agent.
3 And so, we know from claim differentiation that the Claim 1 does
4 not require the delivery of the therapeutic agent and therefore it is an energy-
5 only requirement across the patents. So, I hope I've answered your question
6 on that, Judge Snedden. Okay.
7 JUDGE SNEDDEN: Yes. Thank you.
8 MR. BRIGGS: If Your Honors could please go to Slide 12. As
9 Your Honors are aware, the written description for this specification has to
10 show possession of the invention. And in institution, Your Honors rightly
11 pointed out that the patents discuss reversible porated energy.
12 But what was not discussed in the institution decision or in the
13 petition is the section of the patent that we have here where there is a
14 disclosure of non-reversible poration. And I'd like to read through this
15 because it's important to understand what the language here means. And so,
16 it says, "According to the present invention," and it lists a bunch of toxins, it
17 says, "are delivered to a patient's nasal membrane while applying energy" --
18 while applying energy -- "to target cells within the membrane under
19 conditions which cause a reversible (or in some instances non-reversible)
20 poration of the cell membranes to enhance delivery of the toxin cells."
21 What I think's really important here is we're talking about
22 delivering energy and that's a genus and we have two species of energy
23 delivery. We've got reversible delivery, energy delivery, and we've got
24 irreversible energy delivery.
25 And then, if you read through the rest of the patent, the inventors

1 chose to say energy over and over and over again. They did not choose to
2 say reversible poration over and over and over again, they chose to say
3 energy delivery over and over again, which evidences an attempt to have any
4 broader encompassing amount of energy, it can be reversible or it can be
5 non-reversible.
6 JUDGE MAJORS: Mr. Briggs, I have a question.
7 MR. BRIGGS: Sure.
8 JUDGE MAJORS: Even accepting this, your premise about being
9 a genus, as I read this passage, it's still saying energy is given along with a
10 toxin. So, where is there a disclosure in the priority applications and if you
11 want to point to the patent disclosure, that's fine, it's been done throughout
12 this proceeding, but where is there a disclosure where only energy is applied
13 without the combination of a toxin?
14 MR. BRIGGS: So, yes, and let's talk about that, Your Honor. So,
15 let's read this paragraph or this sentence one more time, "… energy to target
16 cells within the membrane under conditions which cause a reversible," this
17 time let's skip the parentheses, "which cause a reversible … poration of the
18 cell membranes to enhance delivery of the toxin into the cells." That makes
19 sense, reversible energy enhances delivery of toxin into the cells.
20 Now, let's not skip and let's just talk about the non-reversible side
21 of it. "…energy to target cells within the membrane under conditions which
22 cause (in some instances non-reversible) poration of the cell membrane."
23 So, that's expressly disclosed.
24 And then if we talk about the next few words, "…to enhance
25 delivery of the toxin into the cells." That doesn't make any sense, to read it

1 that way. This is how Petitioners are reading it, that you're going to use non-
2 reversible poration to enhance delivery of the toxin to the cells.
3 That's not what happens. When you apply irreversible poration,
4 you have cell death, as Judge Mitchell asked about. And if you have cell
5 death, they're a) it's not clear that you can actually get toxin in because
6 there's no pores; and b) there's no reason to do so because the cells are dead.
7 And so, in answer to your question, if you now go to Slide 16, in the very --
8 JUDGE MITCHELL: Can I ask you a question --
9 MR. BRIGGS: -- below the, I'm sorry.
10 JUDGE MITCHELL: Go ahead, go ahead.
11 MR. BRIGGS: In the very next paragraph, below the one we were
12 just talking about, we have again, talking about energy. The energy is
13 preferably selectively applied to targeted regions containing a variety cells,
14 including goblet cells and it goes on.
15 The second sentence, and I think this is what is our point, "it will
16 be appreciated that the energy may be applied to the regions of the nasal
17 membrane which are the same or different from the regions to which toxin
18 has been introduced."
19 So, that's an express disclosure of applying energy to a region
20 where you're not going to apply toxin. And so that, in our opinion, is written
21 description support for the application of energy without applying toxin.
22 So, Judge Mitchell asked on opening, you know, what is the
23 definition or what is irreversible poration disclosed to a POSITA, and if we
24 could please go to Slide 13, Dr. Bu Saba's opening testimony pretty much
25 proves that irreversible poration is equivalent to ablation in the context of

1 these patents.

2 This is before Dr. Bu-Saba realized that the patents disclosed non-
3 reversible poration. He does not address in his opening declaration what this
4 non-reversible poration means. So, we pointed out what it means, that he
5 changes he opinion. But his initial opinion is, "irreversible poration occurs
6 when the cell membrane does not reseal, the cell breaks down."

7 I think that's conclusive proof from their own expert that we do
8 have cell breaking down, cell death. Dr. Bu-Saba continues in that opening
9 declaration to contrast reversible electroporation to ablation. And this is
10 another excerpt from his opening, "While reversible electroporation is
11 designed to maintain the operation of cells and enhance their treatment by
12 other therapeutic agents, ablation on the other hand is designed to alter or
13 destroy the cells."

14 And that testimony right there is consistent with what happens with
15 irreversible poration. And don't even believe us, believe their own
16 reference, Rubinsky, which is what Dr. Bu-Saba cites in his opening brief on
17 what does irreversible electroporation mean.

18 Rubinsky itself explains that irreversible poration, and I'm going to
19 quote Paragraph 113 of Rubinsky. It says, "The present invention shows
20 that irreversible electroporation by itself produces substantial tissue ablation
21 for the destruction of undesirable tissues in the body."

22 So, it's our opinion that the record evidence clearly shows that
23 when you have irreversible poration as disclosed in the patents at issue, you
24 have ablation.

25 JUDGE MITCHELL: Can I ask you a question about, on Slide 12,

1 and how you're reading the parenthetical? In your mind, is this giving an
2 either/or, you either have pretty much reversible poration or you have non-
3 reversible?
4 So in some instances means pretty much you've got almost all the
5 cells are ablated or they're non-reversibly porous now. Is that sort of how
6 you're reading it as an either/or? Not that, I'm treating and so I'm going to
7 kill some cells just because that's going to happen, but I'm going to have a
8 lot of porosity in most of the cells there, but some are going to die?
9 MR. BRIGGS: We're reading it, I think, in the way you mention
10 it, the first way, Your Honor. Which is, the express language it says, "or in
11 some instances," it doesn't say and in some instances. If they wanted to
12 really tie the inventors -- tie reversible to non-reversible occurring at the
13 same time, I think they would use the word "and", but they say "or in some
14 instances non-reversible poration."
15 Now, we'll see later Petitioners have a different take on this but
16 that also proves our case on written description support. But our
17 understanding of this reference -- as this disclosure, excuse me, is that it's an
18 option. You can do reversible or in some instances you can do non-
19 reversible.
20 JUDGE MITCHELL: And then you're saying, then that last part
21 of the sentence would not modify the instances that are non-reversible so --
22 MR. BRIGGS: Exactly, because it's parentheses around it. And in
23 the writing of this, maybe the inventor is a little sloppy, but I think by clearly
24 conveying that energy over and over and over again, as opposed to using
25 reversible over and over again, evidences intent that the energy delivery was

1 supposed to be broad, reversible or non-reversible.
2 And then they also talk about applying energy -- could you please
3 go back to Slide 16, as we've talked about, to regions or toxins not delivered.
4 And it's our position that those two things together evidence an intent to
5 apply energy in a non-reversal manner to tissues that include goblet cells
6 right above that, goblet cell tissues.
7 And if you please go to Slide 17, it's pretty much undisputed that
8 when you ablate goblet cells, you are achieving what the claims require.
9 You're achieving the reduction of mucus secretion. You're achieving the
10 reduction of congestion and you're treating rhinitis. And if we could please
11 put up Petitioner's '675 petition, page 13.
12 JUDGE MAJORS: Mr. Briggs, how does the skilled artisan know
13 from reading the specification that accepting your premise that irreversible
14 electroporation equals ablation, how do they know that that provides the
15 treatment contemplated by these claims?
16 MR. BRIGGS: That's exactly why I'm putting up the petition at
17 page 13, Your Honor. My co-counsel -- I'll just -- I have it right here. So,
18 I'm in the '675 petition at page 13, the third full paragraph, it says, "A
19 distinct but well-known technique was to use ablation devices to deliver
20 energy to destroy cells that caused rhinitis symptoms."
21 So, and we heard Mr. Stern, and I think it's Petitioner's Slide 62
22 talk about over and over again, oh, when you ablate cells, you're going to
23 treat rhinitis. So, I don't think it's a dispute. And both experts agree that
24 when you're ablating goblet cells, you are treating rhinitis, you're reducing
25 mucus secretion, you're reducing congestion.

1 JUDGE MAJORS: Is the therapeutic result inherent once you
2 ablate some of the goblet cells?
3 MR. BRIGGS: I don't know if inherent is the correct word. But
4 let's go -- excuse me. I think it's understood by persons skilled in this art as
5 evidenced by their own expert's testimony and our expert's testimony that
6 when you apply irreversible porated energy to goblet cells, you are going to
7 treat these conditions.
8 JUDGE MAJORS: That sounds like inherency, no?
9 MR. BRIGGS: I think it's more that you understand what's going
10 to happen, not that it necessarily happens, which I think an inherency is a
11 necessarily standard. And we're talking about a disclosure standard for
12 written descriptions for it, not like inherency, in the context of anticipation
13 or obviousness, so that's why I'm hesitant to adopt inherency here, Your
14 Honor. I think it's an express disclosure.
15 JUDGE MAJORS: Okay. Let me ask a slightly different question.
16 And so, if I'm looking at Claim 1 of the '675 Patent, now that's when I have
17 my medical device, my catheter or what, in distal portion, et cetera, et cetera,
18 and I apply energy to that, it's sufficient to irreversibly electroporate the
19 target cells in the nasopharyngeal passage, have I practiced this claim?
20 MR. BRIGGS: Let me just restate it to make sure I'm sure getting
21 this right. If we stick one of the devices that's described in the patents into
22 the nasopharyngeal passage and we apply irreversible porated energy to the
23 target tissue ablating goblet cells, yes, you are practicing the scope of this
24 claim.
25 JUDGE MAJORS: Okay.

1 MR. BRIGGS: If Your Honors could please go to Slide 18. Slide
2 18 summarizes our positions throughout the briefing. We have energy,
3 which is a genus being disclosed throughout the patents over and over and
4 over again. One species of that is irreversible poration energy, which the
5 record suggests, disclosed it to POSITA, ablation. That region is applied to
6 an area that is different than the area of the toxin delivery.
7 It's also applied that energy is also applied to goblet cells and by
8 doing that, you are going to reduce mucus secretion, you are going to reduce
9 congestion, you are going to treat rhinitis. And we believe for those reasons
10 alone, there is written description support for the claims.
11 But even more, Petitioner's reply argument proves we're correct.
12 Now, if you could please go to Slide 19. This is Dr. Bu Saba's reply
13 testimony. This is not us cross-examining him or trying to get answers out
14 of him or trick him or anything like that. This is him on his own saying
15 what he believes the non-reversible disclosure means in the '675 Patent.
16 And he says, "That is, the '675 Patent's single reference to non-
17 reversible poration simply acknowledges that some cells will be incidentally
18 destroyed when reversible poration energy is applied." So, after looking at
19 the patents and not addressing it in opening, but after looking at the patents,
20 Dr. Bu-Saba seems to agree with us that you are destroying cells when you
21 apply non-reversible porated energy. If we go to Slide 20.
22 JUDGE MITCHELL: Can I ask you a quick question?
23 MR. BRIGGS: Sure.
24 JUDGE MITCHELL: So, at that point when you have irreversibly
25 porated the cells, so I mean, they're dead in your view, so there can be

1 obviously no uptake of the -- any toxin?
2 MR. BRIGGS: Yes. If we could please go back to Slide 19. I'm
3 going to make two points. One is you asked earlier, Your Honor, Judge
4 Mitchell, if non-reversible poration destroys the cells. Clearly, the answer to
5 that is yes, by their own expert.
6 So, if the cells destroyed, my understanding they can coagulate,
7 there's no pores left over to put the toxin in at that point in time, in fact, it
8 makes no sense to do so. That's why in our opinion, the patents allow for a
9 region of energy delivery that is different than a region of toxin delivery.
10 So, does that answer your question?
11 JUDGE MITCHELL: Yes, very good.
12 MR. BRIGGS: Now if we could please go to Slide 20. Again, Dr.
13 Bu-Saba in reply, this is not on cross-examination, this is him just talking
14 about what the challenged claims require. He says, "…the challenged
15 claims at issue do not require any efficacy measure or" any "particular
16 degree of efficacy." And then if we go to Slide 21.
17 JUDGE MAJORS: Do you agree with that, Mr. Briggs?
18 MR. BRIGGS: We do for the purposes of written description, we
19 do. So, if we go to Slide 21. So, we know from the patent so, if you have
20 energy delivery, that energy delivery can be co-extensive or partially
21 overlapping or different than where the toxin is delivered.
22 And as we pointed out in reply, the energy or the toxin delivery
23 may be in -- and I'm in the middle of kind of this paragraph here where it
24 says, "The region where the toxin is introduced may comprise a portion of
25 the nasal cavity…" and I'm going to skip, "…the nasal passage, two or more

1 paranasal sinuses, or in some cases may comprise substantially the entire
2 nasal cavity of the patient…."
3 So, we've got toxin delivered to the entire area and if we believe
4 what Dr. Bu-Saba says, that when you're applying reversible energy, you're
5 going to get in some instance -- you're going to get incidentally destroyed
6 cells and you're applying all of that energy to the nasal cavity, you are going
7 to be treating a substantial volume of tissue with irreversible energy
8 according to his own analysis. And that also shows written description
9 support for the claims.
10 If we could please go to Slide 22. So, what we've overlayed here
11 is what we had earlier on top of what the reply shows, which just confirms
12 that what the patents disclose reasonably conveys to a person of ordinary
13 skill in the art that they had possession of energy-only delivery to achieve
14 the things that are claimed in the patents. And if Your Honors have no
15 further questions on written description, I'll move to priority.
16 The only thing I want to mention on priority in the interest of time
17 is Slide 29. So, Counsel for Petitioner encouraged Your Honors to go look
18 at the rule, we agree. And Your Honors in the opening cited the Maziere
19 case, that's been cited repeatedly throughout Patent Office proceedings for
20 decades as allowing for exactly what happened here.
21 And they somehow say that Maziere is not good law anymore
22 because it was overruled by this rule. Well, that's plainly not true, because
23 we look what the MPEP actually said, it says in 2004, which is after
24 Maziere, the Office codified in those rules existing practice. Maziere was
25 existing practice, so we know that it was -- Maziere was codified in to the

1 rule.

2 I will now move to Makower. If you could please go to Slide 31.
3 So, it's our position, Your Honors, that the patents are entitled to the July
4 21st, 2006, date. And with that being the case, the only ground that remains
5 are the Makower based grounds and I will now address those grounds.

6 If Your Honors could please go to Slide 34. As we pointed out in
7 our briefing, Makower has some very long background. It has 40
8 paragraphs where it's explaining the state of the art and also provides the
9 reason why Makower is offering this invention.

10 And if we look on Slide 34 here, we're at Paragraph 36. And
11 Makower says, "One of the reasons why FESS and sinus surgery is so
12 bloody and painful relates to the fact that straight instrumentation with rigid
13 shafts are used."

14 And many, many paragraph before this, he's talking about all the
15 problems with rigid shafts. So, at the bottom of the Paragraph 36, though,
16 he says in bold and underlined here, "…there exists a significant opportunity
17 to reduce the morbidity of sinus intervention through the use of flexible
18 instrumentation and guidance." If we could go to Slide 35, please?

19 The very next paragraph, Makower says, "If flexible tools could be
20 developed…" it goes on, "Further, as described here, flexible
21 instrumentation may allow," so we've got a background problem, we've got a
22 background solution. And if we go to Slide 36.

23 In kicking off the summary of the invention, Makower provides an
24 overview paragraph, 42. But the very next paragraph kicking off the
25 summary of the invention is, "In accordance with the present invention,

1 there are provided methods wherein one or more flexible catheters or other
2 flexible elongate devices as described here are inserted in the nose…." And
3 Makower then has a litany of devices that can employe his flexible catheter
4 teachings.
5 If Your Honors could please go to Slide 37. We pointed out in the
6 reply, Makower is not small, Makower is a very large disclosure at 73 pages
7 long, 242 paragraphs of text, and with over 40 figures implementing
8 Makower's flexibility teachings.
9 If Your Honors could please go to Slide 39. Why did Petitioner's
10 select Makower? Well, we would submit that they selected Makower
11 simply because the examiner selected Makower. But the problem with that
12 is that the examiner said that Makower was the closest prior art, but that is
13 actually not the case.
14 If we actually look at Makower, we have a whole bunch of stuff on
15 flexible catheter teachings and we have one device, the Figure 5H device,
16 that has RF energy teachings. Now, I understand that you're allowed to take
17 a reference for all it teaches, but the question is why are you taking
18 Makower when it's relating to flexible catheters and has one device, Figure
19 5H, with nine sentences.
20 If we could please go to Slide 40. When it has nine sentences
21 describing this device. It just doesn't make sense in our opinion unless
22 you're applying hindsight analysis which is what we believe happened here.
23 So, what do we know about the Makower device? Well, not much,
24 because there's only nine sentences on it. And if you go to Slide 41, please?
25 We asked both experts, have you ever seen the device like Makower before

1 in your practice and both doctors, over 80 years of combined clinical
2 experience have never seen a device like Makower then or now.
3 If Your Honors could please go to Slide 42. Just like the Makower
4 device, Fang's device is unknown. We asked both experts have you heard of
5 this radio frequency device that Fang discloses? No, we never heard of it.
6 And if you could please go to Slide 43. We also asked the experts,
7 so you've looked at Fang, why isn't the efficacy criteria? I don't know.
8 Next, Slide 44. We also asked the experts, well, how did Fang calculate that
9 efficacy? I don't know.
10 Slide 45. It is undisputed that Fang did treat 63 patients. But we
11 don't know exactly what happened with those 63 patients. Dr. Bu Saba
12 agrees that Fang's unclear on this. Some of them received RF treatment
13 alone potentially, we don't know.
14 But many of them, a sum of them we also don't know, received
15 other medical procedures on top of the RF energy-only treatment. If Your
16 Honors could please go to Slide 46. So, as we pointed out in reply, what
17 does this mean?
18 And I'm going to read here, "Simply put, too many variables were
19 changed by Fang at once across an unknown number of patients while the
20 criteria for perennial allergic rhinitis and efficacy according to Fang
21 remained unknown."
22 So, we've got an unknown Makower device, we've got an unknown
23 Fang device, we've got an unknown efficacy criteria and somehow a person
24 of ordinary skill in the art is going to be motivated to use these references.
25 And if you could please go to Slide 47. Here's a summary of

1 Petitioner's obviousness analysis. The first part is Makower and Fang are
2 analogous art. The second is that there's a motivation to combine these
3 references, and the third is that there's a reasonable expectation of
4 successfully achieving what is claimed. I will deal with the reasonable
5 expectation of success argument first.
6 If we could please go to Slide 49. As we've already talked about,
7 the claims require applying energy-only to achieve a therapeutic result,
8 whether that's reduction of mucus secretion, reducing congestion, or treating
9 rhinitis. So, the Makower device has to be able to achieve those results,
10 reasonably be expected to achieve those results for Petitioners to succeed on
11 their obviousness argument.
12 Slide 50, please. So, here is Petitioner's entire argument on
13 reasonable expectation of success in their petition. "Because Makower and
14 Fang are directed to the same problem … types of energy delivery devices,
15 and solutions … a POSITA would have had a reasonable expectation of
16 success in using Makower's known RF device according to a known method
17 to reach the predictable result taught in Fang and Chen." That's it. That's
18 their entire reasonable expectation of success analysis. If we go to Slide
19 51 --
20 JUDGE MAJORS: Mr. Briggs, Petitioner stated in his
21 presentation that Patent Owner didn't address at all the Chen reference, is
22 that accurate?
23 MR. BRIGGS: Well, we address what put in the grounds, Your
24 Honor, and the grounds are based on Fang. And if we look at all their
25 grounds, they don't have Chen in any of their grounds. By the way, they

1 also don't have Imran in any of their grounds which I can get to later.
2 And so on your In re Magnum Oil Tools and other Fed Circuit case
3 law, Patent Owner addresses what Petitioner puts forth in their grounds. We
4 understand they believe Chen discloses certain things, but we don't need to
5 address Chen in our reply because that's not part of their grounds.
6 JUDGE MAJORS: Well, I understood their position to be that
7 they were using Fang for purposes of targeting a certain region of the, like
8 you said, the nervous complex, or the cellular complex in the nasal cavity,
9 and to provide RF energy against that. And it seemed to me on reading
10 Chen, it does something very similar.
11 So, Petitioner's position seems to be that it was well-known as
12 reflected in both Fang and Chen that this is a region that you want to target
13 in the nasal cavity for therapeutic effect. I understand your point that it's not
14 officially part of the combination of references.
15 But I would disagree that Petitioner's position is so narrow that
16 they weren't pointing to other references, Chen, Arora, and others that they
17 stand for the proposition that it was well-known that you ablate these tissues
18 in certain region of the nasal cavity that you provide therapy.
19 MR. BRIGGS: I understand your point, Your Honor. I still am
20 not understanding why they didn't use a different reference than in
21 combination with Makower as part of their grounds. They chose to use
22 Fang. That's their choice.
23 As Petitioner, and as they say in SAS, you're allowed to direct this
24 panel to where you want to go. I don't know why they didn't use Chen or
25 any of those other references, their secondary references, and so as part of

1 our duty as a Patent Owner, we addressed what's in their grounds. And if
2 Chen discloses certain things to support their case, I don't know that that is
3 helpful as it relates to the grounds at issue here.
4 JUDGE MAJORS: Well, you don't dispute that Chen is addressed
5 in their papers and in their expert's testimony though, do you?
6 MR. BRIGGS: Of course, it's in their papers and it's in their expert
7 testimony as part of the record, but it's not a part of their grounds.
8 JUDGE MAJORS: Okay.
9 MR. BRIGGS: So, returning to Slide 51, Your Honors. What we
10 have here is nearly the entirety of Makower's disclosure on the Figure 5H
11 device. There's a few sentences toward the bottom that wouldn't fit nicely,
12 so I just cut them off, because they sure don't matter for this discussion
13 anyway.
14 But this is it, out of 242 paragraphs and 73 pages of text, this is
15 what we know about the Makower Figure 5H device. And there's very little
16 detail. We know that there's struts, we know that there's electrodes, we
17 know that there's a hollow interior, but that's about all we know.
18 And if we go to the next slide, Slide 52. Petitioner says, oh, those
19 aren't ring electrodes and we disagree, they never undertook analysis of what
20 Figure 5 actually is. And so as we pointed out in our Patent Owner
21 response, that this is a perspective view of Figure 5H, this is not a cross-
22 sectional view.
23 And with that perspective, our expert, Dr. Bickson testified, oh,
24 this is a perspective view and a person of ordinary skill in the art is going to
25 know that those are ring electrodes because they wrap around the entire

1 strut, they're not placed on the surface of the strut. So, the most straight
2 forward and correct reading of the Figure 5H device is that these are ring
3 electrodes and there's nothing in Makower suggesting that they're anything
4 else. Slide 53.
5 JUDGE MAJORS: Mr. Briggs, I have a question about Makower.
6 Patent Owner is not taking the position that Makower is non-enabled, is it?
7 MR. BRIGGS: So, non-enabled has not been used in these
8 proceedings. So it's two different terms that have been used. The
9 obviousness standard is a reasonable expectation of success which is what
10 I'm trying to address now.
11 And in the Petitioner's view there's some type of inoperability
12 argument. That's not what we made, as we pointed out, in our papers, the
13 device can be operable and still not have a reasonable expectation of
14 successfully doing what the claims require. And so, I'm not sure about the
15 non-enablement question.
16 JUDGE MAJORS: So, just for clarity, Patent Owner is not
17 arguing that Makower is either inoperative or non-enabled?
18 MR. BRIGGS: If you apply energy to Makower, we believe the
19 electrodes would power up. Now, where the energy would go is a
20 completely different issue and that's why there is no reasonable expectation
21 of success.
22 JUDGE MAJORS: But that's a different issue. The question is, is
23 Makower enabled for what it teaches?
24 MR. BRIGGS: I don't know that that's been briefed in this
25 proceeding, Your Honor, so I don't have a straight question to this. What we

1 did brief in this proceeding was whether enabled or not, whether there was a
2 reasonable expectation of successfully achieving the claimed conditions the
3 Figure 5H device, so I'm not prepared to give an enablement answer at this
4 time, Your Honor.
5 JUDGE MAJORS: You don't dispute that there's a presumption of
6 enablement here for a printed publication -- patent application, do you?
7 MR. BRIGGS: Correct. There is a presumption that generally,
8 things that are disclosed in the patent application should work the way they
9 say they work. But then even though Makower says that we'll heat or
10 cauterize tissue, we disagree, because I think that's what Your Honor is
11 getting at, we disagree that that's actually the case.
12 When you actually dig in -- this is a completely theoretical device,
13 never been seen before, Makower throws it in, into one of over 40 figures,
14 and says, hey, maybe you could ablate the nose with this.
15 And there's nine sentences. There's no actual description on how
16 this thing would actually function. And so while there may be a
17 presumption that it's enabled to energize the electrodes, even when you
18 energize the electrodes in a clinical setting, you're not going to treat the
19 target tissue.
20 So, if we could please go to Slide 53. I would like to remind Your
21 Honors that in the petition, Petitioner said there are no modifications to
22 Makower required. It's highlighted on the screen here, "Makower's device
23 would not require modification to achieve Fang's result."
24 So, their petition position is, oh, let's take Makower, use it, you'll
25 be fine. That is not true. Go to Slide 54, please. The problem with

1 Petitioner's analysis is that they failed to actually address what happens in
2 the clinical setting, which is there are liquids present during operation of the
3 Makower Figure 5H device.
4 Our expert testified that when you're ablating the nose with RF
5 energy devices or otherwise treating, there is going to be liquid present,
6 blood, mucus, saline, irrigation, whatever it is. And so, our expert testified
7 that -- excuse me, if you'll please go to Slide 54.
8 So, on cross-examination, Petitioners jump up and down and say,
9 oh, Dr. Levine testified that there is no issue. We've just, well, this is the
10 full quote of Dr. Levine's testimony. And what's clear from this quote is he's
11 not saying that you are getting rid of the liquids that are in the nose.
12 What he's saying is there's mucus present and it's very, very thick,
13 we'll irrigate with saline solution. But the mucus isn't the issue, it's not
14 talking about the mucus being the issue relative to an RF full ablation
15 technique, he's talking about it being an issue relative to the procedure.
16 And if Your Honors could please go to Slide 56. Dr. Levine's
17 testimony is entirely consistent with Petitioner's primary reference.
18 Petitioner's primary reference discusses liquids all over the place. Why?
19 Because liquids are in the nose and they're a problem when they're in the
20 nose or potentially a problem in the nose for choking and other hazards.
21 So, if we look on the left-hand side here, Makower, talking about
22 the present invention provides a comprehensive system of devices that effect
23 a fluid tight seal of the operative field. This fluid tight sealing of the
24 operative field permits the retention and collection of any blood or flushing
25 fluids released during the procedure.

1 And then in Paragraph 135, Makower specifically ties continuous
2 turnover of fluid within a sealed operative field to the Figure 5H device.
3 This confirms what our expert said, is that there are liquids in the nose
4 during operation.
5 So, how much of these disclosures did Petitioner address on reply?
6 None. Not an iota of Makower's liquid disclosures do they address on reply.
7 And I would submit, Your Honors, that if Petitioner has a primary reference,
8 and their primary reference talks about liquids in the nose and their
9 argument is there's no liquids in the nose, that they should have, and were
10 required to, address the teachings of the primary reference on this issue and
11 they didn't.
12 It's our position that if you don't even address what the primary
13 reference talks about in terms of liquid in the nose, you can't possibly carry
14 your burden to show obviousness, especially in a reasonable expectation of
15 success context as we have here. They have no evidence that counters
16 Makower's disclosures of fluid in the nose other than their own expert's say
17 so.
18 Your Honors, please go to Slide 57. With liquids in the nose, it is
19 undisputed that the energy delivered from Makower's device will go into
20 those liquids and not into the tissue. They don't dispute that in their reply
21 that if there's liquids, the energy delivery will be preferentially into the
22 liquid and not into the tissue and therefore there is no ablation or treatment
23 of that tissue.
24 If Your Honors could please go to Slide 58. So, with that, Your
25 Honors, even if there is a motivation to combine, which I will deal with in a

1 second, we believe that they have not carried their burden to show that there
2 was a reasonable expectation of successfully achieving the claimed
3 therapeutic methods of the patents.
4 I want to point out one other thing. If we could look at Petitioner's
5 Slide 52. And we don't even need to do that. We heard from -- we can, but
6 we don't need to do that because on opening Petitioner's Counsel mentioned
7 that, oh, Makower is not limited to flexible devices. It's limited -- it also
8 talks about working devices. In fact, those are claimed.
9 Let's look -- and they point to Claim 1 in their briefing, not only
10 the reply at 10, but in the petition of the '675, that's at page 69. So, let's go
11 look at Claim 1 of Makower and see what it says. And this is located on
12 page 25 of Makower. There's a claimed method, it said, "The method for
13 diagnosing and/or treating sinusitis or another disorder…" and I'm going to
14 skip in the interest of time to Step A, and it says, "…placing a port device in
15 the nostril or nasal cavity on at least one side…" so on and so forth, a few
16 lines down, "…a valve that is operating it to allow a working device to be
17 inserted through the device, insert port, while preventing blood or fluid from
18 back flowing out of the device into a port at least when no working device is
19 entered there through, advancing the device in…" excuse me, go down,
20 "…and using the working device to perform a diagnosed therapeutic effect."
21 What Makower describes about this, is you have these ports that
22 allow the working devices to go in, but not let the liquid leave. So, if we're
23 to believe Petitioner on face value that Claim 1 supports their working
24 device construction, we also have to agree that there are liquids in the nose
25 as shown by Claim 1 during operation of those working devices.

1 With that, Your Honors, I will now move to motivation to
2 combine, which is, if we could please go back to the Slide 62 of Patent
3 Owner's. Check the slides.
4 I briefly touched on this -- so I've already touched on this, I will
5 just briefly point out that we have an unknown devices, we have unknown
6 efficacy criteria with an unknown number of patients being treated, so why
7 would a person of ordinary skill in the art combine all of these unknown
8 things.
9 And I think the obvious answer to that from my perspective, Your
10 Honors, is Petitioner needed Makower to eliminate all claims of the patents.
11 If you really want to treat perennial allergic rhinitis with a known device or
12 with any device, you're going to go after devices of at least a person of
13 ordinary skill in the art devices that aren't unknown, why not just use Fang's
14 devices. The hanging question that nobody's asked.
15 So, that's the most obvious solution here is to use Fang's device, or
16 Chen's device, or another device to treat perennial allergic rhinitis. The
17 answer is not to go to an unproven, unknown Figure 5H device that's a throw
18 away device and a patent that's got over 40 embodiments related to flexible
19 catheters. So, but what I'd really like to do is to dive into a few of
20 Petitioner's rationales.
21 Please go to Slide 63. We've already talked about that they say
22 Makower is the closest prior art. That's just adopting the examiner's
23 contention without any analysis. We don't think that's a sufficient rationale
24 to support a motivation to combine.
25 If Your Honors could please go to Slide 64. Their second rationale

1 is Fang provides more details on Makower's device. That's plainly false.
2 Neither expert knows what this device looks like and they don't know how it
3 works or how it operates. So that is just incorrect.
4 If Your Honors could please go to Slide 65. The third rationale is
5 that Fang teaches RF energy treats rhinitis and they cite certain portions of
6 Fang. Well, the portions of Fang that they cite is Fang citing other people's
7 references or citing other references with which the footnotes or endnotes
8 right next to all of those sentences clearly indicate.
9 If Your Honors could please go to Slide 66. Their fourth rationale
10 is because Makower says additional details of its devices were well known
11 one would be led to Fang. I don't quite get the logic behind this, how
12 Makower's additional details of its devices were well known. Well, if it's
13 well known, where are those details and it's certainly not in Fang which had
14 an unknown device that who knows how it's going to be compared to the
15 unknown, unproven Makower device.
16 If we could please go to Slide 67. Petitioner's fifth rational is that
17 Fang explains the mechanism and outcome of Makower's method. That also
18 is plainly false. Fang used a completely different device, that we don't what
19 it looks like, and we don't know how Makower's outcome would be affected
20 in view of Fang. That's another illogical rationale.
21 If we please go to Slide 68. So, in sum, we believe that the
22 rationales are improper and illogical. We believe that there's an entirely
23 hindsight driven analysis here to get to the claimed invention. And under
24 those circumstances, we don't believe the Petitioners carried their burden to
25 show that the claims are invalid.

1 If Your Honors could please go to Slide 70, I'd like to address the
2 lateral issue. So, all dependent claims of the patents require the energy
3 element or some type of energy configuration that concentrates or delivers
4 energy laterally.
5 And what I'd like to point out, Your Honors, is that the patent
6 owners here or the inventors here act as their own lexicographer. This is
7 pointed out in our briefing. If we could please go to Slide 71. What we
8 have here are two excerpts from the patent and we also have a -- excerpt of
9 figures from the patent so we also have an excerpted statement verbatim
10 from the patent. "Figure 5A," as per the patent, "depicts an arrangement of
11 electrodes that produces an electrical field concentrated in the lateral
12 direction."
13 So, that according to the inventors, that electrical field that's shown
14 in Figure 5A is a lateral energy delivery. Figure 5B, conversely, is uniform
15 energy delivery. Again, this is the inventors as their own lexicographer.
16 So the question becomes when you evaluate the prior art, is that
17 energy delivery more consistent with Figure 5A? If so, then it's delivering
18 energy laterally. Or, is it more consistent with Figure 5B? If so, it's
19 delivering energy uniformly, per the parlance of the patent.
20 If Your Honors could please go to Slide 72. As we pointed out
21 earlier, all the record evidence indicates the Makower's ring electrodes are --
22 or Makower's electrodes are ring electrodes. And at this point in time, if I
23 could go back to Slide 53 one more time.
24 Again, in the petition, they say Makower's device would not
25 require modification to achieve this result. So, they have to live with

1 whether Makower alone discloses the lateral energy delivery requirements.
2 The claims, if you could please go back to Slide 73 -- 72, excuse
3 me. Ring electrodes do not deliver energy laterally. They deliver energy
4 uniformly as our experts testified, therefore, Petitioner cannot carry its
5 burden to show that the dependent claims are obvious.
6 Now, if we move to Slide 73. Petitioner's use Imran to try to fix
7 Makower. Recognizing that Makower does not disclose energy uniformly,
8 they go, well, let's use Imran instead. Are they entitled to use Imran? No.
9 If we could, could you please go to Slide 74.
10 Here is the actual language from Makower as it relates to Imran
11 and the 19 other patents that are listed in this paragraph. As we pointed out
12 in our surreply, the actual language of Makower is some of the working
13 devices shown in Figures 5A through 5Y, which includes Figure 5H, and
14 described herein, incorporate assemblies. It doesn't say may incorporate or
15 could incorporate or could contemplate to be incorporated.
16 They incorporate, i.e., they already have the things that are
17 required to operate. We believe that this is Makower making an enablement
18 argument saying, hey, these things have certain assemblies already, a person
19 of ordinary skill in the art knows how those are constructed, go look at these
20 patents if you need additional help on your enablement issue.
21 I'd also point out that after the long listing of patents here, there is
22 no incorporation by reference to any of these patents, it's just a long listing
23 of patents. So, Petitioner's use of Imran in the petition for the lateral claims
24 is completely inappropriate and it's not part of their grounds especially when
25 they say they will achieve Makower's device alone should achieve Fang's

1 result. And so if we could please go to Slide 75. We point out --
2 JUDGE MAJORS: Mr. Briggs, why is Makower's disclosure that
3 the, well, tissue adjacent to the struts will be cauterized or heated. Why isn't
4 that sufficient to teach or suggest lateral energy?
5 MR. BRIGGS: Because the energy delivery of a ring electrode is
6 uniform across the whole circumference. So while it -- we -- first of all, we
7 don't believe energy is being delivered to the tissue, given the liquid issue,
8 but even assume that you could be delivered to the tissue, it's also -- the
9 energy is emitting in all directions from a ring electrode. That is not within
10 the scope of the claims of the patents as per the parlance of the patents.
11 Uniform energy delivery, when it goes in all directions, if we could please
12 go back to Slide 71, please.
13 JUDGE MAJORS: Give me one second to get back there, please.
14 MR. BRIGGS: Sure. In the Figure 5B device here, which does
15 not have a hollow interior like Makower does, by the way, this device would
16 also presumably cauterize tissue, but it's delivering energy uniformly
17 because it has ring electrodes just like Makower does. So, it's inconsistent to
18 interpret Makower to be aligned with Figure 5A when the record evidence
19 certainly shows that it's aligned with Figure 5B.
20 JUDGE MAJORS: None of this was argued in the Patent Owner
21 response, was it?
22 MR. BRIGGS: Yes, it was. It was argued in the Patent Owner
23 response. I believe one of them, I think the '077, may have missed some of
24 these arguments, but certainly the '675, the '011, have all of these arguments.
25 JUDGE MAJORS: All right.

1 MR. BRIGGS: So, just going back to Slide 75, please. Imran is
2 not in any of Petitioner's grounds. There's no analysis of why Imran's
3 teachings should be used with the Makower device whatsoever. In fact,
4 Imran are a completely different type of catheter, it's an endocardial catheter
5 that has a new basket assembly for mapping or ablating a chamber of the
6 heart.
7 There's no analysis of why that disclosure's pertinent to Figure 5H
8 of Makower at all. And in reply, Petitioner realizing they have an issue, they
9 all of sudden start arguing Imran should be used for Claim 1. Well, that's
10 completely impermissible under Henny Penny and other Fed Circuit case
11 law that shows obviousness theory -- well, entirely new obviousness theories
12 on reply are required allowed.
13 So, Imran's use in the dependent claims in the petition, not
14 supported, not allowed. Certainly, Imran's use in the reply to try to
15 correcting the independent claims is completely improper.
16 And the last thing I will address Your Honor before I cede the rest
17 of my time is on -- actually one more thing, sorry. If we could please go to
18 Slide 76. As we pointed out in our reply, Imran's electrodes stay above the
19 surface, so even if it is considered, it still doesn't deliver energy laterally
20 because the energy's going more uniformly.
21 If we could please go to Slide 78. So, I think it was Judge Majors
22 who asked if there was any other overlapping IPR issues with the three
23 Aerin patent IPRs and as counsel for Neurent had already indicated, there is
24 one overlapping issue and it's relative to Claim 4 of the '077 Patent.
25 And here as counsel indicated, there's a Stern reference as being

1 applied, not only in this proceeding but in the three other IPR proceedings
2 which for the record are IPRs 2024-00277, IPR 00278, and IPR 00282.
3 And I mean, we just rest on the papers on this one, Your Honors
4 and we ask that Your Honors in this proceeding and the proceeding try to
5 interpret Stern and the claims consistently across the six proceedings.
6 Unless Your Honors have any questions, I will cede the rest of my time.
7 JUDGE MITCHELL: Okay. Thank you. You'll have 19 minutes
8 for rebuttal.
9 MR. STERN: Thank you, Your Honor, may I proceed?
10 JUDGE MITCHELL: Yes.
11 MR. STERN: Thanks very much. So, if it suits the Board, I will
12 address all of the issues in our rebuttal time. I first want to talk about written
13 description. And we're aligned here on what the standard is. The standard
14 is, does the specification demonstrate or reasonably convey to a person of
15 ordinary skill in the art that the inventors possessed the claimed invention?
16 What we heard from counsel and we saw on Patent Owner's side
17 18 is, well, if you take 1 plus 2, plus 3, plus 4, which is actually not in the
18 specification but it's sort of some understanding of a person of ordinary skill
19 in the art, then you can sort of put it together.
20 And that's not possession. Possession would be 10, the sum of 1,
21 2, 3, 4. There's -- yes, 1, yes, 2, yes, 3, and various parts of the specification,
22 but there's no pluses, there's no connection between these disclosures that
23 they relied on and the ultimate issue, which is does irreversible
24 electroporation in the specification, is it taught, is it described that the
25 inventors possess treatment with that element?

1 It is not. It's nowhere in the specification. There's not a single
2 discussion of the consequence of irreversible electroporation in the
3 specification. I'm sorry, did Your Honor have a question?
4 And we heard Patent Owner's Counsel refer a number of times to
5 the intent of the inventors and what the intent that might be conveyed from
6 various disclosures is. That's also not the standard, the standard is
7 possession, does the written description convey that the inventors possessed
8 this invention? It does not.
9 To Judge Majors' question about inherency. The Patent Owner has
10 not made an inherency argument, which I think they've conceded. And just
11 to confirm, the result here is not inherent. And that's what Dr. Bickson's
12 testimony confirms. Dr. Bickson testified that the consequences and the
13 results of irreversible electroporation depend. They depend on the energy
14 you use, where you use it, how you use it, there are a lot of different factors.
15 So, why is irreversible electroporation mentioned in the
16 specification? The answer is, we don't know. There's no connection, there's
17 no discussion of what irreversible electroporation leads to, at least in terms
18 of treatment.
19 The testimony, and we've identified this in our reply, and Dr. Bu-
20 Saba talked about this in his declaration to the 1098, 56 to 61. A person of
21 ordinary skill would read this passing reference in six words to irreversible
22 electroporation as noting a potential undesirable effect, an incidental
23 occurrence. That doesn't teach -- or let me rephrase, that doesn't describe
24 that irreversible electroporation leads to treatment in any way, shape, or
25 form.

1 Counsel sort of described this as a genus species issue, that there's
2 a genus of energy and there are species of energy and the various
3 disclosures, we've cited in our papers and it's on Slide 26 marked as the
4 Idenix case, that's a genus case.
5 And it discusses that if you can disclose something for one part of
6 the genus, but if you wanted it to describe the other, you have to blaze
7 marks. You have to have some description, some direction that the inventor
8 possessed the invention for the other members of the genus, not just the ones
9 that are extensively discussed.
10 And just to confirm, what is extensively discussed throughout the
11 specification and Mr. Cavanaugh described on Slides 20, 21, 22, and 23 of
12 our deck, the portions of the specification that Patent Owner has identified
13 all relate to toxin delivery, the mention of irreversible electroporation in the
14 context of toxin delivery.
15 The overlapping portions in the context of toxin delivery and
16 emphasizing that the area of treatment will be in the overlap, not in the
17 portion where there's energy alone, but in the overlap. That's what the full
18 context of the specification conveys.
19 Unless Your Honors have questions about that, I will move to
20 Makower on the obviousness grounds. There's this sort of looming question,
21 why Makower, and why would you look at Makower? And I think the
22 threshold is, there is no dispute, none, that Makower is analogous art.
23 So, we've identified in our petition, we discussed that at length,
24 why Makower is reasonably pertinent to the problems of the challenged
25 claims, it's in the same field, and there's no dispute that it's analogous.

1 What the Netflix says, and I raised this in my initial argument is
2 that a person of ordinary skill is presumed to know about the analogous art
3 and consider it for all that it teaches. You heard that there's no commercial
4 device, it's not required, we've got the Galderma case we cite in our papers.
5 We heard that the length of the disclosure with Makower is too
6 short. Well, it's not a matter of how much disclosure there is, the question is
7 what is the disclosure? And the disclosure is a of working device that
8 ablates tissue in the nasal cavity, nasal pharynx, it describes how it works,
9 that an electrodes, that it delivers energy into tissue, and it's basic
10 construction.
11 The Sony case and others say that reference must be considered for
12 all that it teaches. A person of ordinary skill would not simply ignore pieces
13 of it because there are other disclosures in the reference like flexible
14 catheters.
15 There was a question about enablement and sort of the arguments
16 that had been made. And Judge Majors, I think you asked this. We did brief
17 that Makower is enabled for all that it teaches. For example, in the '077
18 reply in note 11, we cited the Amgen case. The Amgen case says that there's
19 a presumption of enablement and we've gone back and forth on what exactly
20 the argument is that Patent Owner is making.
21 And I think they said it best themselves and I think I wrote this
22 down correctly, they said, even though Makower, it, says it will deliver
23 energy to tissue, we disagree. So, there's no dispute Makower says in its
24 disclosure, in Paragraph 187, it will deliver energy to tissue. Patent Owner
25 just says they disagree. They are taking on the burden or the argument that

1 Makower does not do what it says it does. And they haven't shown that that
2 is the case for all the reasons we've discussed.
3 Then there was a suggestion that we didn't address what the
4 electrodes are in the Makower device, whether they're ring electrodes, or
5 surface electrodes. We did in the '675 petition which is the 279 proceeding
6 at page 86.
7 We discussed how Makower teaches a general disclosure of
8 electrodes, they could be bipolar, monopolar, any suitable form of energy,
9 and for example, incorporate well-known constructions which include those
10 of patents and references like Imran.
11 And then on the fluid point, the idea that there be fluid in the
12 operative area, the quotes that they included from Dr. Levine, which are the
13 same ones we include, Dr. Levine says the mucus is there and it's not an
14 issue.
15 And in the additional sections, he clarifies exactly why. You
16 suction it out, you irrigate it out, and as Dr. Bu-Saba explains, or you just
17 position the patient so that it's not an issue, that it runs down to the bottom of
18 the treatment area instead of being caught.
19 Now, there was an accusation that we -- how much of these
20 disclosures in Paragraph 132 to 135 did Petitioner address on the fly? None,
21 not an iota. Well, there's a reason for that. They're not cited in the POR at
22 all.
23 So, Patent Owner made this argument that there's fluid in the area.
24 All they cited, all the cited in the POR was their expert testimony, which, as
25 we've demonstrated, it's not complete, it doesn't accurately reflect what's

1 happening in the nose. They didn't cite Paragraphs 132 to 135 of Makower
2 for this proposition.
3 But just to respond to this, and I think the -- and if you read
4 Paragraphs 132 to 135, it makes it clear, what 132 to 135 are talking about
5 are occluders, and this is just a ubiquitous component that's used in these
6 procedures. It basically cuts off the back of the nasal pharynx so that the
7 patient doesn't choke during the procedure.
8 So, if there is fluid that runs through that you use to irrigate and
9 you can suction out of the way, or if there is blood that is released, it runs
10 down away from the area, and there's a stopper there so you don't choke
11 during the procedure, that's what 132 to 135 are about.
12 For example, in Paragraph 134 it says the occluder is to, quote
13 "prevent undesirable drainage of blood or debris from the operative site."
14 Paragraph 135, "it's to clear blood and debris from the operative site." So,
15 there's a reason we didn't address it, it wasn't raised. It's a new, brand new
16 argument on surreply that shouldn't have been raised at all.
17 With respect to Fang, there's this sort of back and forth, well, what
18 do we know and what do we not know from Fang? And, let's just focus on
19 what we do know. What we do know from Fang is that it used an RF
20 electric device. When we talk about the similarity between Fang and
21 Makower, that's what's similar. That's always been our theory in the
22 petition, in the reply, and today.
23 The similarity between the devices is that they use RF electrodes to
24 deliver energy to tissue in the relevant area. That's the commonality. And a
25 person of ordinary skill looking at Makower's device, which has RF

1 electrodes deliver energy to tissue in the relevant area, will look to Fang for
2 its teachings of what happens, of what's going on behind the hood, right.
3 Fang has an extensive discussion of that.
4 We know its results and conclusions because it states them. In the
5 abstract it says there is statistically significant data showing that the RF
6 treatment group is better than the non-RF group. It teaches that explicitly.
7 And to Your Honor's earlier question, the role of Chen and Arora
8 and these other references, it's a gut check. We've been accused of using
9 hindsight in our analysis. We didn't, but how do we know that? Because the
10 reasonable expectation of success, the motivation to combine that we have
11 advanced in this proceeding is confirmed by multiple independent
12 references, all of which are cited in our petition, none of which outside of
13 Fang, is contested.
14 There was also this sort of pall cast on Fang, that, well, it doesn't
15 have the efficacy criteria, and we don't know exactly what they are. The
16 Patent Owner response acknowledges that the efficacy criteria are in
17 Footnote 1 of Fang.
18 So, it's not that it's some unknown thing, it's in a footnote and the
19 Patent Owner response, they decided not to submit that. And so, in reply,
20 facing the specter that there's something incomplete or wrong about Fang,
21 we submitted footnote 1 and we translated it, included it for the record so
22 that Your Honors could review it.
23 And what we did, is we asked Dr. Levine, what efficacy criteria,
24 what things would you look at when you're performing these procedures,
25 and we had this on Slide 63, which Your Honors have, they are the same.

1 It's the same criteria that a person of ordinary skill would look at that Fang
2 looked at as well.
3 Just quickly on the lateral claims. There's no claim construction
4 that's been proposed in this case and or this idea, that there's lexicography,
5 that's not something that Patent Owner advanced anywhere in its papers.
6 They have not advanced a claim construction that would be limiting.
7 And what Dr. Levine testified about lateral and uniform, is that
8 uniform is broader and encompasses lateral. So, the idea that uniform
9 delivery with ring electrodes would somehow not disclose lateral is wrong.
10 And I think it was Judge Majors who asked the question, doesn't
11 Makower deliver energy into tissue and isn't that enough? The answer is
12 yes. The claims require delivery or concentration of energy laterally from
13 the distal portion of the device into tissues.
14 That's exactly what Makower teaches, it teaches that the energy
15 going from the device into the tissue. The tissue is lateral to the distal
16 portion, that's all that's required by the claim. There's no further narrowing
17 limitation.
18 JUDGE MITCHELL: Do we need to construe lateral?
19 MR. STERN: You do not. The plain meaning of lateral is into
20 tissue away and we've established that throughout our papers.
21 On Imran, we identified in our petition, for example, the '675, page
22 86 to 87, how Makower teaches the lateral, or excuse me, the surface
23 electrodes. And the suggestion that we're somehow saying something that's
24 improper by an incorporation, I encourage Your Honors to look at the Patent
25 Owner response at page 63 to 64 in the '675.

1 In the Patent Owner's language, and they changed this at sur reply,
2 but in the Patent Owner response, they said, Imran's, quote, "is one of 20
3 patents incorporated into Makower's specification." End quote. We're not
4 arguing wholesale incorporation by reference. What we're saying is
5 Makower is general about what the electrodes are and it would include at
6 least surface electrodes.
7 Your Honors, we thank you for your time, we appreciate your
8 careful consideration. The institution decision we think got it right and
9 nothing about the trial has changed where we are. There's not written
10 description for the asserted claims -- for the challenged claims and as a
11 consequence, it's undisputed that Saddat anticipates the claims and if at any
12 priority date, the claims would have been obvious. Thank you very much
13 for your time.
14 MR. BRIGGS: Thank you, Your Honors. I have roughly six
15 points I'd like to make on surrebuttal. Counsel argued that there's no
16 connection between energy delivery and treatment or something like that in
17 the written description section of his argument.
18 I can't think of a closer connection to our first paragraph, which is
19 Slide 12, talking about the delivery of energy and that that energy can be
20 reversible or non-reversible. And then in the very next paragraph, Slide 16,
21 talking about that the energy, not reversible, not any characterization of that
22 energy, can be applied to goblet cells and it can be applied to areas outside
23 the area of toxin delivery. Those are back-to-back paragraphs.
24 There is no closer connection that you can have on those two
25 disclosures as it relates to the delivery of energy, the treatment of goblet

1 cells, and applying irreversible energy to areas where the toxin does not go.
2 Counsel also mentioned that toxin is extensively discussed in the
3 patents at issue. You know, what is also extensively discussed, energy
4 delivery, not reversible. Reversible occurs a handful of times and we admit
5 non-reversible is once, but that's because the inventors wanted to use energy
6 delivery to convey the scope of their invention and not reversible.
7 I'll move to the Makower issue. The first, well, one of the points
8 counsel made was that they weren't on notice that Makower discloses liquids
9 in the nose. Well, we put them on notice in the POR that there are liquids in
10 the nose.
11 And instead of actually looking at Makower and seeing what it
12 says on that issue, because it is their primary reference and whether Figure
13 5H would be exposed to liquids in the nose, instead of looking at that, they
14 said, no, we'll just ask the experts. We don't really need to look at the prior
15 art here, let's look at what expert testimony says and let's not look at the
16 reference.
17 But they've been on notice of Makower, at least of the liquids and
18 nose issue at least since we said that there's liquids in the nose in our Patent
19 Owner reply. And if we could go to our Patent Owner surreply of the '675
20 for instance, at page 13, it's not like two throw away paragraphs in Makower
21 they're talking about liquids in the nose.
22 We have, we say in E, "Fluid issues are so important in Makower
23 that he repeatedly addresses them over at least 23 paragraphs of his
24 disclosure." Again, they have Makower as their primary reference and they
25 address none of these paragraphs. That is not carrying your burden as a

1 Petitioner.

2 The next -- or one of the things, I'll move to Fang. One of the
3 things counsel mentioned is, oh, Patent Owner chose not to submit the
4 efficacy criteria in its Patent Owner response. Well, I'm sorry, but the
5 burden's on Petitioner here to carry their case in the initial instance.

6 If they thought the efficacy criteria was important, they should
7 have submitted it with their reply, I mean with their petition. And so, we
8 point out that it is really unclear, I asked Dr. Bu-Saba many questions about
9 Fang and he repeatedly testified it's unclear what Fang means on certain
10 issues.

11 So, we point out, if it's unknown with the efficacy criteria is, it's
12 your own expert didn't even say, and that's our duty as Patent Owner jobs,
13 the Patent Owners show that their case is unsupported.

14 Now they want to put the burden on us to put in Fang's efficacy
15 criteria. That burden relies on them and it should have been on them from
16 the outset. And that's not the only issue here. We filed a motion to exclude
17 on one document, Fang's efficacy criteria.

18 Why did we do that? They had it in their possession, they refused
19 to show it to our expert during his cross-examination, and then they
20 backdoor it in in their reply, knowing very well that we do not get expert
21 testimony on surreply.

22 As we pointed out in the briefing, that is gamesmanship. If we
23 want a full record as to what Fang's efficacy criteria is, both experts should
24 have been given an opportunity to read Fang's efficacy criteria and opine on
25 it. Only one expert in this proceeding was allowed to do so, their expert.

1 That's why we believe their use of the Fang efficacy criteria is improper.
2 If we could please go to Slide 71. When we were talking about
3 lateral versus uniform, I agree that its plain and ordinary meaning in view of
4 the specification and the specification is very clear on what lateral is and
5 what uniform is.
6 And when we're looking at the prior art again, what does the prior
7 art do? Well, the prior art is ring electrodes and that energy delivery is
8 consistent which is what it is in Figure 5B and is not consistent with what is
9 in Figure 5A. So, Makower does not disclose lateral energy delivery.
10 And the last point I'll make is if we could please go to Slide 74.
11 JUDGE MITCHELL: Can I ask you a quick question about lateral
12 versus uniform? So, is Patent Owner positing a construction based on these
13 figures that would be different than the plain and ordinary meaning for those
14 terms?
15 MR. BRIGGS: No, Your Honor. We're saying those figures along
16 with the specification under Phillips informs what the claims mean. And so
17 if we are informed by those disclosures and then we say, well, does the prior
18 art read on those disclosures, because the claim construction is versus the
19 prior art, obviously, our position is it doesn't. Because the specification
20 itself shows what the inventors intended when they say lateral energy
21 delivery.
22 JUDGE MITCHELL: Okay.
23 JUDGE MAJORS: Mr. Briggs, your claims, I'm looking at Claim
24 7, of the '077, and I think the answer of what I'm going to ask you is no, but I
25 don't know if you have the other claims handy, that the disclosure in the

1 specifications you're pointing to concerning that figure says concentrated
2 lateral, do the claims use the term "concentrated"?
3 MR. BRIGGS: The claim of the '675 uses concentrated, the other
4 two dependent claims of the other two patents did not use the word
5 concentrated. But really, the issue is whether energy is being delivered
6 laterally, and that's what's shown in Figure 5A. And in Figure 5B, the
7 energy is not being delivered laterally, it's being delivered uniformly. Does
8 that answer your question?
9 JUDGE MAJORS: Thank you.
10 MR. BRIGGS: Yes?
11 JUDGE MITCHELL: Could I ask you if you agree with Mr. Stern
12 that he believes that lateral would mean into the tissue or away? Would you
13 agree with that construction for lateral or are you saying it's going to be
14 more (INDISCERNIBLE) because of the figures in the patent?
15 MR. BRIGGS: Yes. The figures -- these figures are not, should
16 not be taken out of context. When the energy field is applied, we can see the
17 energy being applied, so presumably this is in connection with tissue. As the
18 left-hand side, Figure 5A shows that a lateral energy delivery in connection
19 with tissue, but those aren't ring electrodes, those are electrodes that are
20 buried beneath the surface so they can deliver energy in the lateral direction.
21 And in Figure 5B, those are ring electrodes, which is exactly what Makower
22 has, those electrodes deliver energy uniformly.
23 JUDGE MITCHELL: So, Patent Owner's position would be
24 uniform and lateral are separate delivery?
25 MR. BRIGGS: Absolutely. And --

1 JUDGE MITCHELL: Okay.
2 MR. BRIGGS: I'm sorry to interrupt you.
3 JUDGE MITCHELL: So, lateral's not subsumed within uniform
4 delivery?
5 MR. BRIGGS: Correct.
6 JUDGE MITCHELL: Okay. Okay. Thank you.
7 MR. BRIGGS: Your welcome. If we could please go to Slide 74.
8 The last thing I want to address is that we somehow agreed Makower
9 incorporates Imran. We do not agree. It's very clear in our briefing that
10 Imran's an improper use. It's not in their grounds, Makower doesn't
11 incorporate it, it incorporates assemblies and it has a bunch of patents that
12 could have those assemblies.
13 So, that, I want to be clear on the record, we do not agree that
14 Makower incorporates by reference Imran or any other of those patents.
15 Makower incorporates assemblies in the present tense language that we
16 pointed out in our briefing. And with that, unless Your Honors have
17 questions, I will rest. Thank you.
18 JUDGE MAJORS: Okay. Thank you, Mr. Briggs. Thank
19 everybody for their attendance and participation today, your presentations
20 were very helpful. The matter are submitted to the Panel for preparation of
21 final written decisions. We would ask that counsel briefly stay behind and
22 help the court reporter if there are any spellings or other issues that the court
23 reporter identified that you could help with. And with that, we're adjourned.
24 Thank you, very much.
25 (Whereupon, the foregoing matter was concluded at 11:31 a.m.)

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