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Transcript of Nicolas Bu-Saba, M.D.

Date: October 17, 2024
Case: Neurent Medical Inc., et al. -v- The Foundry, LLC (PTAB)

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL, INC. AND
NEURENT MEDICAL, LTD.,

Petitioners,

CASE.: IPR2024-00280
U.S. Patent No. 10,894,011

-against-

THE FOUNDRY, LLC,

Patent Owner.

DEPOSITION OF

DR. NICOLAS BU-SABA

BOSTON, MASSACHUSETTS

October 17, 2024

REPORTED BY: KIARA MILLER

FILE NO.: 557128

UNITED STATES PATENT AND TRADEMARK OFFICE

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Deposition of DR. NICOLAS BU-SABA, taken on behalf of PATENT OWNER, at 60 State Street, Boston, Massachusetts, commencing at 9:03 AM, October 17, 2024, before Kiara Miller.

A P P E A R A N C E S:

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N I C O L A S B U - S A B A, after having first been duly sworn by a Notary Public of the State of Massachusetts, was examined and testified as follows:

EXAMINATION BY

MR. BRIGGS:

Q Good morning, Dr. Bu-Saba. Am I saying that correctly?

A Yes.

Q And is it with a hyphen or without a hyphen? I've seen it both ways.

A It is a Lebanese last name, so it was not intended to be written in the Latin alphabet. So the legal name is Bu-Saba, so that's why we put the hyphen. But sometimes because easier, we join it together as Bu-Saba.

Q Okay. Thank you. That is helpful.

So my name is Heath Briggs. I am a patent attorney with Greenberg Traurig, and I represent the patent owner in this case, which is The Foundry.

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Do you understand that?
A Yes, I do.
Q Okay. I see your attorneys are here. Do these folks represent you?
A They represent, yes.
Q Okay. Can you state your full name for the record?
A Nicolas Bu-Saba, Nicolas Youssef Bu-Saba.
Q Can you spell the Nicolas portion for us, please?
A N-I-C-O-L-A-S.
Q And you understand you're here in connection with a deposition in relation to three proceedings before the US Patent and Trademark Office; is that right?
A Yes.
Q Okay. And have you been deposed before?
A Yes.
Q How many times have you been deposed?
A I can't recall the numbers of times, but I've been deposed before.

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Q More than five?
A I can't recall the number, so I don't want to give you an inaccurate number.
Q I'm just trying to figure out how many ground rules I need to give you since if you've been deposed a lot, I'm going to do a lot less ground rules; if you've been deposed a little, I'm going to give you way more ground rules.
A Again, I am guessing, but my guess is -- I shouldn't guess, but it is more than five.
Q More than five.

Okay. So since you've been deposed before, I think you kind of know how this works. So I'm going to ask questions, and I would ask that you would answer those questions if you can.

The court reporter is taking down everything we say, so it's important we don't have nods as answers. We have verbal communication back and forth.

Do you understand that?

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A Yes, I do.
Q Okay. So going back onto the three proceedings before the US Patent and Trademark Office, those three proceedings, for the record, are known as IPR 2024-00279, IPR 2024-00280 and IPR 2024-00669, okay?
A I see 0281. I don't see --
Q Do you want to talk about that for a minute? So what happened is the 00281 IPR appears to have been terminated in view of the 00669.
Is that your understanding?
A I don't know the numbers exactly. All I know is that the number in front of me says 00281.
Q So what I'm going to hand you right now is your declaration, Nicolas Bu-Saba, it's Exhibit 1083 in IPR 2024-0669.
Do you see that?
A Okay.
Q If you could just read through that, please.

A Okay.
Q So if you could look at Paragraph 3 of Exhibit 1083 from IPR 2024-0669 and just confirm that you say, "I execute a declaration that became Exhibit 1002 in IPR 2024-00281."
Do you see that?
A I confirm that.
Q Okay. So the reason you're looking at 00281 is because that is the main declaration that you submitted in that case and you're resubmitting it in this case.
Is that your understanding?
A It is my understanding, yes.
(Whereupon, U.S. Patent No. 10,894,011 was marked as Exhibit 1001 for identification as of this date.)
Q Okay. So the reason we're talking about IPR 2024-00669 instead of IPR-00281 is because the 00281 was canceled, but your declaration was reused in the 00669.

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Do you understand that?
A I do.
Q Okay. So you say you've been deposed, but you don't know how many times, correct?
A That's correct.
Q And you've been deposed in the last five years?
A Yes.
Q In connection with what cases?
A It was one personal injury case, and the other one was -- my understanding was about also personal injury pertaining to someone's exposure. It was, like, multiple plaintiffs in multiple states.
Q So if I understand you correctly, that testimony was in connection with personal injury proceedings, correct?
A Correct.
Q So in the last five years, have you had any testimony outside of personal injury proceedings?
A The personal injury proceeding was

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pertaining to a device that they said could be defective in the way it's supposed to perform, so I am labeling this as a personal injury proceeding, but I don't know how the law would interpret that.

Q I understand.

A But these are the kinds of cases I recall being deposed about.

Q So that seems to be more of a product liability case. Is that a better characterization of what that testimony was about?

A Some of the depositions, yes. Others were personal injury.

Q So there's a few depositions, some relating to personal injury and some relating to product liability over the last five years.

Is that a fair characterization?

A Yes.

Q Okay. Have you had any testimony in patent-related cases ever?

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A I have not.
Q Okay. So this is your first patent case?
A That's correct.
Q Okay. So I see -- how many documents do you have in front of you there?
A I -- you gave me one document. Besides that document, I had four.
Q So is the bottom one the same as the one I gave you?
A Yes.
Q Okay. So we can put that one aside. We're not going to use that one anymore.
A Which one? This one?
Q Both of them 'cause they're identical. That's just to confirm that your testimony in the 00281 is being reused in the 00669, okay?
A Okay.
Q So then you have three other bound documents in front of you, for the record, What are those?
A These are the declarations, the three

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declarations that I made pertaining to this case.

Q For the record, can you tell me what's on the face of each of those declarations, please?

A One of them, it says, "United States Patent and Trademark Office."

Q Let me just interrupt you. Can you just give me the IPR number for each of them?

A So one of them, the IPR number is IPR 2024-00279.

Q Great.

A The second one is IPR 2024-00280.

Q Great.

A And the third one is IPR 2024-00281.

Q Okay. Thank you.

So those -- is it your understanding that those declarations that are in front of you are the declarations you submitted in those proceedings?

A Yes.

Q Okay. Are those clean copies of those

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declarations? And what I mean by "clean copies" is there's no extraneous notes or handwritten comments or anything on those documents.

A That's correct.

Q Okay. So completely clean copies, okay.

Can you go to the one -- the IPR 2024-00279, please, and go to the signature page, which I believe is -- looks like it's Page 144?

A Yes.

Q So here there's an electronic signature, correct?

A That's correct.

Q It says, slash, S, slash, and then your name, Nicolas Bu-Saba, correct?

A That's correct.

Q And the date is January 17, 2024, correct?

A That's correct.

Q And so your actual, physical signature, handwritten signature, is not on this page,

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correct?
A That's correct.
Q So did you authorize counsel to electronically sign this for you?
A Yes, I did.
Q Okay. So you understand this to be -- the document that's in front of you to be the true and correct copy of your declaration in IPR 2024-00279, correct?
A I do.
Q Okay. Let's do that same thing with your other two. Can you please go to the signature page?
A It looks like Page 158, so we're talking about 00280.
Q Okay.
A Page 158.
Q So, again, we see the electronic signature with the date of January 17, 2024, correct?
A That's correct.
Q And so, again, you believe this to be

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the true and correct copy of your declaration from the IPR 2024-00280, correct?
A That's correct.
Q Okay. One more time. IPR 2024-00281, please go to the signature page, Page 167.
A I am on that page.
Q Okay. So, again, I see in my copy a date of January 17, 2024, electronic signature of Nicolas Bu-Saba.
Do you see the same thing?
A I do.
Q Okay. So you, again, believe this to be the true and correct copy of the declaration you submitted in IPR 2024-00281, correct?
A That's correct.
Q Great.
So since you've been deposed before, you know how this works. One thing I failed to mention is that I typically take a break about every 60 minutes.
Is that okay with you?
A That's okay with me.

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Q If you need a break sooner, that's fine, but the only thing I would ask is that if we have a pending question, you answer the question before we take a break.

Does that work for you?

A Yes.

Q Okay. Great.

The third thing I would like to mention is that from time to time counsel may object to questions I ask today.

Do you understand that?

A I do.

Q Okay. And unless they instruct you not to answer, you're still required to answer my questions, okay?

A Okay.

Q Okay. So earlier you had taken the oath for your testimony that you're going to testify truthfully today, correct?

A That's correct.

Q Is there any reason you cannot testify truthfully today?

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A Not that I can think of.
Q You're not on any medications or anything that would impair your testimony today?
A That's correct. I'm not on medications that would impair my testimony today.
Q Okay. Great.
Did you prepare for today's deposition?
A I did.
Q Okay. How so?
MR. STERN: You can answer the question, but please just don't reveal the content of any communications with attorneys.
A I reviewed my three declarations. I reviewed some of the prior art. I met with counsel yesterday.
Q When you say "some of the prior art," what do you mean by that?
A The prior art which I cited in my declaration.
Q But some, not all?

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A I can't recall whether I looked at every single one because this has been one year, but I looked at things that are most relevant or very relevant to my declarations.
Q Can you give me an example of one that you thought was particularly relevant?
A I looked at Makower's. I looked at Saadat. I looked at Fang. These are as far as the prior art.
Q Okay. So if -- so you said "Makower." So if I say "Makower" today, you'll know that I'm referring to Exhibit 1005 across all three IPR proceedings, correct?
A I don't recall the exact exhibit number, but if this is where Makower is, then yes.
Q Let's just work off IPR 2024-00279 for now, okay?
A Okay.
Q And let's go to the list of exhibits, and that is on Page 181 of that declaration. And do you see 1005?
A 1005, I see that.

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Q And do you see the last name Makower?
A I see that.
Q So Makower, according to your appendix, is Exhibit 1005, okay?
A Okay.
Q So then we go down one below because we're going to be talking about Fang as well. So we see 1006, and then there's a big, long citation but then at the end of it, it says "(Fang)."
Do you see that?
A I see that.
Q So if we talk about "Fang" today, we're going to be talking about 1006, correct?
A Correct.
Q And these same exhibits are the same numbers across all three IPRs, I will represent to you, okay?
A Okay.
Q And you also "Saadat," so Saadat is Exhibit 1003. Do you see that?
A I see that.

Q Okay. So if at any time today you need to refer to your appendix to understand what documents we're talking about, please feel free to do so, okay?
A Okay.
Q So you prepared yesterday with counsel. Was anybody else present at that meeting besides counsel?
A It was only counsel.
Q Counsel and you?
A Yes.
Q No outside parties?
A No outside party.
Q Did you prepare for your deposition today with anybody else besides counsel?
A I did not.
Q Did you talk to anybody else about your deposition today besides counsel?
A I did not.
Q Okay. Since you submitted the three declarations in these IPR proceedings, have your opinions changed related to any of those

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declarations?
A They have not.
Q Okay. Is there any typographical errors that you found that you would like to correct?
A There were a few typographical errors, but I don't remember them now. They're not material. They wouldn't change the opinions listed in these declarations, but I cannot sit here and recite them. There were few typographical errors.
Q Okay. How about this, as we're going through today, if you see one, can you please note it for the record, so we can make sure we have a clean understanding of what your opinions are?
A I would.
Q Thank you.
So I looked through your three declaration. It seems to me that you have many similar sections across the three.
Would you agree?

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A I agree.
Q So for instance, I think the introduction section, generally, matches across all three IPR declarations.
Would you agree?
A I have to pull up the introduction section just to be sure.
Q Sure. Take your time.
A I will give you a complete and accurate answer.
Yes. It looks like it.
Q Great. Can you do that same exercise for Qualifications and Experience, under Section 2, and confirm for me that those section are generally the same?
A They look the same.
Q And then in the Materials Considered section, Section 3, can you do that same exercise and confirm that those sections across all three IPRs are basically the same.
A Page 11.
I looks like there is some more stuff

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listed in Appendix B that's different, different declarations.

Q Oh, okay. For Appendix B, yes, agree. There are a couple of documents here that are in some IPRs and not in the others.

But if you just look at the words in Section 3 alone and not looking at Appendix B, do you generally agree that the words of Section 3, not including Appendix B, are generally did same?

A It looks like, also, in Declarations 00281, I -- there is one more sentence saying, "I have also relied on a conversation with Dr. Gregory Martin and have reviewed his declaration for this IPR." And then I list Exhibit 1007.

And then I need to look at the other documents also to be sure that it's the same.

Q Sure. Take your time?

A So it I looks like 00280 and 00279 are similar, but 00281 I added. That is another sentence -- that is another materials

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considered that is not listed in the other two.

Q Great. So just for the record, we're look at 0281 that IPR, and we're looking at Paragraph 25 on Page 11, correct?

A Correct.

Q The sentence says, "I have also relied on a conversation with Dr. Gregory Martin and have reviewed his declaration for this IPR (EX.1007)."

Correct?

A That's correct.

Q So that sentence is in this 0281 IPR, but not in the other two IPRs?

A I did not see it in the other two IPRs, but there is a reason it is only in this IPR.

Q And that's because you relied on a conversation with Dr. Gregory Martin in the 0281, but not in 00279 or 00280, correct?

A That's correct.

Q Why did you rely on a conversation with Dr. Gregory Martin for 00281?

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A Because Dr. Martin's declaration was in the field relevant to the declaration for this case, which is 00281, so I reviewed his declaration. I had a chance to chat with him and that was his opinion -- his declaration, his opinions were consistent with mine, but the opinions are mine. But I relied -- I discussed it and I reviewed it.

Q Why didn't you have a conversation with Dr. Martin about 00279 or 0280 IPRs?

MR. STERN: Objection to form.

A You're asking me why I also referred to him in the other declaration, because when I formulate my opinion I did feel the need to.

Q So you felt the need talk to him in 00281 but you did not feel the need to talk to him in 0279 and 0280?

MR. STERN: Objection to form.

A All I can say is that I did not cite Dr. Martin in the other two declarations. So I did not rely on Dr. Martin's declaration for the other two declarations, which are

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0279 and 00280.
Q Oh, I understand that. But the question is why?
MR. STERN: Objection to form.
A As I said, it was not there. I did not feel the need to include it in my declaration. When I formulated my declaration and opinions and I reviewed the prior art and reviewed the patents, I did not feel the need to include his testimony when I formulated my opinions and I wrote my declaration.
Q Okay. We'll probably come back to this later when we dug more into the references and understand more what the claims are saying, okay?
A Okay.
Q Okay. So just to continue on with making sure that I understand that there's really not many material differences, if any, across several sections of your three declarations.

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Can you please look at Section 4 of your declarations.

I'm sorry.

A Section 4 is material.

Q Yeah, sorry. I have the wrong thing. So Section 5, my bad.

A Okay.

Q And that is level of ordinary skill in the art, correct?

A That's correct.

Q So can you just confirm again for me, generally, the same testimony occurs as it relates to the level of ordinary skill in the art across all that section, across all three declarations?

A The last paragraph of this is different in each of one of them. Each one references different patent. So I -- if you look at Paragraph 30, for instance, in Declaration 00280, the last paragraph, it is -- it references the '011 Patent. While Paragraph 30 in 00281 references the '077

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Patent, and Paragraph 30 in 00279, it references the '675 Patent.

Q Yes. I totally agree, since you're putting in three declarations for three different patents, patent numbers would change.

Outside of that, is the text generally the same?

A Yes.

Q Okay. And since you brought it up, if I say the '675 Patent today, you know what I mean?

A I do.

Q So that is US Patent No. 10,610,675, correct?

A I would take the number that you cited, okay.

Q It's on the front page.

A US Patent 10,610,675.

Q Right. And let's just do the same exercise, so the record is clear.

If I say the '011 Patent, you will know

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I mean US Patent No. 10,894,011?
A 10,894,011.
Q Okay. And then one more.
If I say the '077 Patent today, you will understand I mean US Patent No. 11,679,077?
A That's correct.
Q Okay. Great.
Two more sections. If you could, please, look at the overview of technology section across the three.
This is a little bit longer, so take your time and just confirm for me that they are generally the same?
A Without the benefit of being able to read them word for word, they look the same.
Q Okay. I'll represent to you that we've done an analysis, a computerized analysis and they appear to be generally the same to us as well, so thank you.
Last one. There's a section in your declaration called Claim Construction.
Can you just read through and confirm

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besides patent numbers, which I understand are different, that the claim construction testimony across all three of your declarations is generally the same.

A Also, without looking, I mean, word for word, they look the same, in general, yes.

Q Great thank you.

So you have three declaration submitted in these proceedings, correct?

A That's correct.

Q How did you prepare these declarations?

A I reviewed the claims in question, or of concern. I reviewed the patents. I reviewed the prior art. I relied on my experience as a person with ordinary skin in the art. I formulated my opinion. I discussed my findings with counsel. And I formulated the declarations.

Q Did you create the first draft of the declarations?

A I cannot recall here about the -- there was a lot of editing and review and

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discussion over the past -- I mean, this has been, as stated, was filed January of 2024. So I understand that declarations will have to be made in a certain legal format. So after I came up with my opinions, I sat with counsel, and they basically helped me format it in a way that fits in the declaration in this case.

Q Okay. Did you work with anybody besides counsel to prepare these declarations?

A I did not.

Q Okay. So this product that you produced, these declarations, is the collaboration between you and counsel and nobody else?

A That's correct.

Q Okay. If you could make sure you have the 00279 IPR declaration in front of you, which relates to the '675 Patent, please.

A I got it.

Q So on that front page of this declaration, there is the words "Neurent

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Medical Inc." and "Neurent Medical Limited."

Do you see that?

A I see that.

Q If I refer to the -- if I just use the word "Neurent" today, is it okay that if I do that, that you'll understand it's both of those parties?

A I do.

Q Do you know Neurent Medical Inc. or Neurent Medical limited?

MR. STERN: Objection to form.

Q Do you know those companies?

A I know of the companies.

Q Okay. So you know of both of them or just one of them?

A I know of Neurent, but I never thought of Neurent Medical Inc. verses Limited, but yes, I know of Neurent.

Q Fair enough.

How do you know of Neurent Medical?

A It is through my work in the field as an otolaryngologist.

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Q So what do you know about them?
A I know they're in the field of otolaryngology.
Q That's it?
A Yes.
Q You never worked with a Neurent device?
A I have not.
Q Do you know any people who work for Neurent?
A I don't.
Q Okay. So you've never spoken with anybody at Neurent?
A I have not.
Q And if we go down underneath that we see patent owner is "The Foundry LLC."
Do you see that?
A I see that.
Q Do you know of that company?
A I only came to know about it when I was involved in this case.
Q So you learned about The Foundry through working on this case?

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A That's correct.
Q So you did not know about The Foundry before you were engaged to work on this case?
A I did not.
Q Do you know the company Aerin Medical, A-E-R-I-N?
A I know of the company.
Q How do you know them?
A Also because they're in the field of otolaryngology.
Q Do you know anybody who works at Aerin Medical?
A I do not.
Q Okay. Have you worked with any Aerin Medical devices?
A I have not.
Q Okay. If you can please go to Paragraph 3 of the 0279 Declaration.
If you could just read that and let me know when you're finished.
A You said Paragraph 3?
Q Yes.

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A Yeah.
Q So you're finished?
A Yes.
Q Thank you.
So it says here:
"My curriculum vitae, which describes my education experience, professional activities, and lists, among other things, my publications and patents is attached as Appendix A."
Do you see that?
A I see that.
Q Can you go to Appendix A please. So that's on Page 145, I believe; is that correct?
A 146 -- I mean, it starts -- my CV starts at 146.
Q That's right.
Can you point me to the patents in your curriculum vitae?
A There are no patents in my curriculum.
Q Okay. So is there a typo, then, in

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Paragraph 3 of you declaration?

It said -- because the last few words say, "my publications and patents"?

A This was more of a generic term. I don't have any patents. I have not filed any patents. I don't have any patents.

Q Okay. So it would be better to say, that -- list -- to list among other things my publications, but without listing the word "patents," correct?

MR. STERN: Objection to form.

A As stated, I've never filed a patent. I don't have a patent. My CV does not include any patent.

Q So do you consider this a mistake or not?

MR. STERN: Objection to form.

A I've already answered this question. And I don't know how to answer it in a different form. I don't have any patents. I have not filed any patents. My CV does not contain any patents.

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Q So you just don't want to say it's a mistake?

MR. STERN: Objection.

Q I asked you earlier if there is any typos. If this falls into the category of typo, that's fine, but to sit here and tell me that that's not a mistake, I just don't find that helpful.

MR. STERN: Is there a question?

MR. BRIGGS: No.

A I've answered your question before, I explain it to the best of my ability. There's nothing for me to add.

Q It's your testimony that is not a mistake?

MR. STERN: Objection to form.

A I'm stating that I've never filed a patent, I've never owned a patent, and my CV does not contain any patents.

Q Okay. So on Page 146 of your CV.

Do you see that, first page?

A Yes.

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Q It says, "Date prepared, October 22, 2023"?
A Yes.
Q Are there any updates that you would like to make to your CV at this time?
A There were -- I was an invited lecturer for several meetings between then and now, but I don't believe the talks I gave would change my opinions. But I do have a more updated CV because I keep updating my CV regularly. And, as I said, it includes invited lectures and national and international meetings.
Q Is it fair to say there's nothing material missing from your CV as it relates to these three IPR proceedings?
A That's correct.
Q Okay. So below your name it says "Office address."
Do you see that?
A Yes.
Q What company or university is that?

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A By the way, by the time of that CV, so I am no more at VA Boston Healthcare System, which is the second office address. I retired from the VA in October 2023, but I'm still at the department of ortho oncology Massachusetts Eye and Ear, which is within Harvard -- the department of the ortho oncology, the medical school is Harvard Medical School, but my office is at the Massachusetts Eye and Ear.

Q I'm just trying to understand. So the first office address that says department of otolaryngology, sorry, that's at Harvard?

A No. This is -- well, the academic department is at Harvard, but my office is at the Massachusetts Eye and Ear. Massachusetts Eye and Ear is at 243 Shore Street in Boston, Mass, while Harvard Medical School is in different location, different address.

Q So Massachusetts Eye and Ear, is that what you're saying?

A Correct.

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Q Okay. Sorry.

And it looks like, staying on Page 146 of your declaration, that you got a Bachelors of science in biology/chemistry in 1981?

A That's correct.

Q Then you went and got your MD and completed that in 1985?

A That's correct.

Q Those were both in Beirut?

A That's correct.

Q If you could please go to Paragraph 7 of your declaration, which is on Page 4. Just go ahead and read that and let me know when you're finished.

A Do I read the whole paragraph?

Q Yes. Please.

A Okay.

Q So in the middle of Page 4, there's a sentence that says:

"For instance, in and around 1999, I popularized radio frequency soft palate ablation (somnoplasty)."

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Do you see that?
A I see that.
Q Can you explain what that is, please.
A So this was a treatment for snoring and sometimes people with mild sleep apnea. Basically, it aims stiffening the soft palate by ablating the submucosa tissue, which would make the soft palate shrink and stiff, using RF, radio frequency. This is done under local anesthesia typically. Typically done in the office.
Q What's the soft palate?
A The roof of the mouth, to be generic, has a palate, and we divide it into the hard and the soft. So the hard is the front part which is the bony part, and the soft is the back part of roof of the mouth. So we call it the soft.
Q And does somnoplasty relate to just the soft palate?
A Somnoplasty pertains -- somno means sleep and snoring. So Somnoplasty was to the

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soft palate, but at that time we also used the same machine, the somnoplasty machine, to ablate the inferior turbinate. Then we used it later on to ablate the base of the tongue.

Q So my question is, what does the word somnoplasty mean here in the parenthesis? Is it referring to soft palate or something else?

A Somnoplasty was used more as a generic term. So somnoplasty, in a strict sense, would be the soft palate, but the device we call it generically the somnoplasty machine. So if I'm referring to somnoplasty machine, I've used it in other parts, such as turbinate, base of tongue, and soft palate. If I'm talking about somnoplasty as a procedure, that pertains to the soft palate.

Q I see. So you just mentioned somnoplasty machine, correct?

A We started calling that machine, I don't know what the real word, the real name of that radio frequency device was somnoplasty

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or Somnus, but I forgot the name of the machine that I used at that time.

So we refer to the machine as the somnoplasty machine. Referring to that machine, that's that device that we are using. But, as I said, if I'm talking somnoplasty procedure, I'm talking about the soft palate.

Q Understood. You kind of answered my question. So you don't recall exactly the name brand or anything of the somnoplasty machine, correct?

A I recall the company was called Somnus. Now, this is 25 years ago, but this is my recollection, it was called Somnus. If I'm wrong, I apologize about the name, but this is my recollection, it was called Somnus.

Q Just to the best of your recollection. That's fine.

Also in the paragraph, slightly above that, at the very first sentence, it says:

"In the course of my clinical and

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academic practice I have experienced performing and designing methods and devices for the treatment of ear and nose and throat conditions."

Do you see that?

A I see that.

Q Can you explain your experience of performing and designing methods and devices for the treatment of the nose?

A Performing devices -- I mean, methods, I've done various methods about the nose. Some using cold instruments, some using cauterization, some using laser, some using radio frequency, for various indications of whatever the disorder involving the nose is.

Q Are you -- I don't want to interrupt you, if you're still --

A No. That's it.

Q So the sentence says, I experience performing and designing. So, specifically as it relates to designing, you say designing methods and devices. Have you designed

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devices for the treatment of the nose?
A I have not designed devices for the treatment of the nose.
Q So have you designed devices for the treatment of the ear?
A I have not designed devices for the treatment of the ear.
Q Have you designed devices for the treatment of throat conditions?
A I have not designed devices for the treatment of throat conditions.
Q Okay. If we could -- and I'm sorry to jump around on you, go to Page 181 of this declaration, which, again, is your materials considered section.
A Go to Page 181?
Q Correct.
A Okay.
Q So we're back in Appendix B, materials considered section of your declaration, correct?
A That's correct.

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Q Outside of the materials listed here, did you consider any materials in preparing your declaration?
A I considered my experience and my expertise.
Q Okay. But, is it fair to say that the documents that you relied on, as it relates to at least 00279 IPR are all listed in Appendix B of your declaration?
A The documents that are cited in my declaration are listed in this appendix.
Q And did you rely on these documents?
A I did.
Q Okay. So, again, looking at Exhibit 1005 and Makower.
Do you know Mr. Makower?
A I don't.
Q Why don't I just give you copies of Makower and Fang so we're just looking at the same thing.
(Whereupon, U.S. Patent Pub. No. 2005/0240147 to Makower was

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marked as Exhibit 1005 for identification as of this date.)

(Whereupon, Fang Chao-xin and Zhen Shao-Shao, Nasal endoscopy was marked as Exhibit 1006 for identification as of this date.)

Q So I've handed you Exhibit 1005 to Makower and Exhibit 1006 to Fang, correct?

A That's correct.

Q Okay. Let's look at Makower when you're ready.

A I am ready.

Q Let's look at the front page of Makower. There's two inventors.

Do you see those?

A I do.

Q The first one is Joshua Makower, correct?

A That's correct.

Q And you do not know Mr. Makower, correct?

A I do not.

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Q Do you know Mr. John Y. Chang?
A I do not.
Q And then if we go to Fang, which is Exhibit 1006, and we go a few pages in, there's a couple of actually articles in here, I don't know what actual page this is of the exhibit because it's not labeled at the bottom, but for the record, it's Page 876 at the top.
Do you see that?
A I see that.
Q Here we have the title, "Nasal endoscopy combined with multiple radio frequency for perennial allergic rhinitis."
Do you see that?
A I see that.
Q The first named author is Fang, correct?
A That's correct.
Q Do you know this person?
A I don't.
Q And the second named author is a person with the last name Zhen.

Do you see that?
A I see that.
Q Do you know that person?
A I don't.
Q Do you know anybody at the Department of Otorhinology -- I'm butchering it -- but Otorhinology, I'm sorry, in that province of China?
A I do not.
Q I'm going to hand you two more references at this time.
For the record, I'm handing you Exhibit 1008, which is Edwards, and 1009, which is Stern. Here you go.
(Whereupon, U.S. Patent No. 6,517,535 to Edwards was marked as Exhibit 1008 for identification as of this date.)
(Whereupon, U.S. Provisional Appl. No. 60/702,077 was marked as Exhibit 1009 for identification as of this date.)

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Q Let's start with Edwards, Dr. Bu-Saba. I apologize, I don't know why there's no exhibit numbers on this, but, for the record, Edwards is Exhibit 1008. And if you could look at Edwards, please, the front page of Edwards, which is US Patent No. 6,517,535.

A I see that.

Q The inventor is Stuart D. Edwards.

Do you see that?

A I see that.

Q Do you know Mr. Edwards?

A I don't know him?

MR. STERN: Counsel, looks like, maybe it's just a copy issue where something on the bottom got cut off. I'm not seeing anything is missing, but we'll just reserve anything was cut off.

MR. BRIGGS: Fair enough. I agree.

Q Stern, for the record, is Exhibit 1009, across all three IPRs. At the top is US Patent No. 5,562,720.

Do you see that?

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A I see that.
Q And there's several inventors listed here. Let's just go through them.
Roger A. Stern, do you know this person?
A I don't.
Q Next is Vincent N. Sullivan, do you know this person?
A I don't.
Q Roxanne L. Richman, do you know this person?
A I don't.
Q Lauren L. Roy, do you know this person?
A I do not.
Q Robert L. Marion, do you know this person?
A I do not.
Q And, finally, Thomas D. Striegler, do you know this person?
A I do not.
MR. STERN: Counsel, just the same reservation, it looks like the bottom might have been cut off. I'm not

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seeing anything missing, but we'll just reserve.

MR. BRIGGS: Fair enough.

Q If you could please turn to -- if you could please go back to your declarations -- declaration, I'm sorry, 00279. And if you could please go to Page 5, and go to legal principles. Actually, before I start this, we've been going about an hour. Do you want a break or do you want to keep going?

A I'm fine if you're fine.

Q Page 5, there's a section three that says "Legal Principles."

Do you see that?

A I see that.

Q And the first word in paragraph ten is "I am not an attorney," right?

A I am not an attorney.

Q Fair enough. So because you're not an attorney, it looks like, for the purpose of this declaration, you have been informed about certain aspects of the law that are

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relevant to your opinions.

Do you see that?

A Yes. I do.

Q And this is your first patent case, correct?

A That's correct.

Q Okay. And so if you could just look at "Anticipation." Do you see "Anticipation" on Page 6?

A I do.

Q It says:

> "I have been informed by counsel that a patent claim is anticipated and therefore unpatentable if each element of the claim is present in a single prior art reference."

Do you see that?

A I see that.

Q What is your understanding of "is present" in that context as it relates to the legal concept of anticipation?

MR. STERN: Objection to form.

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A This is -- if you read my declaration and you see how I used my arguments to formate my opinion based on anticipation, you'll see how I understood or applied this concept.
Q So can you point me to where you made an anticipation argument in your declaration?
A I have to look over the declaration now and to see where I made anticipation.
Q Sure.
A So for instance, on Page 59 in Heading A right above Paragraph 82. And so I say "Challenged Claims." I list the claims, and I say they are anticipated by et cetera. And the following paragraphs would show how I applied what I understood about anticipation when I came up -- when I formulated my opinions on this declaration.
Q So in the context of Ground 1 of your declaration and "is presence," what do you mean by "is present" as it relates to Saadat?
MR. STERN: Objection to form.

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A As you can see in Paragraph 83, I say, "Saadat discloses a method of treating a nasal condition of a patient." And then in Paragraph 84 I say, "Saadat discloses methods for treating conditions such as rhinitis."
Q Okay. And then if you could please go back to Page 6 of your declaration. It says "Obviousness."
Do you see that?
A I do.
Q What's your understanding of the difference between "anticipation" and "obviousness"?
MR. STERN: Objection to form.
A As I write in my declaration, "I understand that a claim is" -- I'm talking about obviousness now. "I understand that a claim of unpatentable if it would have been obvious to a person of ordinary skill in the art at the time the alleged invention was made. I understand that a claim could have been obvious based on the teachings or

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suggestions of a single prior art reference or from the combination of two or more prior art references. I understand that an obviousness analysis requires an understanding of the scope and content of the prior art, any differences between the alleged invention and the prior art, and the level of ordinary skill in evaluating the pertinent art."

As I state in Paragraph 14, "I further understand that the claim would have been obvious if it unites all elements with no change to their respective functions, or alters prior art by mere substitution of one element for another known in the field, and that combination yields predictable results. Also, I understand that obviousness does no require physical combination/bodily incorporation, but rather consideration of what the combined teachings would have suggested to persons of ordinary skill in the art at the time of the alleged invention."

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And then I go on to Paragraph 15 to explain that "In connection with obviousness, I have been informed that there must have been some reason or motivation that would have lead a person of ordinary skill in the art to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have a reasonable expectation of success in doing so."

And then I go on in Paragraph 16, "While it may be helpful to identify a reason for this combination, I understand there is no rigid requirement of finding an express teaching, suggestion, or motivation to combine within the references. If a person of ordinary skill in the art can implement a predictable variation, obviousness likely bars its patentability. For the same reason, if a technique has been used to improve one device and a person of ordinary skill in the art would recognize that it would improve

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similar devices in the same way, using the technique would have been obvious. I understand that a claim would have been obvious if a person of ordinary skill in the art would have had reason to combine multiple prior art references or add missing features to reproduce the alleged invention recited in the claims."

And then on Paragraph 17 I go on to say, "In sum, I understand that a determination of whether a claim would have been obvious is based upon a variety of considerations, including, among others," and I list, "whether the teachings of the prior art references disclose known components" -- I'm sorry, "known concepts combined in familiar ways, which, when combined, would yield predictable results; whether a person having ordinary skill in the art would" -- sorry, "could implement a predictable variation, and would see the benefits of doing so; whether the claimed elements represent one of a

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limited number of known design choices, and would have a reasonable expectation of success by those skilled in the art; whether a person having ordinary skill" -- here, for instance, ordinary skill in the art. So this could be one of the typo errors that we discussed before. You asked me if you see any typo error to mention it. So --

Q Can I interrupt you for --

A So on Page 8 the paragraph before the last where it says "whether a person having ordinary skill," it should state "ordinary skill in the art" -- "would have recognized a reason to combine known elements in the manner described in the claim; whether there is some teaching or suggestion that in the prior art to make the modification or combination of elements claimed in the patent; and whether the alleged invention applies a known technique that had been used to improve a similar device or method in a similar way."

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And then I add that "I also understand that in considering obviousness, it's important not to determine obviousness using the benefit of hindsight derived from the patent being considered. I also understand that one of ordinary skill in the art has ordinary creativity and is not an automaton."

And then I go on to say, "I further understand that certain factors, commonly referred to as secondary considerations, may support or rebut the obviousness of a claim. I also understand that secondary considerations cannot be used to overcome anticipation. I understand that such secondary considerations include, among other things, commercial success of the patented invention, skepticism of those having ordinary skill in art at the time of invention, unexpected results of the invention, any long-felt but unsolved need in the art that was satisfied by the alleged invention, the failure of others to make the

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alleged invention, praise of the alleged invention by those having ordinary skill in the art, and copying of the alleged invention by others in the field. I understand that there must be a nexus, that is, a connection, between any such secondary considerations and the alleged invention. I also understand that contemporaneous and independent invention by others is a secondary consideration tending to show obviousness."

And then at the end I say, "I reserve the right to respond to any allegations that may be put forth by Patent Owners in this proceeding that any secondary considerations tend to rebut the obviousness of any claim of the '675 Patent discussed in this declaration."

So this is what I understood about obviousness.

Q So, you did a really good job of reading Paragraphs 13 through 20 of your declaration.

My question though was what is your

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understanding of the difference between anticipation and obviousness. And if that is just what is in your paragraphs of your -- Paragraphs 13 through 20 of your declaration, fine. Is that what your testimony is?

MR. STERN: Objection to form.

A It is a combination of what I stated here and how I applied it when I formulated my opinions when I wrote my declaration.

Q Okay. Let's go to Paragraph 55, please.

MR. STERN: And, Counsel, if we're going to go to a different topic, maybe now is a good time for a break.

MR. BRIGGS: Sure. Ten minutes. Okay. Off the record.

(Whereupon, a recess was taken from 10:09 AM until 10:22 AM.)

MR. BRIGGS: Back on the record.

Q So Dr. Bu-Saba, welcome back. During the break did you speak with your counsel about your testimony?

A I did not.

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Q Okay. Great.

Can you please go Page 39 of your declaration in the 00279 IPR?

A This is the 00279, you said, right?

Q That's right.

A Yes.

Q Are you at Page 39?

A Yes.

Q Okay. Great.

So this is the claim construction section that we spoke about briefly before. Can you read Paragraph 58, please.

A "For the purpose of this declaration" --

Q I'm sorry, you can read it to yourself.

A I'm sorry.

Q I apologize.

A Okay.

Okay.

Q So the first sentence says:

"For the purposes of this declaration, I will give the claim terms their plain and ordinary

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meaning."

Do you see that?

A I see that.

Q So since this is your first patent case, can you please tell me what you understand "plain and ordinary meaning" to be?

MR. STERN: Objection to form.

A If you refer to the rest of my declaration and how I formulated my opinion, that would be a good way for me to show how I understood it. So I can refer to my declaration whenever this principal is applied to show -- to demonstrate how I applied this in my opinions and in my declaration.

Q Sure. I'm asking more what is your legal understanding of "plain and ordinary meaning"?

MR. STERN: Objection to form.

Foundation.

A Legal understanding is what I stated in my declaration about the legal component. I

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have nothing to add beyond what I wrote in my declaration about my understanding about the legal aspects.

Q Do you know whether "plain and ordinary meaning" is a legal standard?

MR. STERN: Objection to form.

A What I stated here is that I will give these terms their plain and ordinary meaning, and when you read my declaration and you read my opinions, you will see how I understood "plain and ordinary meaning" and how I applied it in my declaration.

Q That's not what I asked.

What I asked is do you understand plain and ordinary to be a legal standard.

MR. STERN: Objection to form.

Q That's my question.

MR. STERN: I apologize. I didn't mean to interrupt.

Objection to form. Foundation.

A I am not an attorney, and I will refer back to my declaration and what I stated in

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my declaration and how I applied these concepts when I formulated my opinions.

Q Okay. Fair enough.

Let's please go to Paragraph 31 of your declaration.

Again, you could please read this to yourself and let me know when you're finished.

A Okay.

Q So on the right-hand side -- let's just do it a different way.

On Page 14 there's a picture.

Do you see that?

A I see that.

Q And that picture is from an exhibit called 1064 Lane.

Do you see that?

A I see that.

Q Do you agree with this picture?

A This is a representative picture, a sagittal view of the nasal cavity, a two-dimensional view, a sagittal view.

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So what do you mean if I agree with this picture?
Q Is there anything incorrect about this picture?
A I don't see anything incorrect just looking at it, no.
Q Okay. What is -- and I'm going to butcher the name -- choana, it's on the right-hand side of the picture. Can you tell me how to pronounce that please?
A Choana.
Q What is the choana?
A The choana is the opening -- the choana is the opening at the back end of the nasal cavity where the nasal cavity meets the nasal pharynx, so it's the back opening of the nasal cavity.
Q Why did you add an arrow to this picture with the word "choana"?
A This is to explain the nasal anatomy. That was the only picture I added. Again, it's a sagittal view and not a

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three-dimensional view. But just to explain what the nasal cavity, the anatomy of the nasal cavity. So this is more sort of to explain the anatomy of the nasal cavity. And because I referenced in my written description choana so that someone would understand what I'm referencing.

Q And below that it looks like you added the word "nasal pharynx" and an arrow, correct?

A That's correct.

Q Why did you do that?

A This is also to help elucidate the anatomy as I detailed when I'm talking about the relevant anatomy so that the person who's reading my declaration would understand what I'm talking about.

Q Okay. In looking at this picture, at the top middle it says "superior concha." Did I pronounce that correctly?

A You did.

Q So do you see that?

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A Yes, I do.
Q And in my reading, I think I understand "concha" to be equivalent to the term "turbinate."
Do you have the same understanding?
A I do.
Q Is there a difference between a turbinate and a concha?
A No. It depends on how you refer to them.
Q Why do people skilled in the art use turbinate sometimes and concha in other times?
MR. STERN: Objection to form.
Foundation.
A It's more like -- depending which term you like to use and which term become easier to pronounce easier to vocalize. So now we find word turbinate is easier, so we say turbinate. Many of the old anatomic textbooks they say concha, but you understand that, you know, when we say inferior concha

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or inferior turbinate, we understand these are the equivalent.

Q Okay. So if I say turbinate or concha today, we're talking about the same thing, correct?

A That's correct.

Q Okay. It looks like the superior concha is above the middle concha; is that correct?

A That's correct.

Q And is that why the word "superior" is used in this anatomical text?

A That's correct.

Q And below that -- below the middle concha we have inferior concha, correct?

A That's correct.

Q Inferior in this context means below the middle concha; is that correct?

A Correct. So you're talking up to bottom; superior to inferior.

Q I'm also seeing the terms "anterior" and "posterior" used in a lot of these texts.

Are their synonyms for superior concha,

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middle concha, inferior concha that use anterior or posterior that you're aware of?

MR. STERN: Objection to form.

A These are different dimensions; superior versus inferior refers to different dimensions than anterior versus posterior. So when we say an anterior, it means the front of the nose. When we say posterior we mean the back of the nose.

When we say superior, it means coming up towards the top of the head. Inferior is going down towards the lower part of the nasal cavity, we're going down.

So down is inferior. Up is superior. Front is anterior. Back is posterior.

The turbinates are classified as concha. Inferior, middle, and superior; not anterior or posterior. There is not anterior turbinate. So there is an anterior part of the turbinate, but not anterior turbinate.

So there is an anterior part of everyone of these turbinates and there's a posterior

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part of everyone of these turbinate.

As is there is also an inferior part of turbinates and superior part of each of these turbinates.

Q Understood.

So if a person skilled in the art said anterior, superior concha, they would be talking about the front part of the superior concha; is that fair?

MR. STERN: Objection to form.

A But there is no anterior superior concha. They have to say the anterior part of the superior concha.

Q Yeah, that's what I meant. Is that the anterior part of the superior concha would be the front part of the superior concha?

A Correct.

Q And then the posterior part of the superior concha would be the back or furthest -- I don't know what the right words here, part of the superior concha; is that right?

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A The posterior part of the superior concha.
Q All right. Below the choana, there's the torus tubarius.
Do you see that?
A Yes, I do.
Q What is that?
A Torus tubarius is the structure around the opening of the eustachian tube. Again, this is the sagittal view, so this is a two dimensional view. And you see the opening, the area that says "opening of the eustachian tube," around it there is this inverted U shaped structure, which is the torus tubarius, right, the inverted U shaped structure.
So this is not a circle. This is more of an inverted U, inverted J. And it is a round eustachian tube.
Q Okay. On the left-hand side of this figure it says, "nasal bone."
Do you see that?

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A I do.
Q And below that it says, "upper lateral cartilage."
Do you see that?
A I do.
Q It says, "alar cartilage."
Do you see that?
A I do.
Q What is the alar cartilage?
A Alar cartilage is another term for it is lower lateral cartilage. So as there is upper lateral cartilage and lower lateral cartilage.
And we're talking about the sidewall of the nose. It's hard for me to show it without pointing with my finger, but that would not appear on the transcript.
But it is the sidewall, so the lower part of the sidewall of the nose, where the nasal ala is, the outer part of your nostril, that's the lower lateral cartilage. And then there's a crease above that, and that crease

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demarcates between the lower lateral cartilage, or ala cartilage, and the upper lateral cartilage. And then the upper lateral cartilage ends where you start feeling the edge of the bone on the sidewall of the nose.

So if you run your finger along the side of your nose, you'll feel the bone, then there's a bony edge, then there's a soft part, this is the upper lateral cartilage, then there's a grove, and then there is the lower lateral cartilage, which is the ala cartilage referred to here.

Q Okay. Am I correct that there is -- the nasal septum is not illustrated in this figure?

A That's correct. It's not illustrated. Again, because this is a two dimensional. You need a different view to show the septum.

Q Understood. And speaking of different views, why don't we go the next page -- actually, that's not it.

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It's actually on Page 17, I'm sorry.

So here's what appears to be a picture from Exhibit 1065-Gray, correct?

A That's correct.

Q Why did you feel it was important to include this figure in your declaration?

MR. STERN: Objection to form.

A Because, you know, my declaration talks about nerves that supplied the nose. Nerves that innervate the nose, effect the nasal function. And many of these nerves originate in the sphenopalatine ganglion.

So that people who read my declaration can have better understanding as to what I'm referring to in my declaration, when I talk about these anatomic structures.

Q Is this figure from Exhibit 10065-Gray illustrating nerves plus, I guess, the nasal bone and the cartilage; is that correct?

A It cannot illustrate because this is more to the outside of the nose. So this is in a way a bit outside of what we were

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showing before. Again, these are sagittal views. So this is more towards the side of that previous one.

So the previous one I'm talking about, the figure that we were discussing before, so if you go to the side of the head, outside of what is showing -- again, we're showing only sections, only sagittal sections. So this shows, for lack of a better word, deeper or the side of what was shown in the previous figure.

That's it.

Q Are you done?

A Yes.

Q I didn't want to interrupt you.

Staying on Page 17 on the left-hand side, above "termination of nasal palatine," I can't read that last word, "nerve." It looks like there's a picture of the nose there; am I wrong?

A That's correct.

Q What is shown in this figure here about

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the nose on that section? I thought it was cartilage, but you told me it was not.
A No, so this is different here. So this is talking about the roof of the mouth here, also.
Q Okay.
A So this is the floor of the nose, which is the roof of the mouth. We discussed before hard palate verses soft palate; this is the hard palate part. So one of the branches of the SPG goes down through a foramen and then runs along the hard palate, and then it goes back up to the nose, in the front of the nose.
Q Would you go back to Page 14, please, right before -- or right above the picture, there's a sentence that says "the left and right nasal cavities."
Do you see that?
A Yes.
Q It says, "The left and right nasal cavities terminate at the posterior choana."

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When you say "the nasal cavities terminate at the choana," how do they terminate?

A The back edge of the nasal cavity is where the nasal cavity ends.

Q Okay. So, Dr. Bu-Saba, I'm going to introduce Exhibit 2001 at this point in time.

(Whereupon, Sinusitis, from microbiology to management was marked as Exhibit 2001 for identification as of this date.)

Q There you go. Could you please turn to page -- what I believe is 7 of this document. And it says -- it's got, at the bottom, a "TNF" informer stamp and at the top it's got a date.

MR. STERN: Sorry. Marked Page 7 or actual Page 7?

MR. BRIGGS: Sorry, it's not marked yet, I apologize. I think it's marked -- it'll be marked Page 7 when we get there.

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MR. STERN: So it's the seventh page of the exhibit.
MR. BRIGGS: That's what I believe it to be.
A Where is this again?
Q So this page right there.
And at the top, do you see published in 2006 by Taylor and Francis Group?
A I see.
Q Okay. So this is a book that I understand to be from 2006, okay?
A Okay.
Q Do you recognize this book?
A I don't.
Q You don't recognize this book?
A I don't.
Q Can you please go a few more pages to Chapter 12?
A Okay. I see that.
Q So do you recognize this chapter?
A Now that I see it, I recognize it.
Q So how do you recognize it?

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A I see my name listed there.
Q Do you want to take a few minutes to read through this?
A I mean, I have to go over the chapter, all of the chapters, this is -- I haven't read this chapter --
Q So I'm particularly interested in some discussion around Pages 233 to 240, to start. If you wouldn't mind, take as much as time as you want, to read Page 233 to 240.
A 233 -- so page?
Q 233 through 240.
A 240.
I would need to read it all so that I can refresh my mind about it.
Q I would like you to, yes, please.
MR. STERN: And, Counsel, while he's reviewing it, given we're just receiving this, we'll reserve our objections for this exhibit for completeness or otherwise.
MR. BRIGGS: Understood.

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A You said until Page 240?
Q Yes, please.
Okay.
A So I'm done reading through 240. Anything more you'd like me to read?
Q No, I'd like to ask you some questions.
A Sure.
Q On Page 233, please.
At the top it says, "Surgical management."
Do you see that?
A I do.
Q And below that is the name David Louis, correct?
A Yes.
Q And then below that is Nicholas Y. Bu-Saba, correct?
A Yes.
Q So are you a coauthor of this chapter, then?
A Yes.
Q With David Louis?

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A Yes.
Q How do you know David Louis?
A David Louis was one of our presidents at the time, based on my recollection.
Q So there's an introductory paragraph on Page 233.
Do you see that?
A I do.
Q Like, halfway through it says:
"There's also been a conceptual shift away from attempting to surgically exonerate the disease within the paranasal sinuses to simply opening specific areas in order to improve sinus function and allow better aeration and drainage."
Do you see that?
A I do.
Q And I'm assuming you agreed with that in 2006?
A Yes.
Q And do you still agree with that?

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A It depends on what we are doing the surgery for. So there are many clinical context, as you read the rest of the chapter, there are many indications. So depending on the indication we are doing, so that -- I have to refer to a specific clinical scenario, specific clinical case, to say whether you exonerate tissue or whether you preserve tissue.

Q Fair enough.

The next sentence says:

"The amount of tissue removed during sinus surgery is minimized now and the surgeon relies on opening key functional areas to restore the normal physiology within the paranasal sinuses which thereby helps to reverse the disease."

Do you see that?

A I see that.

Q And I'm assuming you agreed with that in 2006, as well?

A Also, it is in the correct clinical context that we're talking about. It all depends on what the indication is, why we are operating. So the kind of surgery, the extent of surgery we do, how much tissue we remove, is dictated by what we are treating.
Q I agree. I'm just -- was this sentence accurate when you wrote it with Dr. Louis in 2006?
MR. STERN: Objection to form.
A It was accurate for the kind of indication that this sentence applies to.
Q Okay. Since 2006, has there been any efforts to increase the amount of tissue removed during sinus surgery?
MR. STERN: Objection to form.
A It all depends on the clinical indication. So it depends why we are operating and what we are operating on. So the diagnosis, the extent of the disease, and the condition of the whole, i.e. the patient. Multiple factors come into play when we

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decide how to perform a surgery, and how much surgery we do, and what do we perform in that particular surgery.

Q Staying in that sentence, it says, "Opening key functional areas."

In 2006, when this was written, what key functional areas would have been known to a person of ordinary skill in the art?

MR. STERN: Objection to form.

Foundation.

A So I haven't read this chapter for -- since I coauthored it back in '05 or '06. When we talk about key functional areas, it also refers to what we are treating. When we say key functional areas, means opening key functional areas for any particular patient, for any specific disorder.

Q Can you give me examples?

A There are many examples. So if you can give me certain case scenario, certain diagnosis, certain presentation, I will tell you how I would treat that particular patient

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and what are the key functional areas.
Q Well, it says key functional areas, it doesn't say functional areas. So I'm assuming there's like a finite number of functional areas.
MR. STERN: Objection to form.
Foundation.
Q Is that correct?
A When we say key functional areas, we are referring to specific disease, specific disorder, in a specific patient, that's causing symptoms. For that particular case, there would be key functional areas.
Q How many key functional areas are there in the nasal cavity?
MR. STERN: Objection to form.
Foundation.
A Well, the nose is a complex anatomic structure.
Q I said nasal cavity.
A Nasal cavity. The nasal cavity is a complex anatomic structure, depending on what

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we are treating. So depends on the diagnosis, depends on the symptoms. The key functional areas become pertinent to that diagnosis, to that symptom, to that patient.

Q That doesn't answer my question.

I said, how many key functional areas are in the nasal cavity?

MR. STERN: Objection to form.

Foundation.

A There are as many key functional areas as there are disorders and diseases of the nasal cavity, which are numerous.

Q How many surgeries have you performed?

A Thousands.

Q Right. Tell me three or four key functional areas in the nasal cavity during your 4,000 experience -- your thousands of experiences of surgeries.

MR. STERN: Objection to form.

Foundation.

A So I still don't understand. Like, what is the clinical scenario, what nasal

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condition you're asking me about.

Can you please give me an example of a nasal condition, and then I can tell you what are the key functional areas for that nasal cavity condition.

Q Well, I'm approaching it as, this says key functional areas, and the surgeon relies on those opening of the key functional areas. I'm assuming the reader, a person of ordinary skill in the art, reading this textbook, would say, oh, the key functional areas are generally these ten to 20 things.

Is that an improper assumption?

MR. STERN: Objection to form.

Foundation.

A This is probably detailed in the rest of the chapter. This is only introduction. So this states general statements, but these statements are then expanded on when we talk about various indication.

Q So let's go back to your declaration, then. Let's go to Page 14. If you could

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look at the picture again.

Are there any key functional areas shown in the picture on Page 14?

MR. STERN: Objection to form.

Foundation.

A So, again, everything is relevant to what the disorder is.

So if you give me a specific clinical scenario, I'll tell you what are the key functional areas for that particular clinical scenario.

Q So there are no key functional areas without a specific clinical scenario?

MR. STERN: Objection to form.

A That's correct. Because we're talking, we say key functional areas, we're talking about various functions, about various anatomic structures, about various disorders. We have to combine what you're talking about. What's the symptom, what's the function of concern, what do we see on exam, what do we see on imaging, what do we get from medical

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history.

And, then, based on that, as a clinical provider, I say in this particular case scenario, this is the key functional area. Which, if I have to operate, this would be the area that I have to address.

Q So you've done thousands of surgeries and you can't tell me whether anything on that picture is a key functional area?

MR. STERN: Objection to form.

Foundation.

A Anything in that area, if it's causing disease, can be key functional component.

Q Okay.

A So any structure shown here can potentially be a key functional component if it's contributing to the generation of symptoms and the pathogenesis of disease.

Q So let's go back to Page 233 of the chapter.

A 233. Yeah.

Q Okay. So it's not just that sentence,

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there's a sentence above it that says:

"There's been a conceptual shift away from attempting to surgically exonerate the disease within the paranasal sinuses to simply opening specific areas" -- so the word areas comes up again in your opening notes -- "in order to improve sinus function and allow better aeration. The amount of tissue removed during sinus surgery is minimized now and the surgeon relies on opening key functional areas."

So it's not just one sentence, it's tied to opening specific areas in order to improve sinus function and allow aeration and drainage.

What is a key functional area to allow the opening for better aeration?

MR. STERN: Objection to form. Foundation.

A So I have to take this chapter and what's written in this textbook -- sorry,

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what I wrote in this introduction with my coauthor about what this textbook is.

Again, I haven't seen this textbook since I coauthored this chapter, looks like back in '06. So the textbook looks like, the title of the textbook is "Sinusitis, from microbiology to management." So this is the title of the textbook.

So when we talk about the surgical management in this section, we're talking about sinus disease. In the introduction, we said some general statements about how the algorithm of treatment changed with the endoscopic surgery and how we changed our thinking about how to operate. But then in the rest of the chapter, at least the pages that I had a chance to read now, I did not read the whole chapter, we list the host of diagnoses, and how we approach it based on what the diagnosis is and what the indication of the surgery is.

Q I still don't think that answers my

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question.

I simply asked, what are key functional areas to allow for better aeration?

MR. STERN: Objection to form.

Foundation.

A It depends what we are talking about. This sentence is not specific enough for me to say specific clinical diagnosis. This is in the introduction and is not intended to be a detailed explanation, which is in the rest of the chapter.

So, again, what we're saying, if there is a certain area causing disease, that's the key functional area, you open that key functional area for that particular disease, for that particular disorder. Wherever that disease is localized, the key functional area pertains to where that disease is localized and that we aim at opening that area.

Q You've done thousands of surgeries, right?

A Yes.

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Q Over those thousands of surgeries, there are no key functional areas that typically have to be dealt with?

MR. STERN: Objection to form.

Foundation.

A Again, it depends on the indication. Are we talking about inflammatory sinus disease, are we talking about nasal polyps, are we talking about nasal blockage, are we talking about tumor, are we talking about epistaxis, are we talking about eye disease, are we talking about mucus -- I mean, it depends. So the key functional areas -- so I've done thousands of operations for myriad of indications. And every operation is tailored to improve the patient's quality of life by addressing the areas where I feel surgery would help restore that patient's health.

Q Okay. I'm glad you mentioned diagnostics. If we could please look at Page 234, under diagnostic workup, it says

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"Medical history."

Do you see that?

A I do.

Q And it talks about, "The evaluation always begins with a thorough history followed by careful examination of the nose," correct?

A That's correct.

Q Is that still common practice today?

A Yes.

Q And in Table 1, on the right, on the next Page 235, it says medical history, correct?

A That's correct.

Q And then it has some symptoms listed; is that right?

A Correct. This is not an exhausted list of symptoms. There could be other symptoms, but this is the kind of symptoms that we ask about.

Q So one of the symptoms is nasal blockage, correct?

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A That's correct.
Q What is a nasal blockage?
MR. STERN: Objection to form.
A It means the nose is blocked.
Q What are some things that would block the nose?
MR. STERN: Objection to form.
A Many things. Many things can block the nose. Many things, external structures, internal structures.
Q Can you give me an example of a few internal structures that may block the nose?
A Large turbinates, deviated septum, nasal polyps, tumor, foreign body, internal nasal valve.
Q And then staying in Table 1. It says rhinorrhea, correct?
A That's correct.
Q What is rhinorrhea?
A Mucus production by the nose. So mucus dripping. So we mention rhinorrhea and post nasal drip. Both refer to mucus production.

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Here, when we say rhinorrhea, to be more specific, anterior, the mucus that drips from the front of the nose versus post nasal drip which is mucus that drips in the back of nose. So rhinorrhea refers to secretions coming out of the nose.

Q The anterior part of the nose, is that what you said?

A When you talk about -- here, when we refer to rhinorrhea here, we are referring to secretions that drip from the front of the nose.

Q And I think you just answered my question, but just to be clear, you said, can you explain the difference between post nasal drip and rhinorrhea, you may have already done it, but I apologize.

MR. STERN: Objection to form.

A Rhinorrhea indicates secretions produced by the nose. If it drips from the front of the nose, we refer to it as anterior rhinorrhea. Sometimes just rhinorrhea. If

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it goes to the back of the nose and you feel it in your throat, we call it post nasal drip.

Q Just below that is hyposmia.

A Yes.

Q What's hyposmia?

A Hyposmia means reduced sense of smell. Reduced sense of smell.

Q And then hypogeusia?

A Reduced sense of taste.

Q There's a difference between symptoms and diagnosis, is my understanding.

Is that your understanding?

MR. STERN: Objection to form.

A Symptoms are what the patients report. Diagnosis is what the disorder is.

Q So if you could go down and below Table 1 it says physical examination.

Do you see that?

A I see that.

Q And the second line, it says, "Anterior rhinoscopy using a headlight."

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Do you see that?
A I do.
Q What's anterior rhinoscopy?
A It is looking through the front part of the nose. Typically, I mean, there are different ways of doing it, but typically we use what's called nasal speculum. But if I put my finger on the tip of your nose, this is the anterior, meaning, looking with my eyes.
But, typically, to be able to see through the head of the front of the nose, through the section of nose, many times we put what's called nasal speculum. Because it's a cavity in there, we have to shine a light to be able to see.
So, usually, in the past few years we have the head mirror, which is still the category of the otolaryngologist showing that head mirror. But now there are different ways of shining light. You can use a headlight, any light source basically to

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shine light into the nasal cavity while looking with your eyes inside the nasal cavity.

Q Okay. A couple of sentences below that, it says:

"Any evidence of mucopurulent discharge, nasal polyps, enlarged turbinates, nasal septum deviation or disease, mucosus should be noted," correct?

A That's correct. This is among other things that you might note.

Q You mentioned nasal polyps a little bit earlier.

What are nasal polyps?

A Nasal polyps indicate to soft tissue in the nasal cavity that typically forms in response to inflammation. And they form in the nasal cavity.

Q Like a -- do they fill up -- the skin fills up with some discharge or something, is that what a polyp is?

A The polyp, if I want to explain to a

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layperson, I would say it's a fleshy structure, soft tissue, fleshy structure that forms inside the nose, commonly in response to inflammation.

Q What's a nasal septum deviation?

A So the nasal septum is the midline partition of the nose, dividing the nasal cavity to left and right part of the nose. Often, nasal cavities, instead of being a straight dividing wall, when it deviates, you call it deviation. So when it curves to one side, deflects to one side or both sides, we call it deviation.

Q What kind of problems does a nasal septal deviation cause to someone who has that condition?

MR. STERN: Objection to form.

A For reasons we don't understand, the presence of deviation or severity does not always correlate with symptoms, but it can potentially lead to nasal blockage.

Q And what is the problem with nasal

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blockage?
A When people cannot breathe through their nose, it can impact their day-to-day function in many ways.
Q So if you could please turn to Page 236. And then there's imaging.
Do you see that?
A Yes, I do.
Q So it appears that you do a medical history, then a physical examination. And then is imaging consistently done after those two steps?
MR. STERN: Objection to form.
Foundation.
A No. It's not. Depending on the indication and depending on the clinical course.
Q So then down below that it says, "Indications for paranasal sinus surgery."
Do you see that?
A I do.
Q That heading?

And then it says right below that, "The most common indication is for chronic rhino-sinusitis."

Do you see that?

A I do.

Q What is -- and it labels it "CRS." Do you mind if I just use "CRS" to make it easy today?

A That's okay.

Q Okay. Can you tell me what CRS is?

A So "chronic" means it is more than three months. "Itis" means it's inflammation. So it is chronic inflammation of the nose and sinuses of more than three-month duration.

Q Okay. If we go to the next page, and there's a Table 2. It says, "Indications for the paranasal sinus surgery."

Do you see that?

A I do.

Q And the first one in that table is inflammatory or infectious rhino-sinusitis.

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Do you see that?
A I do.
Q What's the difference between inflammatory and infectious rhino-sinusitis?
MR. STERN: Objection to form.
A Any kind of inflammation would be inflammatory. So inflammation may be induced or caused by infection, or it can happen in the absence of infections. So people can have inflammation without infection. But when they have infection, typically they have inflammation associated with it. So infectious inflammation is a category of the broader term "inflammation."
Q So right below that it says, "Chronic rhino-sinusitis that failed medical therapy."
Do you see that?
A Yes, I do.
Q What does it mean by "failed medical therapy," I guess, in this context?
MR. STERN: Objection to form.
A Because it is inflammation, the primary

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treatment is medical. The way we treat inflammation is medical. We only do surgery if the patient remains symptomatic despite what is considered adequate or maximal medical therapy. And there's no straightforward definition of what maximal medical therapy is because many factors play in there.

But basically, if you come to see me and I diagnosis you with chronic rhino-sinusitis, I tell you, "Let me treat you medically," and I tailor the medical management to what I think the diagnosis is. I see you back after I treat you. I might see you a few times before I tell you, "You know what, it looks like we are not getting anywhere. You still have symptoms. Maybe it's worthwhile exploring the option of surgery."

Q Okay. So just going back one page, I apologize, there's a figure, Figure 2, and it says, "Endoscopic view of an inflammatory polyp in the left middle meatus"; is that

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right?
A Yes.
Q Can you tell me what part of the nose we're looking at here?
A So as you see, there's what's marked "middle turbinate." There is what's marked "uncinate process." There is what's marked "deviated septum" and what's marked the "polyps."
So we are looking in the space next to the middle turbinate, so this would be the middle meatus. So we're looking at the middle meatus of the left side of the nasal cavity. And this is the polyp, which is rising and filling the middle meatus in that left side.
Q I think you said "deviated septum," but the words on the page are just "septum." Do you see a deviation, or is it just a regular septum?
A This one here, we're just indicating a septum. So whoever is looking at that figure

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would be oriented. This is just a figure, and whoever is looking at it has to be oriented about the anatomic structure so that the can know what you're talking about.

Q That's what I thought. Just during your testimony you said "deviated septum."

A Did I say "deviated septum"?

Q Yes. You did.

A No. I'm sorry.

Q Just a regular septum.

A Yes. This is just a septum.

Q Okay. So that polyp that's shown, is that a large polyp, in your opinion?

MR. STERN: Objection to form.

A Yes. Based in this case -- I mean, that -- there's no specification what's large, what's small. This is a polyp which is filling the middle meatus, extending below the level of the middle turbinate. It looks to be blocking the nasal passage in that area.

Q And then I think you -- on the

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right-hand side it says "uncinate process." I'm sorry if I said it wrong.

A Uncinate.

Q Uncinate process. What is that?

A The uncinate process is a bone covered with mucosa, which is the anterior boundary of what's called hiatus semilunaris, which is a space behind it where the sinus is drained.

Q And here it says middle turbinate. Are turbinates bony structures?

MR. STERN: Objection to form.

A Turbinates have bony skeleton, and they have soft tissue on both sides, and then they're covered by mucosa.

Q And there's turbinates at both the left side of the nose and the right side of the nose; is that right?

A That's correct.

Q If you could go to Page 238. It says, "Endoscopic endonasal sinus surgery."

A Um-hmm. Okay.

Q And at the bottom of Page 238, there's a

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sentence that says, "When this occurs, the mucus becomes either stagnant or recirculated within the affected sinus rather than freely joining into the nasal cavity and nasal pharynx."

And then it says, "Stagnant or recirculated mucus predisposes the patient to infection, which leads to inflammation that further impedes mucociliary clearance."

That seems to be a problem in 2006, correct?

MR. STERN: Objection to form.

Foundation.

A This is a problem as far as one particular diagnosis.

Q Agreed.

And then above that text there is a Figure 3.

Do you see that?

A I see that.

Q It says, "CT image." I'm assuming that's a CAT scan?

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A That's correct.
Q And it's got a middle turbinate pointed to, correct?
A That's correct.
Q With an arrow?
A That's correct.
Q And then below that, I'm assuming, is the inferior turbinate at that point in time?
MR. STERN: Objection to form.
A That's correct. So, yes, the structure below the middle turbinate, the gray structure -- it's hard for me to point out for the reporter to know what I'm talking about, but the lower structures in that figure, this structure and that structure, are the inferior turbinate.
MR. BRIGGS: So what the witness is pointing to are two curved portions, one of which has middle text directly above it -- on top of it.
Q And then there's what appears to be, I guess, the septum. And the right-hand side

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would be the other inferior turbinate; is that correct?
A That's correct.
Q Okay. And if we look at the middle turbinates, the one on the right-hand side is not, in my view -- and I'm not a doctor -- but is not nearly as large as the one on the left-hand side.
Does the one on the left-hand side have a condition? Is that why it's being pointed to?
MR. STERN: Objection to form.
Foundation.
A The size of the turbinate varies from side to side without necessarily meaning that one size is better.
Q Okay?
A But they can vary from side to side.
In this paragraph, I mean, I don't know where this CAT scan -- the patient's symptoms for which we got this CAT scan, but it's my understanding when I look at the chapter and

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when I look at the figures that we had to point to a middle turbinate without making the pointing very crowded.

So we chose in this particular side the right middle turbinate without implicating that this middle turbinate is anyway different from the other side. But just we had to point to a middle turbinate, and we chose the right side here.

Q Okay. That makes sense.

Looking at Figure 3, do any of the turbinates appear to be improperly sized?

MR. STERN: Objection to form.

A We never look at size in the abstract without looking at the symptoms. So there's -- if I examine your nose now, I cannot say this gentleman's turbinates are large or small. I have to correlate it with the symptoms.

So everything is in the clinical context, that why you came to see me, why I'm examining you, what I'm seeing and if this

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correlates with your symptoms.
Q Okay. So going to the bottom of 239, there's a sentence that says:
"There are two primary goals of FESS. First is to open up the narrow areas described above. The second is to perform the surgery in as atraumatic a manner as possible."
Do you see that?
A I do.
Q Is that accurate in 2006?
MR. STERN: Objection to form.
A Again, for the appropriate indication, yes, it's accurate. So it is always in context of what the indication is.
Q Yeah. I understand.
If you could please now go to Page 265?
A Of this chapter?
Q That's correct.
A Okay.
Q And there's a section called Lasers and Sinus Surgery.

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Do you see that?
A I do.
Q Would you mind just reading that to yourself and let me know when you're finished.
A Okay.
Q So this section is Lasers and Sinus Surgery, correct?
A That's correct.
Q We briefly talked about earlier that you have experience with, I guess, radio frequency use of medical instruments?
A That's correct.
Q What is the difference between laser and radio frequency surgery?
MR. STERN: Objection to form.
A Well, lasers are a form of light. So a laser is applying light, a form of light. Radio frequency is a different form of an energy, so it's different forms of energy.
Q And you've used both, though; is that right?

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A Correct. Lasers, not lately because they're expensive and I don't find them to be useful for what I do, but I've used them before.
Q Is there any reason you did not mention radio frequency treatment in this chapter?
MR. STERN: Objection to form.
Foundation.
A Every chapter we write, I cannot be exhaustive, so we chose to mention lasers here. It doesn't mean -- it's not intended to be a comprehensive chapter about every kind of modality treatment or surgical treatment, so we chose some topics. And it looks like here we chose to mention lasers.
Q Okay. I'm done with this exhibit.
MR. STERN: I think we've gone a little bit over an hour if you want to take a break.
MR. BRIGGS: Can we take 15 minutes?
MR. STERN: Off the record.
(Whereupon, a recess was taken

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from 11:25 AM until 11:41 AM.)

MR. BRIGGS: Back on the record.

Q Welcome back, Dr. Bu-Saba?

A Thank you.

Q Can you please turn to Page 11 of your declaration in the 00279 IPR.

And can you please Paragraph 26 through 30 to yourself and let me know when you're ready.

A Great.

Q So if you could please turn to Page 13, which talks about what we call the POSITA definition.

So POSITA, as you can see as an acronym at the top, that means person of ordinary skill in the art.

Do you understand that?

A Yes.

Q Okay. So here your definition is a POSITA would have had, one, a doctor of medicine or at least a bachelor's of science degree in electrical, engineering or related

discipline; and two, at least three years experience in clinical use, design, development, and/or testing of medical devices including medical devices that delivered energy to tissue, correct?

MR. STERN: Objection to form.

A Correct.

Q So you have a bachelor of science degree in engineering?

A I don't.

Q So are you relying on the doctor of medicine portion of this definition as it relates to your experience as a POSITA?

A Yes.

Q Okay. And in the Part 2 of this definition, it says:

"Clinical use, design, development and/or testing of medical devices, including medical devices that deliver energy to tissue," correct?

A Yes.

Q Is there a reason that you didn't

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require the medical devices experience to be related to the nose?

MR. STERN: Objection to form.

Foundation.

A This is -- we're talking about the definition of a POSITA, in general.

Q But these patents all relate to nose things. So I'm wondering why you didn't include or require nose experience in your definition.

MR. STERN: Objection to form.

Foundation.

A As stated earlier, I'm listing what a definition of POSITA is, and that definition can apply to the nose, as well as it can apply to anywhere where a POSITA is applied to.

Q So does an engineer whose only worked on medical devices that deliver energy to, let's say, for instance, the uterine cavity, they qualify to talk about what's going on in the nose, from an anatomical standpoint?

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MR. STERN: Objection to form.
Foundation.
A It all depends what the someone -- you said electrical engineering degree?
Q Yeah.
A Yeah, so it depends what the person with an electrical engineering degree was asked to opine about. If they're experience applies to what they're opining about, then they are a POSITA for that opinion.
Q Wouldn't it be better to have somebody with nose experience as opposed to somebody who has no nose experience?
MR. STERN: Objection to form.
Foundation.
A Again, here -- what I'm stating in this declaration, the definition of a POSITA, in general, like this is what I define a POSITA in this -- as relevant to my declaration, as is my relevant to my opinions. This is how I defined it.
Q That's not my question.

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My question is: Isn't it better to have somebody with nose experience when dealing with these patents as opposed to somebody who has no nose experience?

MR. STERN: Objection to form.

Foundation.

A I answered this question to the best of my ability. I don't know how else to answer it.

Q Well, you didn't answer the question, because you didn't answer whether you think it's better to have nose experience or not.

MR. STERN: Objection to form.

A It depends what the POSITA is asked to be opining about. So it depends on what particular item that POSITA is opining on.

Q Every claim of the '675 Patent relates to the nasopharyngeal passage; does it not?

MR. STERN: Objection to form.

A There are -- also, I have to go look at every claim.

Q Would you like to look at every claim?

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A Sure.
Q So heres the '675 Patent, which is Exhibit 0771 and IPR 00279.
(Whereupon, U.S. Patent No. 10,610,675 was marked as Exhibit 0771 for identification as of this date.)
Q And the claims are at the back, which I'm sure you're aware of now.
If you could just look at Claim 1, please, which is in Column 27, starting at Line 37.
A The page -- you said, which page, sorry?
Q It's Column 27.
A Yes. I see that.
Q Line 37.
A Line 37. I don't see the lines here.
Q They're in the middle of the page.
A Yes, yes. Okay. Sorry.
Q So if you could just read Claim 1 to yourself, please.
A Okay.

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Q So in the middle of the claim, it says:
"So as to disrupt neuro activity such that mucus secretion is reduced in the nasopharyngeal passage," correct?
A That's correct.
Q So Claim 1 relates, at least in part, to the nasopharyngeal passage, correct?
A That's correct.
Q Do you understand the concept of the Neurent claims?
A As I've already stated in my declaration, yes.
Q So Claim 2 says, "The method of Claim 1."
Do you see that?
A I do.
Q Which means Claim 2 includes all the text of Claim 1 plus the additional text that's recited in Claim 2, correct?
A That's correct.
Q So Claim 2 also requires the nasopharyngeal passage, correct?

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A That's correct.
Q And if we just go down, we can see that all of the claims, 3 through 16, are dependent claims, either directly or indirectly off of Claim 1, correct?
A That's correct.
Q So every single one of those claims relates to the nasopharyngeal passage, at least in part, correct?
A That's correct.
Q Okay. And then Claim 17, which is a new, what's called, independent claim.
Again, we have administering therapy to the target tissue with the treatment device to alter nasopharyngeal cells, such that congestion in the nasopharyngeal passage is reduced?
Do you see that?
A Sorry. Do you mind telling me which claim was that?
Q That was 17. It's right around Line 30.
A Okay. 30, okay.

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I see that.
Q And then after Claim 17, we have dependent Claims 18 through 30, and each of those refer either directly or indirectly to Claim 17, correct?
A That's correct.
Q So every claim, 17 through 30, requires a relation to the nasopharyngeal passage, correct?
A That's correct.
Q So all claims of the '675 Patent recite a requirement that relates to the nasopharyngeal passage, correct?
A That's correct.
Q So my question is, since the claims of the '675 Patent all relate, at lease in part, to the nasopharyngeal passage, wouldn't it be better if somebody with experience with the nasopharyngeal passage or the nasal cavity, in general?
MR. STERN: Objection to form.
Foundation.

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A I've answered. I mean, when I say -- when I define a POSITA, these are the requirements of a POSITA and it all depends on what that POSITA is asked to opine about, which part of this claim, which specific area of that claim that POSITA is opining on.

Q But your definition leaves open the fact that somebody with no nasal experience could be opining on Claim 1, correct?

MR. STERN: Objection to form.

Foundation.

A It depends on what that POSITA is asked to opine on. Which word of the claim. Which phrase of that claim. Which sentence of that claim that the POSITA is asked to opine on. There are many words listed in this claim.

There is "device," there is "target tissue," there is "therapy," there are "administering." I mean, there are many words listed here. So it depends on what that POSITA is asked to opine on.

Q So as it relates to the nasopharyngeal

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passage, should that person have nasal/nose experience?

MR. STERN: Objection to form.

Foundation.

A So you're saying they're opining about nasopharyngeal passage?

Q That's right.

A So that POSITA should be a person with -- person of ordinary skill in the art about the nasopharyngeal passage.

Q Okay. That's what I was asking.

Now, let's go to page -- I'm sorry. Paragraph 37 of your declaration, in the 00279 IPR, please.

A Mm-hmm.

Q So this is a section that has a header called electroporation, correct?

A Yes.

Q All right. And the second sentence says, "Electroporation is defined as the phenomenon that makes cell membranes permeable by exposing them to certain

electrical pulses, and can be either reversible or irreversible."

Correct?

A That is what I stated in my declaration.

Q And you refer to a reference called Rubinsky, Exhibit 1059, correct?

A Yes.

Q So then down below, though -- I'm sorry, on the next page, in fact.

We see a definition from the patent itself, so it's the second line, it says, "EX1001-USP675".

Do you see that?

I'm sorry, on the next page.

A Next page. Yes, I see that.

Q So that's a reference to the '675 Patent, correct?

A Yes.

Q Okay. And then there's a quote here, it says, "The term poration includes various forms of electroporation such as," and it goes on. And then at the end it goes,

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"and/or combinations thereof to create temporary pores in a targeted cell membrane."

Do you see that?

A I see that.

Q Is this definition consistent with the definition of Rubinsky?

MR. STERN: Objection to form.

A When we talk about poration it's to make the cell porus. And that can be achieved by applying energy. So if the energy is -- in electricity form, electronic form, it's called electroporation, if it is another form, than the other part goes before poration.

So if it's ultrasound, it's sonoporation. If it is electronic, it is electroporation.

But the key part is to make the cell porus, so that it can uptake whatever agent you are putting in its vicinity.

Q Are you familiar with the patent law, requirement -- excuse me, not requirement.

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The patent law term of lexicography?

MR. STERN: Objection to form.

A I am not.

Q Okay. So in patent law, a patent inventor is allowed to define what certain things mean, and that takes precedent over external references. So here, it appears you applied for a definition for Rubisnky first without applying the definition that's actually stated in the '675 Patent.

So I'm just asking -- which maybe okay, if they're consistent. So I'm asking is there any inconsistency between the Rubinsky definition and that in the '675 Patent?

MR. STERN: Objection to form.

Foundation.

A Rubisnky, it is -- Rubinsky specifically mentions in the code that I wrote here, certain electronic policies. So Rubisnky defines electroporation, again, it's the code that I included here, as a phenomenon that makes cell membranes permeable by exposing

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them to certain electric pulses.

And then when I refer, in my declaration to Exhibit 1001 USP675, and then when I said that, here we're talking about poration. And then we talked about various forms that I got from that patent, you know, it talks about electroporation. It talks about sonoporation.

So it talks about various ways of achieving that goal, but ultimately, the goal is the same, which is poration, making the cell porus.

Q Can you turn to Column 13 of the '675 Patent, please.

And go to Line 27.

A And you said which line, sorry?

Q 27.

A 27, I see that, yes.

Q So this is where you got the quote from the patent, I'm assuming?

A It looks like it, yes.

Q It says, "For purposes of those

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specifications, the term 'poration' includes," and it goes on to list, correct?
A Yeah.
Q So that means the patent has defined the term "poration."
Is that your understanding?
MR. STERN: Objection to form.
Foundation.
A They defined the term poration as it applies to this -- to that application.
Q Right.
A Yeah.
Q Did you apply this definition in your analysis of the '675 Patent?
A I have to see where I referred to it in my declaration to see how I referenced this. So if you can point me to where in my declaration I mention this, and then I can see and I can tell you how I applied it and how I understood it.
Q Okay. We can do that later.
I was just concerned that you cite

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Rubisnky first when the patent has its own definition. But that's okay. We can move on.

So if you can please go back to your declaration, in the 00279 patent -- or IPR for the '675 Patent please.

And go to Paragraph 60.

And why don't you read Paragraph 60 through 62 and let me know when you're ready.

You can read them to yourself, just to be clear.

A Up to which paragraph would you like me to read?

Q 60, 61, and 62 please.

A Okay.

Q So the first thing I want to point out is in Paragraph 60, we have a definition, it's on the third line.

Do you see it says, "the 077 provisional?"

A Yes.

Q And so that refers to Provisional

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Application No. 60/702,077, right?
A Okay.
Q And the reason that's important is we're going to be talking about it a little. Okay. So we're all on the same page about what 077 provisional means, right?
A Right.
Q Okay. So then we go down to the next paragraph, 61.
And you say, "Following the 077 provisional."
Do you see that?
A Yes, I do.
Q And then you have a bunch of applications listed in the bullet point form under that paragraph, right?
A That's correct.
Q And there's eight of them, right?
A Yes.
Q And they all have different definitions, so if we need to go back and look at the definitions, we can.

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For instance, Application 1 appears to have been identified as the '090 Application.

Do you see that?

A I do.

Q And it goes so on and so forth, I'm not going to go through all of them, we can if we need to.

The very last one, Application 8, says the '893 Application.

Do you see that?

A I do.

Q Which issues as the '675 Patent.

Do you see that?

A I do.

Q So if you could then go over to Paragraph 62, please.

And there you say:

"In my opinion, none of these applications, including the written description in figures of the '675 Patent convey to a person of ordinary skill in the art that the inventors were in possession of

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the alleged invention in the challenged claims."

Do you see that?

A I do.

Q And, then, I'm going to skip down a few lines, and it says, a little below the bolded nasopharyngeal passage, there's a sentence that says "instead."

Do you see that?

A Yes.

Q That sentence says:

"Instead, these applications only disclose applying neurotoxins to the bronchial tubes," right?

A That's what I read.

Q That's what you read.

Now, if you could please go back to the '675 Patent and turn to Column 3.

And if you could read Column 3, lines 50 to 65. Okay.

A Okay.

Q So starting at line 56, the '675 Patent

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says:

"The methods and systems should be capable of providing selective and repeatable delivery of the toxins to define target areas within the nasal cavities, including particular paranasal sinuses, the nasopharynx, and in some cases, substantially the entire nasal cavity," correct?

A Yes.

Q So, in fact, the '675 Patent does disclose applying toxins to places other than the bronchial cavities, correct?

MR. STERN: Objection to form.

A This one, the paragraph that you made me read, yes, apply to the nasal cavity. And the other structures that are listed here.

Q Okay. Great.

So, then, in just sticking in that, it says, that same sentence, it says:

"To define target areas within the nasal cavities, including

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particular paranasal sinuses, the nasopharynx, and in some cases substantially the entire nasal cavity."

Do you see that?

A Yes. I see that.

Q So, in your opinion, does the nasopharyngeal passage include both the nasal pharynx and the nasal cavity?

MR. STERN: Objection to form.

A The nasopharyngeal passage as pertinent to this case, as pertinent to my declaration, includes the nose and nasal pharynx.

Q Does the nose include the nasal cavity in that part, then?

A Yes. I meant the nasal cavity.

Q Okay. We're going to go to another one of your declarations now. It's going to be the, I think it's 281.

A This is different one now?

Q Yes, please. It's the 281 that relates to the '077 Patent. If you could please read again Paragraphs 60, 61. 60 and 61.

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A Okay.
Q So if you could please go to Paragraph 61 of your declaration in 00281, which relates to the '077 Patent that's on Page 43.
A Yeah.
Q Kind of towards the bottom of the page, it says:
"Each challenged claim requires" and it lists a whole bunch of things, including an apparatus for treating rhinitis and elongate body comprising a proximal portion and a distal portion configured for positioning, and so on and so forth.
And then if we go down below, it says:
"The '077 provisional of following applications do not describe each limitation of the challenged claims," right?
A That's correct.
Q And it says:
"Instead, these applications only disclose applying neurotoxins to the

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bronchial tubes."

Do you see that?

A That's correct.

Q So the first thing, and, again, let's go to -- I'm going to give you Exhibit 1001 from the 0281 IPR which also relates to the IPR 00669. If you could again then go to Column 3, I'll get you the right line number in a minute.

MR. STERN: Counsel, I don't know if this is just how the exhibit is or it's just a copy, looks like there's black marks. I assume the exhibit as filed is right.

MR. BRIGGS: Yeah. I mean, these are your stamped exhibits. Exhibits, I'm not sure.

MR. STERN: There's an issue on our end.

MR. BRIGGS: It appears, just for the record, that it only relates to the references cited section. So I think

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we can agree that that's not going to be pertinent for this testimony today.

MR. STERN: Sounds good.

MR. BRIGGS: Okay.

Q So, again, Dr. Bu-Saba, if you could read Column 3, line 56 through Column 4, line four.

A Column 4, line four. Okay.

Q Well, we had the same quote because the specifications are the same. And, again, it says:

"The methods and system should be capable of providing for selective and repeatable delivery of the toxins to define target areas within the nasal cavities, including particular paranasal sinuses, the nasopharynx and in some cases substantially the entire nasal cavity."

Correct?

A That's correct.

Q So, again, the '077 Patent as well also discloses applying toxins to the nasopharynx

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and the nasal cavity, correct?

MR. STERN: Objection to form.

A Well, here, they're talking about the background of the invention. They are talking in general. So, yes, here they mention applying it to the nose. And then when they talk about the written description and the figures, at least written in the description, then that becomes different story.

So here they are talking about the feet of the invention background, and, yes, they are mentioning the nose here or the nasal cavity or the nasopharyngeal passage. But this is more in the background section and not later in the patent when they describe what it is that they are describing.

Q Please go to Column 8 and read lines 11 through 28.

A Lines which one, sorry?

Q 11 through 28.

A Okay.

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Q So this time it says, "According to the present invention," at the beginning of that paragraph, correct?
A I see that.
Q But we have a very similar disclosure. If we go down to line 18, for instance, it says:
"The region where the toxin is introduced may comprise any portion of the nasal cavity such as a single paranasal sinus or a portion thereof, in nasopharyngeal passage, two or more paranasal sinuses, or some cases may comprise substantially the entire nasal cavity of the patient, particular target region for the toxin may comprise a nasopharynx, which is the back of the nasal passage."
Do you see that?
A I see that.
Q So, again, now the '077 Patent is specifically tied its invention to delivery of toxins to those areas, correct?

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MR. STERN: Objection to form.
A In this paragraph they are talking about delivering toxins to these areas.
Q So you agree that the '077 Patent talks about delivering as part of its invention, the toxins to the nasal cavity and the nasal pharynx?
MR. STERN: Objection to form.
A In this paragraph that you just read, so you cited, yes, they are talking about delivering toxins to the areas that you just cited.
Q Okay. If you could please go to Column 7, which is just on the other side, and read lines 41 to 50.
A Okay.
Q And then starting at line 41 of Column 7, it says:
"In other aspects, embodiment of the present invention by treatments for any disease or condition for which rhinorrhea is a result or a symptom."

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Do you see that?
A I see that.
Q And then down below that, it says, "Rhinorrhea," and it goes on, "can be a symptom of a number of diseases such as a common cold, sinusitis or rhinitis," correct?
A I see that.
Q So, again, the '077 Patent specifically ties embodiments of the invention to treatment of rhinitis, correct?
MR. STERN: Objection to form.
A Again, in this paragraph, they talk about any disease or condition for which rhinorrhea is a result or symptom. And then they say rhinorrhea is the term describing the influence of mucus from the lining of the nasal passage, like we discussed before. Nasal passage or nasal pharynx.
Q Including rhinitis, correct?
A Including rhinitis, correct.
Q So if you go back to your declaration. Sorry to make you jump around. Page 43, at

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the bottom, you would agree that the '077 Patent discloses an apparatus for treating rhinitis in a nasal cavity, correct?

MR. STERN: Objection to form.

Foundation.

A In the paragraph that you made me read, it does not mention an apparatus. It mentions three conditions. I could have missed apparatus in the paragraph, but it mentions treating conditions.

Q Fair enough. So if you could go to Column 16.

MR. STERN: Sorry, which one?

MR. BRIGGS: Of the '077 Patent.

Thank you, Counsel.

Q And there's a section called catheter device.

Do you see that?

A Section called catheter devices.

Q Line 20.

A I see that.

Q It says:

"To achieve the goals of the present invention, it may be desirable to employ methods and apparatus for achieving cell membrane permeabilization via the application of the energy source", correct?
A Correct.
Q So now we've got apparatus that are permeabilizing the cells, correct?
MR. STERN: Objection to form.
A It mentions the word apparatus here. So the word apparatus is mentioned in this sentence.
Q For achieving cell membrane permeabilization, correct?
A Correct.
Q The neuro toxins are delivered to those permeable cells, correct?
MR. STERN: Objection to form.
A In the context of poration, so no poration, then the medication or toxin is applied to the areas that are being porated.
Q Okay. If you could stay in the

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paragraph, there's a definition of the catheter starting at line 26.

Do you see that?

A I do.

Q It says:

"For purpose of this specification the term catheter may be used to refer to an elongate element."

Do you see that?

A I do.

Q So then if we go back to Page 443 of your declaration, at the bottom, you say:

"Each challenge claim requires" -- and I'm going to skip over that one -- and it goes, and an elongate body, correct?

A Elongate body. I see elongate body.

Q So the '077 Patent specifically says that its catheters can be elongate bodies, correct?

MR. STERN: Objection to form.

Foundation.

A The '077 mentions -- where was the

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paragraph, the catheter devices.
Q The catheter devices are defined at line 26?
A So it says, may be used to refer to an elongate element. It says elongate element. Whole or solid, flexible or rigid.
Q All of those encompass an elongate body, correct?
MR. STERN: Objection to form.
Foundation.
A It is talking about a catheter and it is talking about elongate element. So it is talking about the catheter. It is talking about the elongate element.
Q Do you believe the '077 Patent discloses an elongate body?
MR. STERN: Objection to form.
Foundation.
A Whatever body we're talking about. Here it says element. Whatever the word element means in a legal definition. I mean, it says element, so I go by what's listed here, which

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is referred to an elongate element.
Q My question is, do you believe the '077 Patent discloses an elongate body as you quote in Paragraph 61?
MR. STERN: Objection to form.
Foundation.
A All I can go is by what this paragraph is stating, elongate element. This is what the patent owner wrote. This is what I can state back to you, which is a catheter can be used to refer to a elongate element.
Q What's your understanding of the term body as it relates to the claim?
MR. STERN: Objection to form.
Foundation.
Q To remind you, we went over claim construction earlier and that requires the application of the plain and ordinary meaning of the word body.
So I'm asking you, in the context of Claim 1 of the '077 Patent, what is your understanding of body?

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MR. STERN: Objection to form.
Foundation.
A Body is a part of that device, whatever that part of the device is. So depending how you apply the term body. If we're talking about the word device, the body of the device is the body of the device.
Q If you can go to sheet five in the drawings of the '077 Patent.
A Sheet five. So which figure are you now?
Q At the top it says sheet number, so I'm trying to get you to the right sheet first.
Sheet 5 has a Figure 5.
Do you see that?
A I see that.
Q And Figure 5 has -- in the text of this is where we just were, so if you want to go back and forth between Column 16 and Figure 5, that's fine. I'll read it out loud.
Starting at Column 16, Line 35, it says,

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"Figures 5 and 5A-5B depict a system utilizing electroporation catheter 22," okay?
A Which page?
Q That was Column 16, Line 35.
A Column 35.
MR. STERN: Sorry, did you mean "column" or "line"?
Q I'll correct myself. Column 16, Line 35. I apologize if I said it incorrectly.
A Okay. "5A and 5B depict the system utilizing electroporation catheter for selective electroporation of the target cell. In certain configurations of the present invention voltages may be applied to the electroporation in order to introduce reversible electroporation at the same time as the catheter delivers the fragmented neurotoxin to the target region."
This what you want me to read?
Q Well, mainly to point out to you that Number 22 is defined as the electroporation

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catheter in Figure 5, okay?

MR. STERN: Objection to form.

A Okay.

Q So with the understanding that Item 22 is the electroporation catheter in Figure 5, do you consider that to be an elongate body?

MR. STERN: Objection to form.

Foundation.

A So as stated, 22 refers to piece of that device, which here looks elongated.

Q So, yes, that's an elongate body?

MR. STERN: Objection to form.

Foundation.

A It looks elongated, as I said.

Q And does that Elongate Body 22 of Figure 5 have a proximal portion and a distal portion?

MR. STERN: Objection to form.

Foundation.

A It has to be in the context and how it is applied to know what is proximal, what is distal.

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Q What's the common usage of "proximal/distal" in the medical field?

MR. STERN: Objection to form.

A "Proximal" means close to; "distal" means away. So it depends on what the reference point is.

Q Assuming that is correct, does this device have a proximal portion and a distal portion?

MR. STERN: Objection to form.

Foundation.

A Everything is relative to a reference point. When you say "proximal," has to be proximal to something. When you say "distal," it has to be distal to something.

Q Okay. Let's read the claim then. It says:

"A proximal portion; and a distal portion configured for positioning in the nose cavity."

Does that help you understand the frame of reference at that point in time?

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MR. STERN: Objection to form.
Foundation.
Q I'm in your declaration at Page 43.
A Page 43, sorry.
Q So there's two requirements "A proximal portion; and a distal portion configured for positioning in the nasal cavity."
Do you see that?
A Yes.
Q So the distal portion is positioned in the nasal cavity, correct?
MR. STERN: Objection to form.
A In this, what I'm referencing here, the distal portion configured for position in the nasal cavity.
Q Right. 'Cause that's part of the claim, right?
A Yes.
Q Okay. And so going back to Figure 5, does it depict a proximal portion and a distal portion?
MR. STERN: Objection to form.

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Foundation.
A Just looking at the figure itself without context, without explanation, difficult to say what's proximal, what's distal, how's this being used, which cavity this is being used. So just looking at the figure without how it is applied in a certain particular case, I cannot look at the figure and say what's proximal, what's distal.
Q Let me help you out. Column 16, Line 49 of '077 Patent says, "The catheter further comprises an electroporation element 26 at a distal 28 end thereof."
A Okay.
Q So 28 is called distal.
With that context, does Figure 5 disclose a proximal portion and a distal portion?
MR. STERN: Objection to form.
Foundation.
A I mean, they're saying 26 is distal without explaining what "distal" means and

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what part -- and how it is being applied. So they are saying 26 is distal, so they are saying 26 is distal. But for me, I can't look just at the figure and say what is distal, what's proximal.

So I'll go with what they define 26 as without knowing distal to what or proximal to what and to which part of the body this is applied. So everything is in context about what's being explained.

Q Do you understand that when you read a patent, you read the whole thing to understand what the inventors are talking about?

A I do.

Q Okay. So they say 28 is distal, correct?

MR. STERN: Objection to form.

A If they say 28 is distal, they're talking about distal. But, again, they have to define distal relative to what. Everything -- when you say "distal," it means

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distal to something.
Q So this is why patent law is important. We've already said plain and ordinary meaning, correct? And in the plain and ordinary meaning of people who use devices that go in the nose, what is the distal end?
MR. STERN: Objection to form.
Foundation.
A You said in devices that are used in the nose?
Q Correct.
A So if a device is inserted into the nose, the distal end of that device -- if I'm holding a device, and I'm inserting it in the nose, the part close to me is proximal, the part which is far from me is distal. If that part which is far from me is inside the nose, then that part is inside the nose. If that part is in a different part, then that part is in a different part.
But distal -- so if I'm holding the instrument, and I'm the reference, distal is

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reference to me and proximal is reference to me.

Q 'Cause that's the common usage in your field, correct?

MR. STERN: Objection to form.

A Everything has to be in context. Again, I mean, every word we say, every statement we say, if I said "proximal" and "distal," there should be a reference point. So if -- you have to define to me what is the reference point here.

Q I think I've done that because the patent is very clear on what the distal end is, and yet I still can't get an answer whether you think this device has a distal and proximal end.

MR. STERN: Objection to form.

Is there a question?

Q Do you have an answer as to whether the device in Figure 5 has a proximal and distal end?

MR. STERN: Objection to form.

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Foundation.
A I answered this question before, and I don't know how can I answer differently.
MR. BRIGGS: I'm going to object to his answer as being nonresponsive.
A I don't know how I can answer it in a different way while being truthful and accurate. I gave you my best answer, and you can refer to my answer.
I believe I defined what distal and proximal is, and I gave the answer in the best way I can give it to you. You can refer to my answer.
Q So sitting here today, you've gone over these various claim elements in Paragraph 61 of your declaration, correct? You've cited those claim elements, correct?
A You're talking about Page 61?
Q That's correct.
A Yes.
Q Paragraph 61, I apologize.
A Paragraph 61. Yes.

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Q And as an expert, your testimony in relation to the claims that you have here is you don't know whether Figure 5 has a distal end or not; is that correct?

MR. STERN: Objection to form.

Foundation.

A As we discussed, everything is based on the -- on the explanations and how this -- if this is a device, how this device is used, and this defines what's distal, what's proximal. As we discussed, everything is relative to a reference point. Distal is relative to a reference point; proximal is relative to a reference point. So this is how I understand it.

Q On Page 44 and Paragraph 61 you say, "The '077 provisional following applications do not describe each limitation of the challenged claims," correct?

A That's correct.

Q How can you do that analysis if you can't even know whether Figure 5 has a distal

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end or proximal end?

MR. STERN: Objection to form.

Foundation.

A Because I have to see what's in the figures, what's in the written description and what claims are being challenged. And then I come up with my conclusion based on the figures, on written description and the claims being challenged.

Q What's your conclusion here? Do the challenged claims have written description support for a proximal portion?

MR. STERN: Objection to form.

Foundation.

A I have to go for every claim. Which claim you are talking about now to see what -- because I have to refer you to my declaration, so which claim you are talking about?

Q I'm looking at your quote in Paragraph 61 that says, "Each challenged claim requires an apparatus for treating

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rhinitis in the nasal cavity an elongate body comprising a proximal portion."

A I see that.

Q What's your conclusion? Does the '077 Patent provide written description support for a proximal portion or not?

MR. STERN: Objection to form.

Foundation.

A You mean based on Figure 5 that you showed me, or you're talking in general whether the '077 has it?

Q These are your words. I'm asking -- since we've gone over this and I pointed you to many, many places in the patent that could potentially provide written description support is, what is your final conclusion.

MR. STERN: Objection to form.

Foundation.

A Again, I mean, you have to read what I wrote. "An elongate body comprising a proximal portion," and here when I say "proximal portion," proximate to the

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operator, "a distal portion positioned in the nasal cavity," so here I define "distal portion" is the portion that goes into the nasal cavity, "that it has multiple radio frequency electrodes coupled with the distal portion of the elongate body," which is the body that is in the nasal cavity. "And a radio frequency generator coupled with the proximal portion of the elongate body," which is -- the proximal portion, which is the one being held by the operator of that device, "for supplying radio frequency energy to multiple radio frequency electrodes to treat target tissue in the nasal cavity and thus treat rhinitis."

I mean, the description, for me, is as laid out in this claim, as laid out in this declaration.

Q Is that your answer?

A Excuse me, sorry?

Q Is that your answer?

A What was the question that you -- can

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you please ask me it?
Q Sure. So at Paragraph 61 in the beginning, it says:
"In my opinion, none of these applications, including the written description and figures of the '077 Patent convey to a person of ordinary skill in the art that the inventors were in possession of the alleged invention in the challenged claims."
So I'm going off that sentence, and I'm going to the next sentence that says, "Each challenged claim requires," lists a few things, "a proximal portion of an elongate body."
My question is do you believe the '077 Patent provides written description support for a proximal portion of an elongate body.
MR. STERN: Objection to form.
Foundation.
A We just -- I mean, we just looked at Figure 5 together, and we looked at the -- at

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my interpretation of Figure 5. And what I see is electro-cell manipulator, which is 24, so I have to see how they define 24.

Q Sure. Take your time.

A And then 20, I have to see how they set 20. I have to look at 22. I have to look at 30. I have to look at 32. I have to look at 28. I have to look at 26. And I have to see what is this being applied to or where this is being applied to and which modality is this being applied to.

So the part of the body -- the reason or the modality, so I have to look at every one of these.

Q Do you know what "written description support" means?

A Yes, I do.

Q So why don't you go Page 11, Paragraph 25 of your declaration.

A My declaration?

Q Correct.

A Page 11.

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Q And we're in the '077 Patent declaration, just to make sure we're on same page since --
A It is.
Q Okay. Is Page 11, Paragraph 23.
That paragraph's labeled "Written Description," correct?
A That's correct.
Q It says:
"I've been informed and understand that to satisfy the written description requirement, the patent specification must describe the claim invention in sufficient detail that a person of ordinary skill in the art could reasonably conclude that the inventor had possession of the claimed invention at the time of the filing."
Correct?
A That's correct.
Q And you applied this standard in Paragraph 61 of you declaration, which

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relates to the written description; is that correct?
A Page 61?
Q Paragraph 61, I apologize.
A Paragraph 61.
So I reference the written description and the figures of the '077 Patent, the parent, '011 Patent, and the grandparent '675 Patent, and so I mention including the written description.
Q Right. So the test is -- it says, "to satisfy," I'm back in Paragraph 23, "the written description requirement, the patent specification must describe the claimed invention in sufficient detail that a person of ordinary skill in the art could reasonably include that inventor had possession of the claim invention at the time of filing."
Do you see that?
A The -- which page, sorry?
Q Paragraph 23.
A Paragraph 23.

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Q Written description.
A Yes.
Q Just reminding you of the standard.
A Yes. Okay.
Q Does the specification of the '077 Patent reasonably convey the claim limitation of an elongate body with a proximal portion?
MR. STERN: Objection to form.
Foundation.
A I have to refer back to the written description pertaining to this device.
Q Did -- the portions that I gave you are not enough for you to make that conclusion?
MR. STERN: Objection to form.
Q We've went over Figure 5, we've gone over Column 16.
Those are insufficient for you to make a conclusion?
MR. STERN: Objection to form.
Foundation.
A I might have skipped it here. I don't see anywhere nasal cavity. Do you see nasal

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cavity? Can you please help me? Do you see anyplace where nasal cavity is mentioned?

Q I'm not asking about nasal cavity at this time.

I'm simply asking whether the specification of the '077 Patent describes with sufficient detail an elongate body having a proximal portion?

MR. STERN: Objection to form.

Foundation.

A When I look at the claim, we're also talking about the nasopharyngeal passage. So when I list the claim, if you refer me back to the area of the claim so that I can read it for you, so we're talking about this body in the nasal cavity.

Q Sure.

A If I remember correctly. Now -- so, if I can look back. In the paragraphs that you gave me to read in the -- I'm reading the '675 Patent, did you give me?

Q No, the '077.

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A Oh, sorry.
Q The specification is the same, so that's okay. They're just slightly different in where the column and line numbers are.
But I will happily refer you to Column 8.
A Column 8.
Q Line 33, it appears to 36, which reads:
"It will be appreciated that the energy may be applied to the regions of the nasal membrane, which are the same or different from the regions as to which the toxin has been introduced."
Do you see that?
A Yes, I see that.
Q We can see we've got a catheter device that we've talked about, that catheter device is going to apply energy, that energy is going to be the same or different from the region in which the toxin has been introduced. And then above that, in Column 8, Line 18 through 25, we talked about

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already, that the toxin can be applied to any portion of the nasal cavity, including the nasopharynx, paranasal sinuses, and others.

Is that sufficient for you to now understand that the '077 Patent discloses energy applied to the same places as the toxin, which may be any of the ones we talked about relating to the nasal cavity or the nose?

MR. STERN: Objection to form.

Foundation.

A So it discloses delivering energy with toxins to areas that are listed in the paragraphs that you read for me.

Q Great. So going back to my original question. We've gone over the written description standard.

My question is a simple one: Does the specification of the patent disclose to persons of skill in the art, an elongate body comprising a proximal portion, Paragraph 61?

MR. STERN: Objection to form.

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Foundation.

A I mean, I thought -- I mean, I believe, not I thought.

I believe I answered this question. And I don't know how to state it differently.

So they show a device, I have to refer back to the figure now to talk about the device, if you are referring to that same device.

So if we're talking about Sheet 5, Figure 5, 5A and 5B, they show a device, they point to one end as distal. So they point out to one end as distal. I can see the shaft of the device, so it looks long to me, it looks like a shaft.

So this is a device which has distal as they defined it, when they say "distal," so they defined distal, so I have to take their word for distal even though they do not say distal to what, but I assume -- they said distal, so I take them, that this is distal, which means distal.

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Q There's an opposing proximal, correct?
A Correct.
Q Okay.
MR. STERN: So we've been going over an hour, up to you, is this a good place to stop?
MR. BRIGGS: I mean, I've got like five minutes left on this.
MR. STERN: Yeah, that's fine.
MR. BRIGGS: Then definitely.
Q So the next part of your Paragraph 61 that I would like to talk about, is -- it says, "multiple radio frequency electrodes coupled with the distal portion of the elongate body," at the top of Page 44.
Do you see that?
A I see that, yes.
Q And if we could, then, go to the '077 Patent, Column 16, again, please.
And if you could read Column 16, Line 59 through Column 17, Line 8.
A Which line you said, sorry?

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Q Line 8.
A Okay.
Q You're ready?
A Yes.
Q Okay. So starting at Column 16, Line 59, it says, "Figure 5A depicts an arrangement of electrodes, 30 and 32, that produce an electric field."
Do you see that?
A Yes.
Q Does that disclose multiple radiofrequency electrodes?
MR. STERN: Objection to form.
A What was the question? I'm sorry.
Q No problem.
So starting on Column 15, Line 59, it says, "Figure 5A depicts an arrangement of electrodes, 30 and 32, that produces an electric field."
Do you see that?
A I see that.
Q Are those multiple radiofrequency

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electrodes?

MR. STERN: Objection to form.

Foundation.

A It doesn't specify radiofrequency. They reference two electrodes, so it is two electrodes.

Q So it's multiple electrodes; we can agree on that, correct?

A More than one. Yeah, two.

Q True. And so you made a good point about not saying what type it is. But if we go to Column 13 and we look at Line 41.

A Column 13, Line 31.

Q There's a definition of electrode, if you can just read that please.

A I did.

Q And the definition of the electrode includes radiofrequency, correct?

MR. STERN: Objection to form.

A It is one modality of energies, that is listed.

Q So Column 16, Lines -- I'm sorry -- 42

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to 58, it looks like -- why don't you read that, then.
A Okay.
Q Thank you.
Column 16, Line 42, says:
"Referring to Figure 5, electroporation catheter system 20 further comprises a pulse generator 24".
Do you see that?
A I see that.
Q Is that a radiofrequency generator?
MR. STERN: Objection to form.
A They don't specify. They say a "pulse generator."
Q Could it be a radiofrequency generator given that we just saw that the electrodes could be radiofrequency electrodes?
MR. STERN: Objection to form.
A If you are applying radiofrequency energy, it has to be radiofrequency generator.

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Q Correct.
Last question before break.
There's a generator called Cyto Pulse Science.
Do you see that, on Line 3?
A I see that.
Q Do you know that generator?
A I don't.
MR. BRIGGS: Okay. We can go off the record.
(Whereupon, a recess was taken from 12:51 PM until 1:23 PM.)
MR. BRIGGS: Let's go back on the record.
Q Dr. Bu-Saba, welcome back from lunch.
A Thank you.
Q During lunch, did you talk with counsel, at all, about your testimony?
A No.
Q Okay. Why don't we go to -- let's go back to the 279 -- 00279 declaration, and let's go to Paragraph 81.

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A 81 for Fang, the one that starts Fang?
Q That's correct. Why don't you just read that paragraph to yourself and let me know when you're ready.
A I'm okay. Yes.
Q So about half down you say:

> "Fang performed surgery via lining the firing head of a SHP-I5 organ radiofrequency therapy instrument with the sphenopalatine foramen [nasal wall] on both sides."

Do you see that?
A I do.
Q Why did you add nasal wall after the sphenopalatine foramen?

MR. STERN: Objection to form.

A This is the only -- whoever is reading is not familiar with the anatomy, so they understand what you're talking about.
Q I guess, I don't understand. How does the sphenopalatine foramen relate to the nasal wall.

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A So the sphenopalatine foramen is on the side of the nasal cavity. So if I'm going through the nasal cavity from the front to the back. At the back edge of the nasal cavity on the side of the nose, on the side wall of the nose, there is this foremen called sphenopalatine foramen.

Q Okay. And then just continuing on in that paragraph you say, "A SHP-I5 organ radiofrequency," onto the next page, "therapy instrument is a commercially available RF treatment device that comes with many factory preset settings."

Do you see that?

A I do.

Q How do you know it's a commercially available RF treatment device?

A The fact the Fang, the author, used it when he performed the procedures. So it was available in the clinic, hospital, or the surgery center, where Fang was performing his operations.

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Q Had you heard of an SHP-15 organ radiofrequency therapy instrument before reading this article?
A I have not.
Q Okay. And you say it comes with many factory preset settings.
How do you know that?
A I have to go to the paper again and see whether Fang mentioned this.
Q Be my guest. I gave you Fang earlier. It's exhibit 1006.
A He does mention a certain level. Once he mentions certain levels, it means there are different levels.
Q Why don't you take your time. I think that section -- excuse me -- that sentence we're talking about is in Section 1.2, treatment methods.
Why don't you go ahead and read 1.2, because we're going to talk about it anyway.
A So he mentions with the Level 3 intensity selected. So when I read Level 3,

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I conclude that there has to be Level 1, Level 2, at least 3, so at least 3 Levels for him to say Level 3.

Q Okay. So it says "factory preset settings," though. Does Level 3 connotate to you preset settings?

MR. STERN: Objection to form.

A As -- if I'm reading this -- as I told you before, I'm not familiar with the device, I've not used this device.

When I read this sentence, when I see Level 3, it looks like, based on what the author is saying, there is a preset factory setting, which is level 3, that the author, Fang, and his coauthor, set the machine to at that level. Which he says this is factory preset.

Q So your next sentence in your declaration, at Paragraph 81, says:

"It is an example of an off-the-shelf device, of which there are many available in the two thousands."

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Do you see that?
A Yes, I do.
Q How do you know it's an off-the-shelf device?
A I mean, it is available on the market.
I don't see, when I read Fang, that it was purely solely designed for this indication. So off-the-shelf, I mean, it is available in the market, at least where Fang practices.
Q Okay. And, then, you say, in your declaration, in that same sentence, and I am quoting:
"That those of ordinary skill in the art would routinely use and know how to operate."
Do you see that?
A I do.
Q How do you know that based just off this one disclosure in Fang?
MR. STERN: Objection to form.
A Then I listed, there are many available, many others available in the two thousands.

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I've used an RF machine and I know how to operate it. Obviously, Fang knows how to operate this machine.

So it looks like people with ordinary skill in the art, who use this machine, this particular machine that's listed by Fang, or other machine, other radio frequency machines.

Q So you don't know specifically whether there are SHP-1 was routinely used, correct?

MR. STERN: Objection to form.

A Routinely looks like it was used by Fang and his coauthor. I don't know how routine he was doing it. It looks like Fang and his coauthor used it on 63 patients. So whatever the word routine is, so they used it on 63 patients.

Q I just want to make sure, before reading Fang, you have not heard of the SHP-1, correct?

A This particular machine, I have not.

Q Okay. Let's start going through Fang in

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detail, please.

Why don't you go ahead and read the -- there's two abstracts that are generally similar, it looks like, I think the first abstract is slightly larger, and I'm not sure exactly what it has different. It looks like it's maybe the statistical P part of it.

But both abstracts refer to the methods -- why don't you go ahead and read the methods section of the two abstracts of Fang Exhibit 1006.

A They have both abstracts of Fang?

Q It's on the same page, they're just one above the other.

A I never realized that these are two separate abstracts. I always assumed they were the same abstract.

So what's the question?

Q Just go ahead and read the methods portion of each abstract and make sure you're familiar with that.

A Sixty-three patients with...

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Okay, yeah.
Q Both abstracts appeared identical, at least as to the methods part.
It says, "63 patients" -- and I'm reading from the second abstract -- "with perennial allergic rhinitis whose symptoms failed to be controlled by medication received nasal endoscopic surgery for sub mucosus resection of the nasal septum combined with radio frequency ablation of the bilateral Sphenopalatine foramen, anterior ethmoidal nerve, and inferior nasal concha", correct?
A Correct.
Q What does it mean by bilateral sphenopalatine foramen?
MR. STERN: Objection to form.
A The sphenopalatine foramen in the left side and sphenopalatine foramen in the right side of the nasal cavity.
Q Of both sides of the nasal cavity, is what it means?

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A Correct.
Q Okay. Can you read the first paragraph below the abstract. It starts, there are many, to yourself, and let me know when you're ready.
A I did.
Q So it says:
"There are many surgical treatments for perennial allergic rhinitis but a single treatment method has a higher rate of long-term reoccurrence."
Do you see that?
A I see that.
Q So single treatment method has a higher rate of long-term occurrence, what does he mean by single treatment method?
MR. STERN: Objection to form.
A Fang believes that there is one single method which has a higher grade of long-term recurrence, among the many surgical treatments. So it looks like Fang is referring to one of these treatments that he

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refers to.

So he says, many surgical treatments. And it looks like, in his experience, one of these, one among the many that he says single treatment, he says has a higher rate of long-term recurrence.

Q Okay. So then moving down, he says:

"From March 1998 to January 2003 various methods such as nasal endoscopic surgery for submucous resection of the nasal septum, combined with radial frequency ablation of the sphenopalatine foramen, anterior ethmoidal nerve, and inferior nasal concha were used in our department for the treatment of 63 patients with perennial allergic rhinitis," correct?

A Correct.

Q So the contrast between sentence one, single treatment, and now sentence two, with multiple treatments, is Fang trying to overcome the problems of a single treatment

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by applying many treatments at once?

MR. STERN: Objection to form.

Foundation.

A I did not chat with Fang and ask him about his rationale. I never met Fang. So I can only go by what he's stating here. It looks like, for these 63 patients, he did what he listed he performed on these patients.

I don't know whether he means the whole all of these are single treatment or each one of these is treatment. I don't know. I don't know what Fang exactly means. I've never spoken to him to ask him what he exactly means.

Q Okay. But I think we could agree that he did resection of the nasal septum combined with whatever he lists afterwards, correct?

A That's correct. On these 63 patients, yes.

Q So each of the 63, and we'll find this in other locations, all had a submucous

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resection of the nasal septum, correct?
A I have to look whether all had submucous resection of the septum.
Q Why don't you read the Section 1.1 down below, I think that might clarify it for you.
A So it looks like the 63 patients that they selected for this study had a deviated septum.
Q Right. And we see down towards the bottom, it says:

> "The 63 patients were randomly selected as the treatment group according to the admission period, another 20 patients with the same disease who underwent nasal septum surgery alone were selected as the control group."

So does that indicate to you that the 63 had nasal septum surgery, plus, what we're about to discuss, and then the other 20 only had nasal septum surgery without the other treatments?

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A That is my understanding, yes.
Q Okay. So going back to the top paragraph, which says, "There are many surgical treatments for perennial allergic rhinitis."
Do you see that?
A I see that.
Q There's several documents I've seen that say sinusitis, and there's several documents I've seen that say rhinitis. What does a person of ordinary skill consider the difference between sinusitis and rhinitis?
MR. STERN: Objection to form.
Foundation.
A As it pertains to Fang or in general?
Q To a medical doctor working in your field, what's the difference between sinusitis and rhinitis?
MR. STERN: Objection to form.
Foundation.
A As we discussed earlier, itis means inflammation. And the first part of the word

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refer to the anatomic site. So sinusitis, inflammation of the sinuses. Rhinitis, inflammation of the nose. Rhino is nose, rhinitis is inflammation of the nose, sinusitis, inflammatory of the sinuses.

Q Is rhino sinusitis infection of both potentially, is that what rhino sinusitis is then?

MR. STERN: Objection to form.

Foundation.

A We discussed before that itis means inflammation. Inflammation can happen with the absence of infection. So Itis means inflammation. With or without infection. And then the part of the word before it refers to the areas involved. So if it is rhino-sinusitis, it mean rhino sinus itis, inflammation of the nose and sinus.

Q Okay. Thank you.

What are common symptoms of perennial allergic rhinitis?

MR. STERN: Objection to form.

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A So we said -- we mentioned three terms, there are three terms in what you said, perennial means year round. Allergic means produced by allergy. And then rhinitis means inflammation of the nose. So it's inflammation of the nose, caused by allergy, that's year round. So this is what the term, perennial allergic rhinitis means. The symptom are variable. There are many symptoms. Would you like me to list -- I mean, it's hard to -- I don't want to miss one symptom. I mean, I can list as many symptoms as you want.

Q My question was the common ones. You don't have to list them --

A It can be nasal blockage. Some people call it congestion. So a layperson, congestion and blockage might be the same, some refer to congestion as mucus, blockage is blockage. But basically, to be more specific from medical term, nasal blockage and rhinorrhea, post nasal drip, sneezing,

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nasal itching, among others.
Q Okay. In the clinical data paragraph that we reviewed, there's a sentence that says:
"All the patients complied with the diagnostic criteria for perennial rhinitis." Then there's a citation to one.
Do you see that?
A I see that.
Q And then if we go to the next page, there's a reference one.
Did you review the reference one on Page 877 to determine what the criteria were?
A I did not review the reference one, no.
Q Okay. If you could please read the treatment methods paragraph and let me know when you're finished.
A Okay.
Q Great. So the first sentence says:
"The patients in the treatment group were put in a supine position and treated with 2 percent dicaine and 1/1000th

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adrenaline cotton pad for surface anesthesia and contraction of the nasal mucosa."

Do you see that?

A I see that.

Q Is that a common process in 2005 for such surgeries?

A I don't know what diacane means. I use lidocaine in my practice. So I usually use 1 percent or 2 percent lidocaine. I use a lower concentration of adrenaline. I use one -- I dilute it more. So I use one to 100,000. But basically it is anesthesia and decongestants. And there are different ways of achieving that, there are different solutions.

Q So the next sentence says:

"Under nasal endoscopy the SHP-15 organ radio frequency therapy instrument" --it's got a manufacturer in parenthesis -- "was firstly used with the level three intensity selected and the firing head aligned with the

sphenopalatine foramen on both sides to carry out radio frequency at the anterior upper part of the nasal septum on both sides."

Do you see that?

A I see that.

Q So when he says, "the firing head aligned with the sphenopalatine foramen on both sides," what does that mean?

A It means we discussed where the sphenopalatine foramen are on the side wall of the nasal cavity, in the back of the nasal cavity. So he wanted to align the firing head towards the sphenopalatine foramen so that he can deliver radio frequency to the sphenopalatine foramen area.

Q But that's where I get confused, because it says, "to carry out radio frequency at the anterior upper part of the nasal septum."

A I agree with you, and I don't like the explanation because now he's talking about the different anatomic areas. So he lists

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the anatomic areas earlier in the manuscript. He lists the sphenopalatine foramen. He lists the septum. He lists the lateral medial wall. He lists the inferior concha, inferior turbinate. But in the wording here, I don't know if the translation part is like this, or whether the Chinese paper is like this, but my understanding, when I read the manuscript, my understand that he is, he and his coauthor are saying they treated the sphenopalatine foramen area, they treated the septum, they treated the lateral nasal wall, and they treated the inferior turbinate.

Q So the language, "To carry out radio frequency at the anterior upper part of the nasal septum on both sides" -- now I'm going to continue on, I'm going to skip parenthesis -- "and at the anterior upper part of the lateral wall of the nasal cavity."

Do you see that?

A I see that.

Q I thought the lateral wall was the same

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as sphenopalatine foramen?

MR. STERN: Objection to form.

A The lateral wall is the whole wall. It goes from the nostril all the way back. So the sphenopalatine is in the back and here he's referring to the front part.

Q Because he says anterior?

A Correct.

Q So in the parentheses, six or seven lines down, I can't see it, which one that is, it says:

"The radio frequency points on both sides are staggered by five millimeters to prevent perforation of the nasal septum."

Do you see that?

A I see that.

Q What does he mean, "Points were staggered by five millimeters on both sides"?

MR. STERN: Objection to form.

A Again, based on my understanding of the manuscript, here he's talking, when he applied the radio frequency to the upper part

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of the septum. So he did it at multiple locations, and he applied them so that the application in the right side and the application in the left side are not in the same -- corresponding to the same area. So that you don't burn both surfaces of the septum at the same spot, at the same level, so as to avoid septum perforation.

Q A few lines down from that, in parentheses, it says:

"For those with severe hypertrophy of the inferior turbinate, partial resection of the inferior turbinate was performed."

Do you see that?

A I see that.

Q Explain to me what you understand that to mean as patients who received that particular procedure?

MR. STERN: Objection to form.

A Again, I'm interpreting as I read Fang and as I understand from Fang. When the inferior turbinate is also physically

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enlarged, blocking, contributing to the blockage of the nose, you need to reduce its volume. And that's when he performed the submucous resection to reduce its volume.

Q When he says partial resection, is that typically used with a scalpel or something like that?

MR. STERN: Objection to form.

A There are different ways of performing reduction of the inferior turbinate with instruments. We don't like to resect it. It's very important in the function of the nose. So we do partial resection. Typically preserving the mucosa. There are different techniques of doing it. That's why we call it the partial resection.

Q Would he have used radio frequency to do that?

MR. STERN: Objection to form.

A There are different ways. Here, he does not specify it. But radio frequency is one way of reducing inferior turbinate, but there

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are other ways of reducing the size of the inferior turbinate.

Q Okay. So if I'm understanding correctly, Fang used radio frequency to -- I guess I'll use the term ablate sphenopalatine foramen on both sides; is that right?

A You cannot ablate the sphenopalatine foramen. He's ablating the -- whatever is exiting from the sphenopalatine foramen. The foramen is an opening. You cannot ablate an opening. But he is ablating structures that exit that foramen.

Q Okay. And then he also uses the firing head to carry out radio frequency and, I guess, ablation at the anterior upper part as well?

A That's correct.

Q And then also at the anterior upper part of the lateral wall?

A That's correct.

Q And at the nasal ridge?

A Did he say nasal ridge? Which line?

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Q So I don't know which line, but it's right after the parentheses. And I'll just read it. It says, "And at the anterior upper part of the lateral wall of the nasal cavity" --
A The nasal ridge.
Q It says "the nasal ridge." So is he also treating the nasal ridge with RF energy?
A I don't know what he means with the nasal ridge in this -- in this paper, I don't know what he means by the nasal ridge.

So I read it based on what he mentions in the abstract. If you look at the introduction part, he mentions the anterior ethmoidal nerve. So it looks like he's targeting the areas where the anterior ethmoidal nerve supply. And that would be the lateral wall of the nose anteriorly, the upper part of the septum.
Q And then right after the nasal ridge, it says, "And the anterior part of the inferior nasal turbinate."

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A I see that.
Q So he also did RF energy to anterior part of the inferior nasal turbinate?
A That's correct.
Q And then on top of that for those with severe hypertrophy, he also did a partial resection of the inferior turbinate, correct?
A That's correct.
Q The next sentence says, "It was advisable to have a white ring around the radio frequency head."
Do you see that?
A I see that.
Q Why do you think it was advisable to have a white ring around the radio frequency head?
MR. STERN: Objection to form.
A Again, I don't know the device. I have not used the device. I don't know how they had it configured. So I don't know -- I cannot sit here and answer you why he's saying what he says here.

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Q Okay. So the next sentence says:

"The anterior part of the inferior turbinate could undergo radiofrequency at 3-5 points, and the nasal ridge and lateral wall of the nasal cavity could be cut to the periosteum using a radiofrequency knife."

Do you see that?

A I see that.

Q Are those additional procedures, or are those more explanations of what he did in the procedures above?

MR. STERN: Objection to form.

A When he is cutting the periosteum, he's doing more stuff. So I did not have a chance to review the raw data to understand what he did. So I have to take things as they are written in this translation.

Q The next sentence says:

"Further submucosal resection of the nasal septum was performed, and

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uncinate process resection, sinus opening, lateral part resection of the middle turbinate or nasal polypectomy were performed for those who had hypertrophy of the uncinate process, sinusitis, hypertrophy or polypoid lesion of the middle turbinate, or nasal polyps."

Do you see that?

A I see that.

Q Are those additional procedures he did when people had those conditions beyond the RF energy application?

A Yes.

Q So after the surgery -- next sentence:

"After the surgery, both nasal cavities were filled with expanded sponges, and the fillers were removed 48 hours later."

Do you see that?

A I see that.

Q Is that common practice after a surgery?

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A Not in my practice, but sometimes if we're worried about bleeding, we pack the nose. The duration of packing varies, depending on how much bleeding we expect.
Q And in the last sentence in treatment method, as we've already confirmed:
"For patients in the control group, only submucosal resection of the nasal septum was performed."
Correct?
A That's correct.
Q So we know we've got 20 patients in the control, only submucosal resection, and 63 in the --
A Experimental group.
Q Experimental group.
A For lack of a better term, yeah.
Q And those 63 received RF treatments that we've talked about, but they could have also received a variety of other treatments on top of that, correct?
MR. STERN: Objection to form.

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A That's correct.
Q So Section 1.3, Evaluation criteria for efficacy.
Do you see that?
A I see that.
Q "The efficacy was evaluated according to the evaluation criteria for allergic rhinitis." Again, we have the same document cited there.
Do you see that, Document 1?
A That was evaluated, yes.
Q And we don't have a copy of that document, and you've not evaluated it, correct?
A I have not. I don't have a copy of it.
Q Okay. So let's look at the results. If you could just read the results section to yourself and let me know when you're ready.
A Okay.
Q So I'm going to look at the one month after surgery paragraph, okay?
A Yeah.

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Q It says:

"The rate of excellent recovery was 92.1 percent, the efficacy rate was 7.9 percent, and the total efficacy rate was 100 percent."

Do you see that?

A I see that.

Q What is the difference between efficacy rate and total efficacy rate?

A I cannot sit here and answer you what Fang meant with this. I don't know which outcome measure he used, whether that was a validated measure. All I can say that based on his specification, the specification that he relied on, he categorized outcome as excellent recovery, efficacy rate and total efficacy.

So this is -- I don't know which outcome measure he used. I don't know whether this is validated. I don't know the outcome instrument.

Q Have you commonly seen papers that

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report both efficacy rate and total efficacy rate?

MR. STERN: Objection to form.

A We see -- I mean, when we talk -- so we've seen papers where people, for instance, say complete remission, there's partial remission. So we've seen people where they categorize outcome, whether all symptoms disappeared or symptoms were reduced. And we use different instruments to quantify these.

Q Do you know why in the one month if the efficacy rate is 7.9 percent, why the total efficacy is a hundred percent?

MR. STERN: Objection to form.

A Because I love math, I see 92.1 plus 7.9; this is 100 percent. So when I look at the math, it looks like he added 92.1 to the 7.9.

Q Okay. All right. Let's read the discussion.

Why don't you read all of the discussion, which is one, two, three, four

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paragraphs and let me know when you're ready.
A Okay. Yeah.
Q Thank you.
So the first sentence is very long. It starts "Numerous studies."
Do you see that?
A I do.
Q And then at the end of it, it's got a citation to Articles 2 through 4. Do you see that?
A I see that.
Q So my understanding of that sentence is that Fang is referring to other folks to support the -- either analysis or conclusions he has in that first sentence.
Is that your understanding as well?
MR. STERN: Objection to form.
A Yes. That's correct.
Q So next sentence does not have any citation. He says:
"The treatment of perennial allergic rhinitis mainly relies on

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medication, but for cases with abnormal nasal structures, medication alone often has poor efficacy."

Do you see that?

A I see that.

Q He does not refer to any citations there, correct?

A That's correct.

Q Okay. So then the next one:

"Reasonable surgical interventions should be carried out based on the specific structural characteristics."

Do you see that?

A I do.

Q No citations to any external articles, right?

A That's correct.

Q Okay. What do you think he means by specific structural characteristics?

MR. STERN: Objection to form.

A We discussed this before when we're

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talking about key functional elements. So basically, which structures are involved, whether these structures -- so as a surgeon, when a patient comes to see me with certain symptoms and I examine them, if I want to operate, I have to see things on my exam that correspond to those symptoms that are structural, which I can fix as a surgeon.

So I, as a surgeon, address structure, hoping by addressing structure I can improve function, treat you, reduce your symptoms, improve your quality of life. So this is what he's referring to here.

Q The structure of the nose/nasal cavity/nasal pharynx structure, is that kind of what you're saying?

A The structures that impact your airway, whichever part of the airway you are talking about.

Q Okay. So the next sentence is pretty long, but I'm going to read it:

"Due to the complex innervation

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of the nasal mucosal nerves, radiofrequency technique was used to process multiple parts in the nasal cavity."

I guess it's not that long. But let's keep going:

"In two cases, the radiofrequency ablation of sphenopalatine foramen was used to block the posterior parasympathetic fibers of the sphenopalatine nerve, and the medial and lateral branches of the anterior ethmoidal nerve were damaged by radiofrequency ablation of the anterior upper part of the nasal septum of the lateral wall of the nasal cavity."

Do you see that?

A I see that.

Q And then he's got citations now to References 3 and 5.

Do you see that?

A I do.

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Q It's really confusing to me that he says "in two cases." Does he mean the two cases out of his 63, or does he mean the two articles that he cites?

MR. STERN: Objection to form.

Foundation?

A I cannot sit here and -- and answer this question because to me it's also not clear whether these two cases, two patients or two cases to two references. I don't know the answer.

Q Okay. So then the next sentence says, "In addition, inferior turbinate contains cholinergic nerves and their parasympathetic plexus," references 6, so I assume that is a reference to an exterior article that says that that's the case.

Do you have the same understanding that that first part of the sentence is supported by Reference 6?

MR. STERN: Objection to form.

A I do.

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Q Okay. So then he goes:

"So 3-5 points were selected for radiofrequency ablation at the anterior part of the inferior turbinate."

So the second part of that sentence, do you agree that relates to the technique Fang applied and not to Reference 6?

A This is my understanding that he's talking about his technique here when he says "3-5 points." But that's only my understanding of the manuscript without the benefit of reading all the references that are cited in this manuscript and to see what these references mention or cite. So I'm going by what this manuscript is.

Q Okay. So down in the next paragraph, it says:

"The use of radiofrequency technique completely blocks the parasympathetic pathway of the nasal mucosa, reduces the vascular tension, reduces glandular secretion, and thus

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achieves the therapeutic purposes."

Do you see that?

A I see that.

Q And he cites Reference 7?

A I see that.

Q So, again, I think that's a reference that he's supporting his reference to an outside reference, at that point in time.

Is that your understanding?

MR. BRIGGS: Objection to form.

A Yes.

Q Okay. So then it says "pterygoid."

How do you pronounce that word?

A Pterygoid.

Q Pterygoid. Thank you.

"Canal neurotomy alone and/or anterior ethmoidal neurotomy or inferior turbinate treatment preserves one to two parasympathetic pathways in the source and distribution of parasympathetic nerves in the nasal mucosin."

Do you see that?

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A I see that.
Q Why is he saying pterygoid canal neurotomy alone and/or anterior ethmoidal neurotomy or inferior terminate preserves?
MR. STERN: Objection to form.
Foundation.
A As I read this, this paper, he's listing all the potential cites of the nasal cavity, nasal passage. And he's saying if you just treat one of these sources it might not achieve the goal, because you missed other sources of the innervation.
Q Okay. The next sentences says, "However, due to the presentation of the allergic reaction arcs, the postoperative effect is poor and the recurrence rate is high." And then there's two citations to eight and nine.
Do you see that?
A I see that.
Q What does he mean by "allergic reaction arcs"?

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MR. STERN: Objection to form.
A I don't use this term in my practice. I cannot sit here and tell you what he means by what he stated here.
Q The next sentence says, "For the patients in this group, all the nasal mucosa parasympathetic pathways, including the posterior ganglionic fibers of the sphenopalatine nerve, the parasympathetic fibers of the anterior ethmoidal nerve, and cholinergic ganglia within the inferior turbinate mucosa were blocked."
Do you see that?
A I see that.
Q So my question is: he says the patients in this group, does he mean the patients that he cited earlier or does he mean the patients that he treated in the experimental study?
MR. STERN: Objection to form.
A I haven't had a chance to look at the references, but when I read the manuscript, I understand he's talking about the -- his

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experimental group of 63 patients.
Q Is there something in this sentence that indicates that to be the case to you?
A Because he says "for the patients in the group," so "this group" refers to this group.
Q Okay. I think we -- if we could go to the last paragraph, please.
And he says:
"The case study of the experimental group has demonstrated the following advantages; one, acute localization of the surgical area, especially the precise effect of nerve blockade while avoiding accidental injury to adjacent important tissues."
What does he mean "a precise effect of nerve blockade while avoiding accidental injury to the adjacent tissues"?
MR. STERN: Objection to form.
A I have to take him at what he says, "precise effect of the nasal blockage," which

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is what he is treating here, while avoiding accidental injury to adjacent important tissues that he's not treating. There are many important issues or structures around the areas that he's treating, that are not involved with the creation of the symptoms. And that are the vital and that should not be injured.

Q Do you recall that he was talking about in Section 1.2 that he moved 5 millimeters, the firing head?

A Yes.

Q Is one of the reasons that he was moving the firing head 5 millimeters potentially to avoid accidental injury to adjacent important issues?

MR. STERN: Objection to form.

Foundation.

A This can be one of the reasons, which is to avoid creating hole in the septum, septum perforation. So this is one of these reasons, one of these structures.

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Q Okay. If you're treating -- he says he's treating the sphenopalatine foramen and you want to avoid accidental injury to adjacent important tissues when doing so, what important tissues would you be avoiding?

MR. STERN: Objection to form.

Foundation.

A There are many important tissues. Through the sphenopalatine foramen, there are vascular structures, also. There is an artery, sphenopalatine foramen artery. There are veins. And then there is also the nasal mucosa itself. So there's also the lining of the nose, the nasal mucosa in that part of the nasal passage.

So there are many important structures there. The nerves are important, but he is treating the nerves while he has to avoid injuring the artery and getting nosebleed.

Avoid injury in vein, avoid damaging nasal tissue.

Q Okay. Then he also treats, I think the

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anterior upper part of the nasal septum.

Do you remember that from Section 1.2?

A Yes.

Q What are important tissues to avoid when you're doing that treatment?

MR. STERN: Objection to form.

Foundation.

A This is what we discussed about avoiding perforation of the septum. Also preserving the nasal septum mucosa. So you would like the mucosa to stay intact, as much as possible. And you would like to avoid creating a hole in the septum, causing septum perforation.

Q And then the last one I believe was -- not the last one.

But he said, "The anterior upper part of the lateral wall of the nasal cavity."

Do you remember that one from Section 1.2?

A Yes, I do.

Q What are the adjacent important tissues

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to avoid when doing that radiofrequency treatment?

MR. STERN: Objection to form.

Foundation.

A Any structure inside the nasal passage, which is not involved with the disease is an important vital structure for the function of the nasal passage. So the mucosa is a vital structure, the submucosa is a vital structure, the bone under it is a vital structure.

So, basically, you would like to treat what you are treating while not causing damage to structures that are there that serve a purpose, that serve a function, that have that important function.

Q Okay. Moving down in that last paragraph of Fang, it says, "Radiofrequency therapy is the use of high frequency electromagnetic waves to coagulate and denature tissue proteins."

Do you see that?

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A I see that.
Q Do you agree with his characterization of radiofrequency there?
MR. STERN: Objection to form.
A There are different ways radiofrequency achieves its goal. One of them is that it can coagulate and denature protein, it can evaporate tissue, it can -- it has different ways -- different modalities of impacting the tissue. One of them is this, but it can also have other ways of effecting tissue.
Q Okay. The next sentence says, "The temperature at the radiofrequency ablation site is low, 60 to 80 degrees centigrade."
Do you see that?
A I see that.
Q Do you agree that is a low temperature for his purposes?
MR. STERN: Objection to form. I apologize. I didn't mean to interrupt.
Objection to form and foundation.

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A I don't know what he means by "low." I'm not here to characterize what he means by low. I can go by the degrees Celsius that he cites.

He says 60 to 80 degrees Celsius, which is below 100 degrees Celsius, which -- where water evaporates. So it is less than 100 degrees Celsius. It is in that range to be able to achieve its goal without damaging other structures.

MR. BRIGGS: Why don't we take a break, since we've been going about an hour. I probably have maybe an hour and a half, or two more hours to go, to give you guys a heads up on time.

(Whereupon, a recess was taken from 2:18 PM until 2:31 PM.)

Q Welcome back, Dr. Bu-Saba.

A Thank you.

Q If you can, please, grab Makower, we're going to be going through that in detail for the next several minutes, at least.

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If you could please turn to Page 1 of Makower and I mean the text Page 1, not the physical Page 1.

It's after Sheet 41 of 41 to give you a little bit more guidance.

A Okay.

Q So when there's a patent application that publishes, instead of having column line numbers like we were doing with the '077 Patent, for instance, it has paragraph numbers. So now I'm going to be referring to paragraph numbers, okay?

A Okay.

Q So if you could read the background, Paragraph 2, and just let me know when you're ready.

A Okay.

Q So Paragraph 2 of Makower appears to provide --

A I'm sorry. I read Paragraph 3. I'm sorry.

Q Oh, go ahead and read Paragraph 2,

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that's fine.
A Okay.
Okay.
Q So Paragraph 2 appears to be a somewhat anatomical overview of the nose by Makower.
Is there anything you disagree with in Paragraph 2?
MR. STERN: Objection to form.
A Not that I could see while reading this paragraph.
Q Okay. And if you could now -- I think you already read Paragraph 3; is that right?
A Yes.
Q So halfway down, about, it says, "Disorders that interfere with drainage of mucus, e.g. eclosion of the sinus ostia can result if a reduced ability of the peroneal sinuses to function normally."
Do you agree with that.
MR. STERN: Objection to form.
A It is one mechanism how you -- how you define the sinus cannot function normally.

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Q Okay. If you could read the first sentence of Paragraph 4, please.
A Okay.
Q In Paragraph 4 he says, "The nasal turbinates are three (or sometimes four bony proses)."
Do you see that?
A I see that.
Q Why does he say "or sometimes four"?
MR. STERN: Objection to form.
A In some patients, there is what's called the supreme turbinate, this is in a small subset of people, individuals. We talked about the inferior, middle, superior, a small subset of patients, of individuals, of individuals there is a fourth structure above the superior turbinate, we call it the supreme turbinate.
Q Oh, okay. Would you just read the rest of Paragraph 4, then, please.
A Okay.
Q Makower is talking about turbinate,

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mucosal tissues, meatus, et cetera, in Paragraph 4.

Is there anything you disagree with in Paragraph 4 of Makower?

MR. STERN: Objection to form.

A The first sentence I think it is a bit, sort of not as accurate as precise as I would like it to. The nasal turbinates are bone processes. The turbinates have a bony process, but they also have tissue covering that bony process.

So the turbinate, when we talk about the nasal turbinate, we're talking about the entire structure and not only the bone; in this first sentence. So it is not as precise as I would have used, but otherwise, the stuff which I read there is generally, generally, acceptable.

Q You don't think he's dividing turbinates and mucosal tissue because he says, a few sentences down, the mucosal tissue that covers the turbinates, it's capable of, and

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he goes on.

So is he defining turbinate to be separate from mucosal tissue, potentially?

MR. STERN: Objection to form.

A This is what I said, I would have used more precise term. I would have said -- when I talked about the mucosal turbinate, I would have talked about the mucosa and the bone.

Here, he first talks about the bone processes and then he talks about the mucosal tissue that covers the turbinate. It looks like when you combine these two you're talking about the same thing, which is bony structure, bony skeleton, and then the mucosal on the outside.

Q Okay. Why don't you go ahead and read Paragraphs 5 through 14. And let me know when you're ready.

A Okay.

Q So Paragraph 5 and 6 discuss nasal polyps, correct?

A Five mentions nasal polyps and 6 does

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also talking about the nasal polyps.
Q Fair enough.
Is there anything in Paragraph 6 that you disagree with?
MR. STERN: Objection to form.
A I would have used more precise terms. So he says nasal polyps often result from chronic allergic rhinitis or other chronic inflammation of the nasal mucosa, but nasal polyps can also start in the sinuses and extend into the nose. So nasal polyps can be -- they can start in the sinus, extend into the nose, and they can start in the nose. Typically, they are secondary to inflammation.
Q Okay. And Paragraph 7 through 14 relate to his definition of sinusitis, correct?
A Correct.
Q Anything in Paragraph 7 through 14 that you disagree with?
MR. STERN: Objection to form.
A It says -- the term sinusitis refers

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generally to any inflammation or infection. I would say only inflammation. So sinuitis means inflammation, which can be caused by infection or can be caused without infection. So the way I understand sinusitis is that it's an inflammatory disease of the sinuses that may or may not be induced by infection.

Now, when we talk about infection, he's listing some of the organisms that cause infection. Bacteria can cause infection. Viruses can cause infection. Fungi can cause infection. And then he talks about allergies, which can be induced by fungi. It can be things that are inhaled, environmental.

So, basically, he thinks some of the inflammatory causes, there are more disorders that cause inflammation of the nose and sinuses than listed here.

Q Okay. Go ahead and read Paragraph 17 through 19, please, and let me know when you're finished.

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A 17, 18, you said?
Q All of 17 through 19, please.
A Okay.
Q So Paragraph 17 through 19 are discussing deviated septum, correct?
A Correct.
Q And we've talked about deviated septum in relation to Fang, correct?
A That's correct.
Q Is the same deviated septum that's discussed here in Makower, these paragraphs, generally applicable to what Fang was meaning by deviated septum?
MR. STERN: Objection to form.
Foundation.
A Deviated septum is deviated septum. So I understand it as a septum which is deviated.
Q And then could you read Paragraphs 20 to 21, please.
A Okay.
Q So in Paragraphs 20 to 21, Makower is

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discussing reduction/removal of nasal turbinates, right?

A That's correct.

Q At the last sentence of Paragraph 21, he says:

"Thus, a septoplasty to straighten the deviated septum is sometimes performed concurrently with a reduction of the inferior turbinate."

Do you see that?

A I see that.

Q Do you agree with that?

A I agree with that. It all depends what's causing the obstruction. Commonly people will have a deviated septum. And if they have a deviated septum, and I as a surgeon believe that the septum deviation is contributing to their symptom of nasal blockage, and it's not only their inferior turbinates that are swollen, then I tell them, you will need your septum to be fixed, addressed, while reducing your turbinate.

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So sometimes we do septoplasty alone. Sometimes we do inferior turbinate reduction alone. Many times we do both.

Q So it's fair to say you've performed processes on patients that have both fixed a deviated septum and concurrently reduced inferior turbinates?

A That's correct.

Q If you could go one page over to page three, and if you could read Paragraph 38, 39 and 40.

A Okay.

Q So Paragraphs 38, 39 and 40 relate to laser radiofrequency turbinate reduction, correct?

A That's correct.

Q Is there anything in Paragraphs 39 through 40 that you disagree with?

MR. STERN: Objection to form.

A Again, these are general principles, but overall, yes. So when the bone of the turbinate is not the issue, in some patients

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it is the bone of the turbinate is the issue, where we take the bone out. But when we think it's not the bone of the turbinate that's the issue, or just one turbinate, we try to reduce it.

And one way -- one -- a couple of methods that you can do is laser, which I have not done, to reduce turbinate, or radiofrequency reduction, which I have done, but there are also other methods that you can use to reduce the turbinate without laser or without radiofrequency.

Q What kind of methods could you use without laser or radiofrequency to reduce the turbinate?

A Sub mucus resection. Use a tissue shaver, we can off fraction the turbinate over to the side. We can use cauterization, electro cauterization. There are different methods. But here, he's citing two such methods. Laser and radiofrequency.

Q Okay. In Paragraph 40, there's an

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instrument called the Somnoplasty.

Do you see that?

A Yes, I do.

Q Are you familiar with that Somnoplasty system?

A I am.

Q Is that the system you mentioned much earlier today in our discussion when we were talking about --

A That's correct.

Q Were you using the Somnoplasty system in 2005?

A Yes, I was.

Q Do you agree with his characterization of the Somnoplasty system?

A What he talked about here, this is one method I've used to the inferior turbinate, using this submucosal application of radiofrequency to the inferior turbinate.

Q I'm sorry. Let me just ask a better question. The sentence says:

"The Somnoplasty system includes

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a radiofrequency generator attached to a probe."

Do you agree with that?

A Yes, I do.

Q "The probe is inserted through the mucosa into the underlying soft tissue of the turbinate usually under direct visualization."

Do you see that?

A Yes. I see that. And I agree with that.

Q Okay. If you could read Paragraphs 34 and 35 on Page 3 in Makower and let me know when you're finished.

A Okay.

Q All right. In Paragraph 35, there's a sentence that says:

"Since FESS is considered an option only for the most severe cases, though showing abnormalities under CT scan, a large population of patients exist that can neither tolerate the

prescribed medications, nor be considered candidates for surgery."

Do you see that?

A I do.

Q Do you agree with that, as of 2005?

MR. STERN: Objection to form.

A I wouldn't have worded it this way. And so I think, the way the sentence is, is not very precise and I wouldn't have worded it this way. I don't understand what he means by the most severe cases. So I don't understand when he says the most severe cases, what he is applying to or how he is classifying them.

And when he says, a large population of patients, I don't know what he means by a large population of patients, but some patients, due to other health issues, cannot have surgery due to some, we call them comorbidities. And some patients are poor surgical candidates.

So I wouldn't have worded it this way,

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but this is like we discussed before, you recommend surgery for those who are symptomatic, who failed medical therapy.

Q Okay. A couple of sentences below that, he says:

"To date, there is no mechanical therapy offered for these patients and even though they may fail pharmaceutical therapies, no other course of action is indicated. This leaves a large population of patients in need of relief, unwilling or afraid to take steroids, but not sick enough to qualify for surgery."

Do you agree with that?

MR. STERN: Objection to form.

A I don't agree with the term mechanical therapy, because I think of surgery as a mechanical therapy. So I don't know what he means by, there is no mechanical therapy.

So when we operate, to me, the way I understand it, that is mechanical therapy.

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So this paragraph, I don't understand exactly what he's saying. So I have to take it at face value as whatever he's mentioning, but I wouldn't characterize it like this, there is no medical -- there is no mechanical therapy -- I don't know what he means by no mechanical.

What is mechanical, how is he defining mechanical. Is he excluding surgery? I don't know if he's defining the surgery as mechanical or not. I don't know.

Q Go ahead and read Paragraph 36 and 37, and let me know when you're finished, please.

A Okay.

Q So the first paragraph -- excuse me, the first sentence of Paragraph 36 says:

> "One of the reasons why FESS and sinus surgery is so bloody and painful relates to the fact that straight instrumentation with rigid shafts are used."

Do you see that?

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A Yes.
Q Do you agree?
MR. STERN: Objection to form.
Q As of 2005?
A I don't agree with this sentence, no.
Q Which part or the whole thing?
A He says so bloody, I don't understand what he means by so bloody. In most patients blood loss is minimal. And he says so painful, I don't understand what he means by so painful. Many patients only require Tylenol.
And then he says that straight instrumentation are used. No, we use curved instrumentation as well. We have been using curved instrumentation in '05 and before '05. So we have used curved instrumentation when we do nose or sinus surgery.
So this, sometimes many things I don't agree with.
Q Okay. I'm going to go to the last sentence in the paragraph. It says:

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"With the advances in catheter based technology and imaging developed for the cardiovascular system, there exists a significant opportunity to reduce the morbidity of sinus intervention through the use of flexible instrumentation and guidance."

Do you see that?

A I see that.

Q So the next paragraph says:

"If flexible tools could be developed, such as sinus intervention would be able to be carried out with even less bleeding and post operative pain, these procedures may be applicable to a large group of patients."

Do you see that?

A I see that.

Q And the next sentence further describes here:

"Flexible instrumentation may allow the application of diagnostic and therapeutic modalities that have never before been

possible."

Do you see that?

A I see that.

Q So Paragraph 41, I'm just going to read it:

"Many of the above described procedures and techniques may be adaptable to minimally invasive approaches and/or the use of flexible instrumentation. There exists a need in the art for the development of such minimally invasive procedures and techniques, as well as instrumentation, e.g. Flexible instruments or catheters usable to perform such procedures and techniques."

Do you see that?

A I see that.

Q So, then, let's go to Paragraph 42:

"In general, the present invention provides methods, devices and symptoms for diagnosing and/or treating sinusitis or other

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conditions of the ear, nose and throat."

Do you see that?

A I do.

Q Paragraph 43, the top sentence:

"In accordance with the present invention there are provided methods wherein one or more flexible catheters or other flexible elongate devices as described herein are inserted into the nose, nasal pharynx, paranasal sinus, middle ear or associated anatomical passageways to perform an intervention or surgical procedure."

Do you see that?

A I see that.

Q Okay. So if you could please go to Paragraph 132, on page seven.

A Okay.

Q So I think it would be best if you actually read Paragraph 132 and just let me know when you're ready.

A You said 132, right?

Q 132, please.

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A 132. Okay.
Q Great. So Paragraph 132 starts:
"The present invention provides the comprehensive system of devices and associated methods for diagnosing and treating disorders of the ears, nose and throat in a less invasive fashion of current day approaches."
Do you see that?
A I see.
Q "So, specifically, examples of which are described below, the invention provides devices that are wholly or partially effect a fluid type seal of the operative field."
Do you see that?
A I see that.
Q So, I'm going to represent to you that the rest of it talks about fluid tight seal. If you go down about seven or eight lines, it says:
"Another aspect of the invention is a set of methods and devices usable to assess

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static and dynamic nature of the paranasal sinuses and to provide for the guidance of specific therapies to particular sinuses or particular target regions, e.g. Stenotic sinus ostia affected tissues within sinuses, tumors or other target structures."

Do you see that?

A I do.

Q So, now we've got another aspect of the invention is the "use of devices and methods which are designed for minimally invasive entry into the sinus passageways or regional ducts under image and/or endoscopic guidance to provide local therapy such as", blah, blah "ablation."

Do you see that?

A I see that.

Q So we've got three different categories of what appears to be devices set forth by Makower, as he starts to talk about his invention. Would you agree?

MR. STERN: Objection to form.

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Foundation.
A This is what's listed in this paragraph.
Q So we have fluid tight seal at the start of the paragraph, correct?
A He mentions a fluid tight seal.
Q And then he says:
"Another aspect is a set of methods and devices usable to assess the static and dynamic nature of the paranasal sinuses."
Correct?
A That's correct.
Q And then another aspect is "the use of device's methods, which are designed for minimally invasive entry into the sinus passageways or regional ducts under image," and we talked about the language, correct?
A That's correct.
Q Okay. And then down below that sentence, it says:
"In a number of embodiments, the present invention utilizes flexible

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catheters and various working devices that are mounted on or delivered through elongate flexible members or catheter to diagnosis and treat a wide range of ear, nose and throat disorders."

Do you see that?

A I do.

Q Okay. So if you could look at Paragraph 133. I'm going to walk you through how I understand Makower to have set up his patent application.

Do you see 133?

A The one line?

Q Correct.

A Yes.

Q And it says, "A. Occluders and access port devices."

Do you see that?

A I do.

Q Okay. And so then if we go to Page 10 in Paragraph 144.

Do you see that?
A I do.
Q It says, "B. Variations in occluder design and suction apparatus." So that's the second section, correct?
A That's correct.
Q Okay. So then if we go to Paragraph 160. If you could look at that, please. It's on Page 13.
A Paragraph 160. Okay. Sorry, yes.
Q It says:
"C. Working devices for delivering substances or for cutting, ablating, remodeling or expanding bone or soft tissue."
Do you see that?
A I do.
Q So that's a third section, correct?
A That's correct.
Q So then if we go to -- it's several pages forward on Page 22.
A Page 22. Okay.

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Q Paragraph 205 says, "D. Preshaped guide catheters," correct?
A Yes.
Q So that's a fourth section, correct?
A Yes.
Q So on that same page, Paragraph 213, we have another section says, "Devices and methods for treatment within paranasal sinuses."
Do you see that?
A Yes.
Q So that's a fifth section, correct?
A Yes.
Q And then if we go to Page 23, Paragraph 222.
A Okay.
Q It says:
"General examples of interventions using the occluder and access devices and/or working devices."
Right?
A Yes.

Q So that's a sixth section, right?
A Yes.
Q And then Paragraph 239 is the final section. It's on Page 25.
A Yes.
Q It says, "Cochlear implant procedure," correct?
A Correct.
Q And then after that we get to the claims at the right-hand side of Page 25, correct?
A That's correct.
Q So we have seven sections of Makower in the specification, correct?
A A through G. And these are --
Q My first name begins with H, and I'm pretty confident that H is the eighth letter in the alphabet, so I'll represent to you that that's correct.
Okay. So if you could please go all the way back to the first section, Page 7, Paragraph 134.
A Okay.

Q If you wouldn't mind just reading that and let me know when you're finished.
A Okay. You said 134 only?
Q Yeah.
A Yes.
Q So the first sentence of Paragraph 134 reads:

"Many of the procedures of the present invention require the insertion and positioning of one or more flexible catheters or other flexible elongate working devices, examples of which are shown in Figures 5A through 5Y."

I don't know if that's triple prime or whatever he's saying there.

Do you see that?
A I do.
Q So we have -- they tie again flexible catheters or other flexible elongate working devices to Figures 5A through 5Y.

Do you see that?

MR. STERN: Objection to form.

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Foundation.
A I see that.
Q Okay. So if we then go to -- I guess let me just ask you a question: Do you know what an occluder is in the context of the Makower patent?
MR. STERN: Objection to form.
A Occluder is something which occludes. And based on his drawings, it occludes a certain part of the airway.
Q Okay. And why does he need occluders?
MR. STERN: Objection to form.
Q Why does he disclose occluders?
MR. STERN: Objection to form.
A Because if you are treating a certain part, for instance, the nasal passage, and you don't want blood or whatever to spill down to your throat, you need to occlude the back edge of the nasal passage so that stuff wouldn't go to where they are not supposed to.
Q Okay. If you could now turn to Page 13

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of Makower, Exhibit 1005, and just read Paragraph 161 and let me know when you're ready.

A Okay.

Q So Paragraph 161 reads:

"The present invention provides a variety of apparatus that may be inserted into the nasal cavity, paranasal sinus, nasal pharynx or middle ear to perform diagnostic or therapeutic procedures. These devices may be delivered through or incorporated into flexible catheters or flexible rod-like shafts."

Do you see that?

A I see that.

Q "Such flexible construction allows these devices to be delivered in position to perform the desired diagnostic or therapeutic procedures with minimal trauma to other tissues."

Do you see that?

A I do.
Q The sentence below that says:
"It is within the scope of this approach that these devices may be partially flexible or have rigid and flexible portions to facilitate their control and guidance."
Do you see that?
A I do.
Q Paragraph 164, could you look at that please.
A Okay.
Q So Paragraph 164 says, "Also, some of the working device is shown in Figures 5A through 5Y," I guess with the triple quotes.
Do you see that?
A I do.
Q So is it your understanding that Makower uses the word "working devices" when he's talking about Figures 5A through 5Y?
A He's talking about working devices. This is what he states, working devices.

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Q And the reason that's important is he uses the word "working devices" throughout the patent application to refer to certain things that are different from other devices, correct?

MR. STERN: Objection to form.

Foundation.

A I haven't had a chance to consider that part, so I cannot sit here and answer it.

Q Okay. In the bottom part of Paragraph 164, it says, "Nonlimiting examples of some such designs and constructions are set forth," and there's a bunch of patent numbers listed.

Do you see that?

A I see that.

Q Did you consider any of those patents in your analysis of Makower?

A I'd have to go around to look at each one of them. So I have to look at my exhibits. I have the look at these. I cannot sit here and recall if every one here

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was -- I relied on. I know I relied on Makower, and I listed him in my exhibit as materials considered. But unless I go and look at the exhibit and look at every one of these, so patent number, US patent -- so I have to look and see if I listed every one of these.

Q Fair enough. We can skip that.

Paragraph 165 says:

"As shown in the examples Figures 5A through 5Y, these working devices include guide catheters, substance delivery catheters, scopes, injectors, cutters, bone-breaking apparatus, balloons and other dilators, lasers, splice thermal delivery devices, braces, implants, stents, snares, biopsy tools, forceps, et cetera."

A Okay.

Q I just want to point out again the word "working devices" is used to categorize those

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types of devices.

Do you agree?

MR. STERN: Objection to form.

Foundation.

A I see he mentions "working devices." Like I said, I haven't considered all aspects of Makower's patent. I've only considered those relevant to my declarations, so I have not had a chance to consider every one of these, so I cannot sit here and give you an accurate and complete answer.

Q You would agree that Figure 5H is within the scope of 5A through 5Y, correct?

A 5H is between 5A. So when he says 5A to 5Y, he's including 5H.

Q So 5H is a type of working device -- Figure 5H, excuse me, illustrates one type of working device according to Makower, correct?

A As stated here, as shown in the example figures, these working devices. So 5H, being within that that's listed, is one of these working devices.

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Q Okay. Paragraph 166, "Figure 5A shows a side suction or cutting catheter comprising a flexible catheter body 72."

Do you see that?

A I do.

Q Paragraph 167, "Figure 5B shows an injector catheter 76 that comprises a flexible catheter shaft."

Do you see that?

A I do.

Q If you could please turn the page to 16. Paragraph 183:

"Figure 5D shows a guided injector catheter device for delivering a diagnostic or therapeutic substance as defined above. The device comprises a flexible catheter 90."

Do you see that?

A I do.

Q Paragraph 184, "Figure 5E shows a balloon catheter device comprising a flexible catheter 100."

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Do you see that?
A I do.
Q Paragraph 184, "Figure 5F shows a balloon/cutter catheter device comprising a flexible catheter 106."
Do you see that?
A I do.
MR. STERN: Objection to form.
Q Paragraph 186:
"Figures '5G' through "'5G"' show a device 160 and method for delivery of a pressure-expandable stent. This device 160 comprises a flexible catheter 162."
Do you see that?
A I do.
Q Paragraph 187, "Figure 5H shows an electrosurgical device comprising a flexible shaft 210."
Do you see that?
A I do.
Q Paragraph 188, in the middle of the

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paragraph, "This device comprises a flexible catheter 220."

Do you see that?

A I'm sorry, which one?

Q Paragraph 188.

A Okay.

Q In the middle of the page, it says, "This device comprises a flexible catheter 220."

Do you see that?

A Yes, I do.

Q Okay. Paragraph 190:

"Figures 5K through '5K' and 5L show a forward rotary cutting catheter device 700 that comprises a flexible outer tube 702 and a flexible inner tube 704 disposed coaxially and rotably mounted within the outer tube."

Do you see that?

A I do.

Q Paragraph 191:

"Figures 5M and 5N show a side

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rotary cutting device 714 comprising a flexible outer tube and a flexible inner tube 722."

Do you see that?

A I do.

Q Paragraph 196 on Page 19:

"Figure 5O shows a flexible catheter 733 having a working lumen that extends through the catheter."

Do you see that?

A I do.

Q Paragraph 197:

"Figure 5P shows a balloon catheter and pressure-expandable stent system 744, which includes all of the elements of the ballooned expandable stent system shown in Figures 5G through "'5G"'.

Do you see that?

A I do.

Q And do you understand that what means is that 5P also includes the flexible catheter

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described in Figures 5G through '5G', I'm sorry, "'5G"'?

MR. STERN: Objection to form.

A Well, it says it includes all of the elements of the balloon-expanded stint system shown in Figures 5G -- '5G' prime.

Q Great.

Page 20 of Makower, Paragraph 198:

"Figures 5Q and '5Q' show a self-expanding stint and delivery system comprising a flexible outer sheathe 762, a flexible inner tube 764."

Do you see that?

A I do.

Q Below, Paragraph 199, "Figure 5S shows a snare apparatus comprising a flexible catheter 782."

Do you see that?

A I do.

Q Paragraph 200, "Figure 5T," T as in Tom "shows a forceps 790, which comprises a

flexible shaft 792."

Do you see that?

A I do.

Q Paragraph 201 on Page 21 of Makower, "Figures 5U and '5U' show a telescoping system 800 comprising a flexible catheter 802."

Do you see that?

A I do.

Q Paragraph 202:

"Figure 5V shows a side port suction cut slice cutting device 820, which comprises a flexible outer tube 822, a flexible inner tube 830, is disposed coaxially and rotatably mounted within the outer tube 822."

Do you see that?

A I do.

Q Paragraph 203, same page, second sentence, "For example, Figures 5W through "5W" show a device 840 that comprises a flexible catheter 842."

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Do you see that?
A I do.
Q If you could, please, go to Page 22.
Could you just, please, read Paragraph 214 for me and let me know when you're finished.
A Okay.
Q In the middle of the paragraph -- I guess, scratch that.
Now, we're talking about paranasal sinuses, correct?
A Yeah, in this paragraph, yes.
Q In this section, the section starts at one paragraph above, we're in the Section E now, right?
A Yes.
Q Okay. So Paragraph 214 says, second sentence, "In the methods of the prior art, rigid or flexible scopes are sometimes used to visualize the ostia of sinuses, but typically such scopes have not actually been advanced into the interior of the sinuses."

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Do you see that?
A I do.
Q Do you agree, as of 2005, that was the case?
MR. STERN: Objection to form.
A I don't agree. Sometimes we advance these scopes into the sinus cavity and we can see inside the sinus cavity.
Q Okay. Paragraph 215, the second sentence says, "This device, 168, comprise a flexible catheter, 168," correct?
A I'm sorry. So this is Paragraph 215, you said, right?
Q That's right.
A And which lines of -- so you're reading the line which -- the sentence, which starts, "by this device."
Q That's right.
A Okay.
Q So this device -- 168 comprises a flexible catheter 168.
Do you see that?

A Yes, I do.
Q Paragraph 216, second sentence, about four lines down, "This device, 174, comprises a flexible catheter, 176".
Do you see that?
A I do.
Q Paragraph 217, Figure 7C shows a balloon catheter device 180 which comprises a flexible catheter 182.
Do you see that?
A I do.
Q Paragraph 218 on Page 23, Figure 7D shows a sensor equipped catheter device 190 that comprises a flexible catheter 192.
Do you see that?
A I do.
Q Paragraph 219, Figure 7E shows an implant delivery device, 196, which comprises a flexible catheter 198.
Do you see that?
A I do.
Q Paragraph 220, Figure 7F -- actually

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second sentence, my bad. "A flexible catheter 242 is positioned in or near the sphenoid sinus ostium, SSO."

Do you see that?

A I do.

Q Paragraph 221, same page, second sentence, "A flexible catheter, 242, is positioned in or near the sphenoid sinus."

Do you see that?

A I do.

Q Now, if we could just go back to Paragraph 41.

Okay.

I'm sorry, 43. My bad. I had my note wrong.

Having gone through numerous sections of Makower, the majority of which talk about a device with flexible catheters; isn't it fair, as it states in Paragraph 143, that the focus of Makower is to provide "one or more flexible catheters or other flexible elongate devices, as describe herein that may be

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inserted into the nose, nasal pharynx, paranasal sinuses, middle ear, or associated anatomical passageways to perform intervention or surgical procedure"?

MR. STERN: Objection to form.

Objection to foundation.

A Here he says provides methods for one or more flexible catheters, or other flexible elongate devices. So this is what he states in this paragraph.

Q My question is: Isn't it fair that the focus of Makower is such flexible devices?

MR. STERN: Same objection.

A In this paragraph it is flexible. One of the other paragraphs that you read for me, it says the catheter could be rigid or flexible.

Q So let's look at that.

A So there was one of the paragraphs that you read for me where he says it could be rigid or flexible.

Q Let me find that.

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So, Dr. Bu-Saba, yeah, please, you were on Page 13, Paragraph 161.

A Okay.

Q If we look at the bottom of Paragraph 161, as it reads on to the next column, it says, "Is within the scope of this approach that these devices may be partially flexible or have rigid portions and flexible portions to facilitate their guidance and control."

Do you see that?

A I see that.

Q So to me that sentence says, may be partially flexible, or it can have rigid and flexible portions.

Do you disagree with that understanding?

MR. STERN: Objection to form.

Foundation.

A So this sentence itself mentions this, but when I look at other paragraphs, for instance, 187, when it talks about Figure 5, it says, "Comprising a flexible shaft," but

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then he says "example catheter or solid shaft."

So at least in this paragraph, he mentions a solid shaft. So this is what I said, in his description he mentions flexible, but at least in this paragraph, he says it could be solid.

Q I don't disagree.

My question was: Given everything we've gone through in Makower, is it fair to say that the focus of Makower is the development of flexible catheters or devices that allow better insertion of working devices into various cavities of the body?

MR. STERN: Objection to form.

Foundation.

A In the paragraphs that you cited and the paragraphs that you read and made me read, the "flexible" is mentioned repeatedly.

Q Okay. Besides Figure 5H of Makower, are you aware of any illustration in Makower showing RF electrodes on a device?

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MR. STERN: Objection to form.
A I have only considered Makower as it applies to my declaration and to the claims that you are discussing, that's why I chose Figure 5H. I haven't considered other aspects of Makower in the declaration, so I cannot sit here and give you a complete and accurate answer, when I have not considered all the other factors or all the other issues that are out there.
Q Sitting here today, can you recall any figure in Makower besides Figure 5H that has electrodes that -- for a device that is inserted into a body cavity?
MR. STERN: Objection to form.
A Well, I have to go back and look at every figure now. Because I cannot recall every figure listed in the Makower.
Q Sure. If you want to go through the working devices figures, which are the Figures 5A through 5Y, we can do that.
A I mean, just looking at the figure

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quickly and without the benefit of reading Makower word for word and see what he says of every figure, the only one that I see that has radiofrequency is this 5H.

Q Okay. Why don't we talk about 5H, Figure 5H for a little bit.

Do you have Figure 5H in front you, Dr. Bu-Saba?

A I have it.

MR. STERN: And I don't want to interrupt your flow --

MR. BRIGGS: It's a good stopping point. So we can go off the record.

(Whereupon, a recess was taken from 3:27 PM until 3:40 PM.)

Q So, Dr. Bu-Saba, welcome back.

A Thank you very much.

Q You now have in front of you two Exhibit 1005 Makower's, correct, so you can look at the figure in one and the text in the other, correct?

A That's correct.

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Q Okay. If you could, please, in one of those, turn to the page that has Figure 5H, and in the other, please, turn to the page that has Paragraph 92.

Go ahead and read Paragraph 92 and let me know when you're ready.

A Okay.

Q Paragraph 92 says, "Figure H is a partial perspective view of a tissue shrinking electrode device being used in accordance with the present invention," correct?

A That's correct.

Q Do you know what a partial perspective view is?

A No.

Q Do you know what a perspective view is?

A Yes.

Q So when we're looking at Figure 5H and he says "partial perspective view," how do you interpret that?

A Not full perspective.

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Q Okay. But we can agree a perspective view of Figure 5H, correct?
A That's correct.
Q Okay. So if you could, then, please, turn to Paragraph 187 of Makower, Exhibit 1005, please.
A Okay.
Q Paragraph 187, Figure 5H of Makower, correct?
A That's correct.
Q And there are no other paragraphs that describe Figure 5H of Makower besides Paragraph 92 that we just read, correct?
MR. STERN: Objection to form.
Foundation.
A There was the paragraph that you just referred to before that talks about 5H.
Q I agree. So let me ask you a better question.
Other than Paragraph 92, which we just read and Paragraph 187, that you're now looking at, are you aware of any other

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discussions of Figure 5H in Makower?

MR. STERN: Objection to form.

Foundation.

A All I can say is that these two paragraphs do mention and refer to the Figure 5H. I cannot sit here and give you a full answer whether there's any reference anywhere in Makower about 5H. I don't know the answer.

Q Fair enough.

The first sentence of Paragraph 5H says -- or excuse me.

The first sentence of Paragraph 187 says, "Figure 5H shows an electrical surgical device, 208, comprising a flexible shaft (e.g. a catheter or solid shaft) having arched strut members 214 attached thereto."

Do you see that?

A I see that.

Q What's your interpretation of a strut member?

MR. STERN: Objection to form.

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A A member of struts. So strut member is a member with strut.
Q So the plain and ordinary meaning of strut?
MR. STERN: Objection to form.
A With my English, I understand strut as a structure, a framework, strut, yeah.
Q Okay. Do you generally interpret strut to be a rigid structure?
MR. STERN: Objection to form.
Foundation.
A It can be rigid; it can be flexible.
Q Do you believe the strut members of Makower are flexible?
MR. STERN: Objection to form.
A I have to -- what he says collapsable and expandable, so I think it can be flexible, if they are collapsible and expandable.
Q In Figure 5H of Makower, how many strut members does he illustrate?
A Here he points to two; when he says --

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when he use reference 214 as indicating the struts, he points towards two.

Q Okay. In Figure 5H just below the number 214, there appears to be a point extending from the end of the struts.

Do you see what I'm referring to?

A You're talking about the figure or the paragraph now?

Q The figure.

A Okay. So the figure you're saying -- do you mind repeating?

Q No. No problem.

So we've identified the strut members, correct?

A Correct.

Q And extending from those strut members, in what I would call a generally northeasterly direction is a point or a tip.

Do you see that?

A Yes, I do.

Q And what is the purpose of that object?

MR. STERN: Objection to form.

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A I don't know what Makower intends with that object. I see it as part of the shaft, but I don't know what he intends. What does he extend beyond the struts, I don't know.
Q Okay. The next sentence of Figure 5H says:
"Electrodes 216 are located on the strut members 214".
Do you see that?
A I do.
Q How many electrodes are illustrated in Figure 5H?
MR. STERN: Objection to form.
A In his figure when he says 216, Makower points to two. When I look at the whole figure, there are other structures not shown on this figure that resemble them. But Makower did not specify whether these are -- I mean, when he say 217 he pointed to two such structures.
But I see four such structures in there, but he points to two of them.

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Q Okay. Makower says that those electrodes are located on the strut members 214.

Do you see that?

A I do.

Q How are they located on those strut members as illustrated in Figure 5H?

A How? I don't know. But he points to them on the struts. So 214 is the strut, 216 is electrode; 216 in on -- what he refers to as the strut. So these electrodes are located on the strut, but how, I don't know how.

Q Okay. Next sentence says, in Paragraph 187, says:

"In some cases the strut members may be a fixed configuration. In other cases the strut members may be collapsible and expandable."

Do you see that?

A I do.

Q Which one do you think is illustrated in

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Figure 5H?

MR. STERN: Objection to form.

Foundation.

A Just seeing one figure at one point in time, I cannot sit here and tell you which one of these he's referring to in this partial perspective that we talked about when he says partial perspective of Figure 5H.

So just looking at one Figure, one point of time and one -- in one page, I cannot say whether this, he means these are fixed or whether he means these are collapsible, or whether he means they are expandable. I can't make that determination just looking at this figure.

Q How would you need to design Figure 5H to make it both collapsible and expandable?

A If I'm designing it, and if I intend to say collapsible and expandable, I would have '5H', "5H", "'5H"', showing it in different modalities. Within how the medical artist can show it, to show it in collapsed form, to

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show it in an expanded form.

I cannot show it in a flexible or rigid form because this is not dynamic. It's a video. So as far as rigid or flexible, this will not show here unless I describe.

But collapse or expanded, then I have to show you collapsed, and I have to show you expanded. And that way I can tell you, this is collapsed, this is expanded.

Q Okay. Thank you.

My question was slightly different. Which was, how would you configure the device of 5H so that that device could be both collapsible and expandable?

A How would I configure it, even though I am not the patent owner?

Q How do you interpret being able to do that, is my question, given Makower says that that's an option?

A That could be many mechanisms. I mean, I am not the patent owner, but there are many mechanisms. Maybe you can expand strut in

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many ways. It can be mechanical, it can be pneumatic, it can be any form, by injecting fluid into it. I mean, there are many ways that you can make someone go from being collapsed into being expanded.

Q Okay. The next sentence of Paragraph 187 says:

"In operation, the device 208 is advanced into a passageway such as a nostril, a nasal cavity hiatus, ostium, interior of a sinus, et cetera".

Do you see that?

A I do.

Q Do you know which one of those Makower is illustrating in Figure 5H?

MR. STERN: Objection to form.

A No. I do not.

Q Can you look at Figure 5A for me, please.

A 5A.

Q Would be the other way. There you go.

A 5A.

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Q So can you compare the tissue, alleged tissue of Figure 5A, versus the tissue of Figure 5H and how that's illustrated, please, and then let me know when you're finished.
A Just looking at the figures without reading the description?
Q You can read the description if you want to, but I will tell you, it's not stated, but you can go ahead and confirm that, if you want.
A Just looking at the figures, I cannot say what's the difference in tissue. So just looking at the figures alone, I cannot differentiate what kind of tissue is being represented here.

So without the benefit of reading what Makower described about 5A and 5H, there is no way for me to know, just looking at the figures.
Q Well, for Figure 5H, we just read the locations, right, but it's easily not discernible which location he's talking

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about, or illustrating, excuse me, from Figure 5H alone. Is that fair?

MR. STERN: Objection to form.

A From 5H alone and this figure, I cannot know -- I cannot sit here and tell you where it is.

Q Okay. So if you look at Figure 5A, please.

A Yes.

Q And we see that the tissue is represented with lines that are generally angled, but parallel.

Do you see that?

A I do.

Q Is that a common way to illustrate tissue in the medical field?

MR. STERN: Objection to form.

Foundation.

A There are many ways of drawing tissue.

Q Let me ask you a better question.

Is that the way that tissue is labeled, would that readily indicate to a person of

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ordinary skill in the art which tissue that would be?

For instance, what I have in my head is some kind of legend, so certain times use certain labeling characteristics in maps or other things to indicate geographical features.

Is there something similar to that which going on in Figure 5A, where these diagonal lines are indicating a certain type of tissue?

MR. STERN: Objection to form.

Foundation.

A Not that I'm aware of, not that I've used.

Q Does that same answer also apply to Figure 5H, 5I, 5J, for instance, where we have tissue labeled with a series of dots instead of the diagonal lines?

A Any of these figures, I cannot just look at that figure say, uh-huh, this is Makower is referring to tissue A or tissue B or

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location A or location B, I cannot tell this just looking at figures.

Q Okay. Is the device of Figure 5H suitable for use in the sinus?

Specifically, he says, interior of a sinus. Do you consider that device to be suitable for use interior of a sinus?

A I don't know what he means by interior of the sinus, and which sinus he's talking about. There are four sinuses. Which have different shapes, different sizes.

So I can't sit here and answer you if this is appropriate for the inside of the sinus, because I don't know which sinus and what does he mean by inside of the sinus.

I mean, inside, I know that, but I don't know whether he's treating a structure inside the sinus, or what is he treating in the sinus. The lesion in that sinus, is it tumor in that sinus. I don't know what he says inside the sinus, what he means. So I cannot answer you whether this device, I cannot

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answer your question.

You asked me whether this device is suitable for inside the sinus, correct?

Q That's what I said, yeah.

A So I cannot sit here and answer because I don't know what he means and which sinus he's talking about and for which indication.

Q Okay. The next sentence of Paragraph 187 of Makower reads:

"Thereafter, current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated."

Do you see that?

A I do.

Q Is there a difference between cauterizing and heating?

MR. STERN: Objection to form.

A It depends how much -- for me, as a surgeon, cauterize means burn. So you do cauterization, means you are burning tissue. Heated means heating tissue.

So this is the difference, in my mind,

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when I say cauterized or heated.
Q Okay. How does Makower supply the electrical current necessary to energize the electrodes of Figure 5H?
A I have to go back and look entire Makower. But my understanding is that he did not go into specifics about that, and he said people who of ordinary skill in the art would know what to use, what generally to use, depending on what they're doing.
Q And you're a person of ordinary skill in the art, right?
A I am a person of ordinary skill in the art.
Q So, with that understanding, he's saying people would know is there a manner in which you understand Figure 5H to be able to electrically connect electrodes to an external generator?
A If these are electrodes, they can be connected to an external generator. And what generator, what their generator generates is

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the kind of energy you are applying.
Q Would the wires be on the outside of the struts to connect to an electrical generator?
MR. STERN: Objection to form.
A I'm not an electrical engineer, but I can -- the electric engineer would make determination what's the most optimal way, what's the optimal way of connecting these two, which is efficient and safe.
Q Okay. The next sentence of Paragraph 187 of Makower reads:
"The electrode 216 may be bipolar, monopolar or facilitated by any other suitable form of energy such as gas or plasma arc."
Do you see that?
A I do.
Q What is a monopolar electrode?
A So an electrode is an electrode, and monopolar indicates the way you are delivering energy through that electrode.
So monopolar means there is one pole.

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So that electrode is delivering energy. So there is one delivering energy, this is monopolar. There is a point in the body where that energy exits. And, usually, when we use monopolar, there is a pad somewhere in your body where the current will exit. So basically there is an electrode that is being used in the monopolar mode.

Q And how does the bipolar electrode work?

A Again, bipolar refers to the modality of delivering energy to these electrodes. So bipolar indicates two poles. Bipolar. So there are two poles, therefore, two electrodes. One that is active, one where the energy enters, and one where the energy exits. So, hence, becomes bipolar from pole to pole, bipolar.

Q Do you know if the device of Figure 5H is illustrated in a bipolar or monopolar configuration?

MR. STERN: Objection to form.

A It shows multiple electrodes. Again, at

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least two electrodes. So these two electrodes, they can be configured to be each one of them monopolar. They can be configured that they match together and they function in bipolar modality.

So you can activate one of them in the monopolar mode. You can activate two of them in monopolar modes, or you can pair them together in the bipolar mode.

Q Okay. When you're using a device such as Figure 5H in Makower, is it better to use a monopolar or bipolar configuration?

MR. STERN: Objection to form.

Foundation.

A It depends on the indication. And there are many indications. So it depends on the indication. So sometimes monopolar is better, sometimes bipolar is better.

Q When you say indication, I don't know that I understand that term.

What do you mean by indication?

A The reason you are using this device for

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what condition you are treating.
Q Okay.
A So the reason you are using this device will also -- this is the indication, the clinical reason, that's the indication. And then there are some medical conditions that are better treated with the monopolar modality. Some are better treated through a bipolar modality.
Q Is bipolar or monopolar better for controlling bleeding?
MR. STERN: Objection to form.
Foundation.
A Each one has its place. So I've used both monopolar and bipolar for controlling bleeding.
Q In what situations have you used monopolar for controlling bleeding?
A Many times. If you come to me with a laceration and there is bleeding, sometimes I use monopolar, and then I stopped the bleeding site. So many times when there is

bleeding during the case, we use monopolar. And this is very frequently used, many times. But at times we feel that bipolar is the better way of utilizing it.

So, for instance, when you use cauterizing, you always have both modes available, and many times switch between monopolar and bipolar, depending on what we're doing, the indication and so on.

Q Can you ablate tissue with both bipolar and monopolar configurations?

MR. STERN: Objection to form. Lacks foundation.

A Yes.

Q Does ablation destroy tissue or modify tissue?

MR. STERN: Objection to form.

Objection to foundation.

A It can be both. So when you ablate, you can destroy tissue and/or you can modify tissue.

Q What's the difference between modifying

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and destroying tissue?

MR. STERN: Objection to form.

A Destroying means destroying. While modifying, it means the tissue is still there, but modified.

Q When you destroy the tissue, what happens to that tissue typically?

MR. STERN: Objection to form.

Foundation.

A It depends where that tissue is located. If it's externally, it's lost. If I ablate your skin, it's lost, it falls off, and it is on the ground. If it is under the surface, there are mechanisms for the body to take care of that. To take care of that ablated tissue.

Q Would you want to destroy tissue when you're using RF energy on an inferior turbinate?

MR. STERN: Objection to form.

Foundation.

A It depends what is the indication, why I

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am doing it. So what I intend to achieve depends why I'm doing the indication, the symptoms, the structure, the disease.

So sometimes destroying tissue is reasonable. Sometimes preserving tissue, but altering it is more reasonable. So this -- so I, as a surgeon, would have to make that decision. For this indication, this is better, for that indication, that is more reasonable.

Q Okay. That sentence that we have been speaking about concludes with, "or facilitated by any other suitable form of energy such as gas or plasma arc."

Do you see that?

A I do.

Q How would you use electrodes of Figure 5H with gas?

A I am not a gas expert, so I cannot answer that question.

Q How would you use the electrodes of Figure 5H with plasma arc?

A I have to know more about what he means with plasma arc.
Q So as a person of skill in the art, how do you interpret plasma arc?
MR. STERN: Objection to form.
A I have to understand the context of this plasma arc, what does Makower mean with plasma arc.
Q Is the term plasma arc used routinely in this field?
MR. STERN: Objection to form.
A Not by me and not by my colleagues.
Q Okay. So Figure 5H discloses those arched struts, correct?
A That's correct.
Q And if you position those arched struts in the nose, is it possible that some of the electrodes may be in touch with tissue where others would not be in touch with tissue?
MR. STERN: Objection to form.
Foundation.
A I can envision that, yes.

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Q So what happens when the device is working but not touching tissue of Figure 5H?

MR. STERN: Objection to form.

Foundation.

A So for instance, if -- let's say these are four electrodes, and two are touching tissue and two are just floating in the air, the two floating in the air would be inactive, while the two touching the tissue would be used to either ablate or alter tissue.

Q The last sentence of Paragraph 187 says:

"Additionally, sensing elements may also be attached to the catheter, and/or strut member to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, et cetera)."

Do you see that?

A I do.

Q Besides temperature, which is mentioned, what else would be monitored with the

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Figure 5H device of Makower?

MR. STERN: Objection to form.

A I've used devices where impedance is being measured. I've used devices where the total amount of juice -- amount of energy is being measured. So there are different things that you can measure.

Q Okay. If you could now go to your declaration in the 0279 IPR, Paragraph 171, which is on Page 114 of your declaration.

A Okay.

Q If you could just read that to yourself and let me know when you're ready.

A Which paragraph you want me to read?

Q One hundred seventy-one?

A Okay.

Q The last sentence of Paragraph 171 says:

"Fang provides additional details about the well-known design construction and operation of the Makower electrosurgical device that delivers RF energy."

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Do you see that?
A I do.
Q I see no citation to Fang there. Do you?
A I don't.
Q Can you point me to the portions of Fang that provide the additional details about the well-known design, construction and operation of the Makower device?
MR. STERN: Objection to form.
A Setting at a -- setting of three would be one way of operation.
Q Level three?
A Level three.
Seeing where he would place it that would also be operation. He mentions the machine that he mentions, the device that he mentions. And that would be about design and construction. So he specifically mentions a device that he used; therefore, that talks about the design and construction.
And he also describes how he used it,

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how did he apply it, where he applied it and which setting. And that would be operation.

Q We talked earlier about Figure 5H of Makower and that it appears to be the only figure in the Makower having RF electrodes illustrated on the device, correct?

MR. STERN: Objection to form.

A As we -- as I answered this question before, without going through and read it, every word in Makower, 5H shows a device with electrodes.

Q And we've also gone through the numerous disclosures in Makower about the importance of flexible catheters, correct?

MR. STERN: Objection to form.

Foundation.

A We talked about flexible, and we talked about rigid. So we cited many paragraphs where the word "flexible" came up, and we talked about paragraphs where "rigid" also came up.

Q Do you agree that Makower's focus is the

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use of flexible catheters with various working devices, occluders, et cetera?

MR. STERN: Objection to form.

Objection to foundation.

A I haven't considered all what Makowers (sic) writes or what Makowers claim. I just chose parts that are relevant to my declaration and that are relevant to Fang's teachings. So I found Figure 5H with the descriptions about it rather than to Fang's teaching, so that's why I included this -- I included Figure 5H with Fang.

Q Prior to reading Makower, had you ever seen a device like Figure 5H in practice?

MR. STERN: Objection to the form.

A Exactly like Figure 5H?

Q Yeah.

A Not that I recall.

Q If you could please go to your 00281 declaration.

A Okay.

Q Exhibit 1007 from that proceeding.

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(Whereupon, Declaration of Dr. Gregory T. Martin was marked as Exhibit 1007 for identification as of this date.)

Q We'll look at Exhibit 1007 in a second, but why don't we first go to Paragraph 26 of your declaration.

A Paragraph 26, you said?

Q Okay. That's not right. Let me get you to the right place, I'm sorry.

Twenty-five, you already told me about it. Paragraph 25 of your declaration for 00281.

A Twenty-five; yes.

Q The last sentence reads:

"I have also relied on a conversation with Dr. Gregory Martin and have reviewed his declaration for this IPR."

Correct?

A That's correct.

Q And what I handed you, Exhibit 1007, is

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the declaration of Dr. Gregory T. Martin, correct?
A I don't recall how his declaration looks.
Q If you look at the front page, it has his name.
A Okay. Okay.
Q And if you want to leaf through it real quick and make sure that it appears to be the declaration you're referring to here, that would be great.
A I'll take your word for it.
Q Don't take my word for it. I mean, it says Exhibit 1007 --
A Okay.
Q -- right, in your declaration, and that appears to me to be Exhibit 1007, so.
A Okay.
Q Let's assume that is the declaration then.
A Okay.
Q So when did this conversation with

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Dr. Martin occur?
A I don't recall the date.
Q Okay. Obviously prior to January 7, 2024, correct?
A Prior to me writing my declaration.
Q Okay. And what did you guys discuss?
A I had some questions for him. He had some questions for me. We went over his findings.
Q What kind of questions?
A I don't recall the exact questions. This happened almost a year ago.
Q Was there particular topics that you wanted to talk to Dr. Martin about?
A He has engineering background, so it was issues pertaining to the engineering part.
Q Okay. Do you know Dr. Martin -- did you know Dr. Martin before you had this conversation with him?
A I did not.
Q You've never previously met Dr. Martin before this proceeding?

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A I have not.
Q Okay. Did you know Dr. Martin was deposed in conjunction with these proceedings?
A I do.
Q You do know that?
A Yeah.
Q Did you happen to review his deposition testimony?
A No.
Q So when Dr. Martin provided this declaration to you, did you provide any comments to him on it?
A Comments on his declaration?
Q Right.
A Like things to edit?
Q Right.
A No.
Q You simply reviewed it?
A That's correct.
Q Did he review your declaration?
A That I don't know, but when I spoke with

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him, I hadn't written my declaration yet. So I don't know whether counsel gave him my declaration later on and whether he reviewed my declarations later on. I don't know.

Q But you didn't receive any edits from Dr. Martin on your declaration?

A No. I did not.

Q Okay. So in 00281, your declaration, if we could go to Paragraph 214, which is -- starts on Page 161.

A Okay.

Q So Paragraph 214 says:

"As detailed below, the combination of Makower, Fang, Edwards-535 and Stern renders Claim 4 obvious."

Do you see that?

A Yes, I do.

Q And this is the claim that you had a discussion about with Mr. -- or excuse me, Dr. Martin, correct?

A I forgot what I asked him about this

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particular claim. If I cite Dr. Martin in this paragraph of my declaration, it means I referenced my discussion with him. If I don't cite it here, I don't recall.

Q I'm sorry, let me help you. Please go to Paragraph 222.

A Okay.

Q Why don't you go ahead and read that.

A Okay.

Q So it's correct that you talked to Dr. Martin, or at least relied on his declaration, as it relates to Claim 4 of the '077 Patent, correct?

MR. STERN: Objection to form.

A I discussed it with Dr. Martin, but the opinions are mine. And his opinions -- looking for the word -- sort of coincided or reinforced or affirmed my opinions.

Q And Claim 4 requires, if we look at Page 161, the apparatus at Claim 2 when at least two bipolar radiofrequency electrodes comprise multiple pairs of bipolar

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radiofrequency electrodes, correct?
A That's correct.
Q Why did you feel it was necessary to reach out -- or not reach out. Strike that -- to rely on Dr. Martin's declaration to confirm your understanding for this claim?
MR. STERN: Objection to form.
Foundation.
A We discussed the electric circuitry and how you can configure various electrodes to perform in a bipolar mode and which electrodes to be paired together and how do you do that.
Q Did you have knowledge of how to do that before you spoke with Dr. Martin?
A I am not an electrical engineer, so whatever my general knowledge about the field, no, but I'm not an electrical engineer.
Q So since you're not an electrical engineer, you wanted to talk to Dr. Martin about Claim 4?

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MR. STERN: Objection to form.
Foundation.
A To -- so that I can spoke -- so I spoke with Dr. Martin to get his take, his understanding, based on his experience being an engineer about these electrodes.
Q Would you have felt comfortable submitting this declaration without Dr. Martin's analysis?
MR. STERN: Objection to form.
Foundation.
A Just -- I mean, knowing about what I know from physics in medical school about electrodes and electricity and switches, I have knowledge how switches work and how you can pair two electrodes and how -- but I've been -- I don't know the technical how on how to make it, but I know that it can be made.
Q Is there anything you disagreed with in Dr. Martin's declaration?
A I mean, I am not here to say whatever Dr. Martin -- agree or disagree, because my

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opinions are my opinions. And my opinions are based on my review of the case. So I'm not here in the position to say if Dr. Martin is -- agree or disagree -- or I mean, I'm not in a position to discuss Dr. Martin's declaration.

Q You know that conflicts with the reliance on Dr. Martin's declaration, correct?

MR. STERN: Objection to form.

Foundation.

A I relied on it on how he explained these things, but I'm not here to say whether every sentence in there -- I'm not an electrical engineer. So I'm not here to say -- I am not the person to say whether Dr. Martin's declaration is right or wrong, or accurate or not accurate. I'm not the expert. I mean, I'm not in a position to make that determination.

Q Okay. If you could, please, go to Exhibit 1007, which is Dr. Martin's

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declaration.
A Okay.
Q And if you could, please, go to Page 49 and Paragraph 89 says, "As I explained in section Roman numeral 9A2" it cites the grounds "Stern teaches two bipolar radiofrequency electrodes that comprise multiple pairs of bipolar radiofrequency electrodes."
Do you see that?
A I do.
Q So Dr. Martin is referring us to Section 9A2, we should go there. So if we go to Page 27 of Dr. Martin's declaration.
I'm sorry, it's not -- oh, it is Page 27.
Why don't you read Paragraphs 55, 56 and let me know when you're finished?
A 55 to 56, you said -- 55 and 56?
Q Yes, please.
So Paragraphs 55 through 56, Dr. Martin is talking about the Stern reference,

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correct?
A That's correct.
Q And at the end of Paragraph 56 he says:
"In other words, Stern teaches two bipolar radiofrequency electrodes that comprise multiple pairs of bipolar radiofrequency electrodes."
Do you see that?
A I do.
Q Do you agree with that conclusion?
A Stern shows multiple electrodes. And Stern says these can be used either monopolar or bipolar, and that you can chose to pair any of these two electrodes in a bipolar way.
Q So the answer is yes, you agree with Dr. Martin here, that Stern teaches bipolar radiofrequency electrodes that comprise multiple pair of bipolar radiofrequency electrodes?
MR. STERN: Objection to form.
A I mean, I agree with the concept, but I might word it differently. If I'm writing

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this, I would have worded it differently.
Q Do you know why he has the words in italics?
A Because he's copying from Stern, I assume. But I did not write his declaration, so I don't know why he's using italics.
Q I see the issue. So why don't we go back to your declaration, and why don't we go back to Page 161.
A Yeah.
Q And at Page 161, the claim is in bold.
A Yeah.
Q Reading the claim it says, "Be at least two bipolar radiofrequency electrodes comprise multiple pairs of bipolar radiofrequency electrodes."
Do you see that?
A I do.
Q And if we look at italicized language of Dr. Martin, at the end of Paragraph 56, that aligns with the language of Claim 4, correct?
A I'm sorry. Which paragraph now again,

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in Martin's?
Q Paragraph 56, Page 30, the last sentence.
A I see that.
Q So would you agree that Dr. Martin is quoting the claim language in his last sentence, by the use of italics for those words?
A I see the words are similar. I don't know why he's using it in italics, but the words appear to be similar.
Q So my interpretation is he's using those italics because they align with the claim language.
So my question is: Do you agree with his analysis because that analysis relates to Claim 4?
A In his analysis that Stern teaches bipolar radiofrequency electrodes that comprises multiple pairs of electrodes?
So I agree that Stern teaches multiple electrodes, which can be paired together and

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depending on how many of them you pair, they can become multiple pairs if you pair many of them together. So each two can become a pair. So if you decided to activate five of them, then he's activating five pairs; because for every bipolar you need two.

And so they're using -- yes, so you need two electrodes to be able to be bipolar, so to be able to deliver energy in a bipolar form you need two electrodes as we discussed; bipolar from pole to pole. And this can be multiple pairs if there are multiple electrodes.

Q So, yes, you agree that Dr. Martin's analysis that Stern discloses the limitations in Claim 4?

A Yeah.

Q Okay.

MR. BRIGGS: Let me check with my external colleagues real quick, and I will be right back.

MR. STERN: Sure. Should we go off

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the record?

MR. BRIGGS: Off the record, please.

Thank you.

(Whereupon, a recess was taken from 4:33 PM until 4:36 PM.)

MR. BRIGGS: Back on the record.

No further questions for Dr. Bu-Saba, at this time.

MR. STERN: Petitioners don't have any questions, either.

(Whereupon, this examination was concluded at 4:36 PM.)

_____

NICOLAS BU-SABA

Subscribed and sworn to before me on this ____ day of _____, _____.

_____
Notary Public

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I N D E X

WITNESS: DR. NICOLAS BU-SABA

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E X H I B I T S

EXHIBIT	DESCRIPTION	PAGE
Exhibit 1001	U.S. Patent No. 10,894,011	8
Exhibit 1005	U.S. Patent Pub. No. 2005/0240147 to Makower	47
Exhibit 1006	Fang Chao-xin and Zhen Shao-Shao, Nasal endoscopy	47
Exhibit 1008	U.S. Patent No. 6,517,535 to Edwards	49
Exhibit 1009	U.S. Provisional Appl. No. 60/702,077	50
Exhibit 2001	Sinusitis, from microbiology to management	79
Exhibit 0771	U.S. Patent No. 10,610,675	122
Exhibit 1007	Declaration of Dr. Gregory T. Martin	304

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CERTIFICATE OF NOTARY PUBLIC

I, Raechel Meyerowich, Notary Public, do hereby certify that the aforementioned witness was sworn before me at the aforemention location, and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 17th day, of October, 2024.

My Commission Expires: June 7, 2030

Raechel Meyerowich

Raechel Meyerowich, Notary Public
for the State of Massachusetts

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C E R T I F I C A T E

I, KIARA MILLER,, Certified Reporter, do hereby certify:

That DR. NICOLAS BU-SABA, the witness whose deposition is hereinbefore set forth, was duly sworn by me before the commencement of such deposition and that such deposition was taken before me and is a true record of the testimony given by such witness.

I further certify that the adverse party, PETITIONERS, was represented by counsel at the deposition.

I further certify that the deposition of DR. NICOLAS BU-SABA occurred at the offices of WILMER CUTLER PICKERING HALE & DORR, LLP, 60 State Street, Boston, MA 02109, on Thursday, October 17, 2024, commencing at 9:03 AM to 4:36 PM.

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I further certify that I am not related to any of the parties to this action by blood or marriage, I am not employed by or an attorney to any of the parties to this action, and that I am in no way interested, financially or otherwise, in the outcome of this matter.

Kiara Miller

KIARA MILLER

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