UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,

Petitioner,

v.

AERIN MEDICAL INC.,

Patent Owner.

_____

IPR2024-00275 (Patent 9,072,597 B2)

IPR2024-00276 (Patent 9,415,194 B2)

IPR2024-00277 (Patent 11,241,271 B2)

Deposition of JOHN MICHAEL DELGAUDIO, M.D.

Washington, D.C.

Thursday, October 10, 2024

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Pages 1 - 255

Reported by: Karen Young

Deposition of JOHN MICHAEL DELGAUDIO, M.D., held at the offices of:

WILMER CUTLER PICKERING HALE AND DORR LLP
2100 Pennsylvania Avenue, Northwest
Washington, D.C. 20037
(202) 663-6000

Pursuant to notice, before Karen Young, Notary Public of the District of Columbia.

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A P P E A R A N C E S

ON BEHALF OF NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,

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C O N T E N T S

EXAMINATION OF JOHN MICHAEL DELGAUDIO, M.D. PAGE

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EXHIBITS REFERENCED

(Retained by Counsel)

Exhibit 1001 U.S. Patent No. 9,415,194..... 197

Exhibit 1002 Declaration of Dr. John DelGaudio, Patent No. 11,241,271..... 41

Exhibit 1002 Declaration of Dr. John DelGaudio, U.S. Patent No. 9,415,194..... 18

Exhibit 1010 U.S Patent No. 6,517,535..... 47

Exhibit 1011 U.S. Patent No. 5,575,788..... 51

Exhibit 1013 World Intellectual Property Organization, Publication No. WO 2010/077980 A1..... 54

Exhibit 1033 U.S. Patent No. 5,562,720..... 238

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P R O C E E D I N G S

JOHN MICHAEL DELGAUDIO, M.D.,

having been duly sworn, was examined as follows:

- - -

EXAMINATION BY COUNSEL FOR

AERIN MEDICAL INC.

By Mr. Ward:

Q Good morning, or I guess now it's good afternoon by two minutes.

A Good afternoon.

Q Dr. DelGaudio, could you please state your full name for the record?

A John Michael DelGaudio.

Q Can I call you John?

A Sure.

Q John, my name is Trenton Ward. I'm a patent attorney with the law firm of Greenberg Traurig. I'm representing Aerin Medical and the Foundry in these matters, and John, do you understand that your testimony here today is in connection with these IPR proceedings? I'm going to read those numbers just so that we have them in the record. It

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is IPR2024-275, IPR2024-276, and IPR2024-277. John, do you understand that your testimony here today is for those three IPR matters?

A So that's not how I recognize them.

Q Okay. Do you want me to give patent numbers --

A Patent numbers.

Q -- associated with them?

A Exactly, that's how I recognize them, is by the patent numbers.

Q Sure, so I'll do it again. So your -- this is testimony in connection with IPR2024-275. That's the '597 patent, also testimony with respect to IPR2024-276. That's the '194 patent, and then IPR2024-277, and that's the '271 patent. Is that your understanding, that you're testifying to these matters --

A Yes, it is.

Q -- John? Okay. John, do you understand that you're under oath today?

A Yes, I do.

Q And that means that you're sworn to tell

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the truth as if you were in a court in front of a judge and jury, correct?

A Absolutely.

Q Is there any reason you cannot testify truthfully today, John?

A No, there's not.

Q Before we begin, I want to ask, John, are you represented by any attorneys in this matter?

A Am I personally represented, no.

Q Have you signed an engagement with WilmerHale for this matter?

A I'm not -- I don't know what you mean by engagement.

Q Was there a -- any sort of agreement that you signed with WilmerHale for this matter?

A I believe I signed some sort of document at the beginning of this, but I'm not certain.

Q John, have you been deposed before?

A I have.

Q How many times?

A I don't know exactly. Probably over ten.

Q Okay. You sound like you've got some good

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experience there, John.

A I've done it a few times.

Q Any patent cases in those over ten depositions?

A No.

Q No, okay, so what was the nature of --

A They were -- all but one were medical-legal cases where I was an expert witness.

Q Okay, and what do you mean by medical-legal cases?

A So a physician being -- being sued for complication, bad outcome. So I'd either defended the plaintiff or defended the physician, or was the expert for the plaintiff or the physician. So all but one of them were that. The other one was my brother's divorce proceedings.

Q Well, hopefully you were -- you were helpful there. So the -- it sounds like all but one of the cases, would you describe those as medical malpractice cases?

A Yes.

Q And is there a particular niche of doctors

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that you are often relied upon as an expert for?

A Well, my practice -- I'm trained in otolaryngology, head and neck surgery, so most people know that as ENT, and more specifically, I do mostly nasal and sinus and skull-based surgeries, so --

Q Uh-huh.

A -- surgery in the nose and through the nose, so the majority are going to be centered around nasal issues and those things related to nasal issues.

Q And was your testimony in those matters testimony regarding how you would have done the procedure?

A Mostly as it related to standard of care, but obviously there would be my opinion on the treatment that was rendered and the results to the patient, or if I'm obviously defending a physician, the appropriateness of their treatment.

Q Okay. John, in your C.V., you describe something as you'd been engaged in consultantships?

A Uh-huh, yes.

Q I'm just curious, what do you mean by

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consultantships?

A So many physicians do this as companies, such as Aerin or any company will have what they consider key opinion leaders, so people that -- that they will work with either for getting their opinion -- and there's many different types of consultantships.

Q Uh-huh.

A So there's consulting about products or devices, there's consulting in educational venue, there's giving talks for them. So I've done -- most of my consultant -- and I haven't had many consultant agreements, but most of them are related to education, so I might do a -- some talks for them -- or a talk or a panel at an international meeting, and even doing that and being compensated by them, even though I'm talking about my own material, requires a written consultant agreement.

I have consulted -- and most of my consultant -- consulting is with one company. It's Medtronic. I've consulted on how to make some of the products better or trying to trouble -- troubleshoot

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some of their products, which I use many of their products.

Q And when you're engaged in these consultantships, how long do they typically last?

A Oh, it varies. So for instance, if it's an educational, a lot of times it's just for that one talk. It may have a duration, but I'm not doing any other -- you know, they may say it's for a year, but it really is just for that one talk, so preparation time for that one talk --

Q Uh-huh.

A -- and then the talk.

Q Okay.

A And that's really all I do for that. If it's -- and usually if it's a consultantship for a -- regarding a product, usually just however much time I spend that one day usually at their -- their headquarters with their R and D people or their engineers or --

Q And have you done a consultantship for a nasal medical device?

A Oh, yeah, that's -- Medtronic does nasal.

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They do things like microdebriders, which also have drill attachments, various types of packing in the nose. We use something called an image-guided system, which is like a GPS system that we use in sinus and skull-based surgery. So I've consulted on -- on things like that. Many times if -- not many times because I haven't done it very often, but we may do several of those things in one morning, one half day, and that's all the time I spend there.

Q So have you done a consultantship for a nasal device that delivers energy to tissues in the nose?

A I have to think about that. I don't recall any off -- well, it depends on what you consider energy. The microdebriders don't deliver energy, but there is one, and I didn't consult for the company. There is one microdebrider that actually had radiofrequency on the tip that I used and I tried out, but I didn't consult for them. So I tried the product a few times. I use a lot of radiofrequency in the nose, but I haven't had formal consultantship agreements with those companies that I can recall.

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If it pops into my head that that answer is wrong, I'll let you know, because I've been doing this for almost 30 years.

Q Sure, okay. Another thing you mentioned in your C.V., John, that there was a note for patents, and it says patents, none, so have you ever been an inventor on a patent?

A No, I have not.

Q Have you ever been involved in any what we call patent prosecution or the process of obtaining a patent?

A I have not.

Q Well, it sounds like you're fairly experienced in what we're going to be doing here today, John, but just want to go over some kind of ground rules for the deposition. I'm going to ask you questions about some documents that are involved in these IPRs, including your declarations, and I'll provide you copies of those documents when I ask you questions about them.

Karen is going to transcribe everything you and I say, and so something that I'm sure we'll do at

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some point during the day is talk over each other, so apologies in advance for that, but we'll -- I'll try and only speak when you're not speaking, and would appreciate you doing the same for Karen's benefit so we'll have a clear record. When I ask you a question, John, can you tell me if you don't understand the question?

A Of course.

Q And if you answer my question, can I assume that you did understand the question?

A Yes.

Q Is it fair for me to assume that -- well, let me ask this question. If your counsel objects to a question, do you understand that you're generally required to answer the question unless instructed otherwise?

A I do understand that.

Q And another thing for both of us to keep in mind today for a clear record, John, is just to make sure our statements are with words, so nodding your head and those kind of things aren't good for Karen's purposes, so just try and remember to give a verbal

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answer to any question. If you need a break at any point, John, let me know. Typically take a break around the hour mark, but if you need a break, let me know. I will ask that if there's an open question, you finish your answer to the question before we go on break. Does that sound good?

A Sure.

Q Okay. So John, what did you do to prepare for today's deposition?

MS. COHEN: And I'm just going to caution the witness not to reveal the content of any privileged communications with counsel.

A Okay, so yeah, so I -- how far back would you like me to go?

Q Whenever you first started preparing for today's deposition.

A So I would have -- or I have reviewed my declarations --

Q Uh-huh.

A -- more than one time. I have reviewed the patents, the Aerin patents. I have reviewed the prior art. I have reviewed the medical literature,

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I've reviewed the responses by Aerin -- the response of the medical examiner -- or the -- sorry, medical examiner. I might be making medical references accidentally today because --

Q Understood.

A -- that's how I think. The examiner's, the patent examiner's response to Aerin's petition. I don't know if that's the correct --

Q Uh-huh.

A Aerin's response to our declarations, that document.

Q Okay.

A And let's see. What else. I think -- I think that is it.

Q Did you prepare with counsel?

A I did.

Q And which counsel?

A Oh, I'm sorry, yes, I did. So we had several meetings, so I've been here the last two days --

Q Uh-huh.

A -- and met with counsel. Do you want to

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know names?

Q Yes.

A Okay, Alexis Cohen, Brian Lambson, Alex Nemtzow. Nemtzow? Nemtzow. I mispronounce his name all the time.

MR. WARD: How do you pronounce his name?

MS. COHEN: Nemtzow.

THE WITNESS: There's too many --

MR. WARD: How do you pronounce it?

THE WITNESS: Too many consonants.

MS. COHEN: Nemtzow.

MR. WARD: Nemtzow.

MS. COHEN: There's an M-T-Z in the middle.

MR. WARD: Nemtzow.

MS. COHEN: N-E-M --

MR. WARD: Nemtzow.

MS. COHEN: -- T-Z-O-W, Nemtzow.

THE WITNESS: Nemtzow.

BY MR. WARD:

Q Great.

A Alex Nemtzow.

Q Okay.

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A Greg Lantier was there part of the time, so that was the last two days. About three weeks ago, Ms. Cohen and Mr. Lantier and I prepared a day in Atlanta, and then there was one Zoom call, or teleconference in between, in between the Atlanta and here.

Q And what did you discuss as part of these conversations?

MS. COHEN: No, I'm going to object and instruct the witness not to answer that because it calls for privileged information.

BY MR. WARD:

Q So other than the attorneys that you mentioned, did you prepare with anyone else, John?

A I did not.

Q Okay. All right, so the first document that I want to introduce is Exhibit 1002 to IPR2024-276, and John, this is your declaration for the '194 patent case.

A '194, okay.

MR. WARD: Counsel, I have a copy if you guys would like a copy.

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MS. COHEN: Thank you, I'm good.
MR. WARD: Okay.
MS. COHEN: I guess just --
MR. WARD: Sure.
THE WITNESS: Is this the same document that I have here?
BY MR. WARD:
Q Well, let me ask you, John, do you recognize this document?
A Yes, it's the document you just handed me.
Q And what is it?
A It is declaration of Dr. John DelGaudio regarding claims 1 dash, 3, 6, 12, 14, 16, 18 and 19 of U.S. patent number 94159 -- '194, I'm sorry, 9,415,194.
Q And is this document familiar to you?
A Assuming that this is exactly the same document that -- that I submitted, then yes, it is, because I haven't gone through this entire document that you just handed me, so assuming it's the same.
Q Yes, yes, it is the same.
A Okay.

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Q It is Exhibit 1002, which is your declaration that was entered into the 276 IPR. On the front page, the caption identifies the parties, John, and the first two parties that are identified are the petitioners, Neurent Medical, Inc. and Neurent Medical, Limited. When did you first become aware of Neurent?

A I'd heard -- before all of this, I'd heard of Neurent. Honestly didn't -- never used a product, never saw the product. Not going to say I don't know anyone in the company. I could, but I'm not aware of any because people jump company to company. So I really was just peripherally aware of their existence.

Q You said that you were not aware of their products, correct?

A Well, I knew -- I knew they had a product. I didn't know the details of the product.

Q Would you have known the name of the product?

A I would have known what it -- I knew the name Neurent and Neuromark, so yes, I would have

known -- and the purpose of the product, but again, I didn't have much more information beyond that.

Q So when -- when was your recollection of the first time that you became aware of Neurent?

A It was probably at one of our national meetings because most of these companies that have products in my subspecialty, which is rhinology, nasal surgery, will sponsor our national meetings, and they'll have exhibits. They'll have booths.

Q Uh-huh.

A So -- and a lot of these companies, especially companies that are -- that are either big companies or companies that are getting started kind of just trying to generate customers will have events, you know, nighttime events at the meetings. So I know -- I remember that they put on an event somewhere, and I don't remember what meeting it is, what location, but it was in the past few years. I remember they had an event. I wasn't at the event.

Q Were you invited to this event?

A Everyone gets invited to the events. Pretty much anyone who's at the meeting can get --

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gets -- gets an invitation, so -- but I didn't go. It was -- and I can't remember what city it was in.

Q But it sounds as if you had a general knowledge of Neurent, the company.

A Correct.

Q And when were you first approached about these cases?

A I don't know the exact date. It would have been through an e-mail from Ms. Cohen would have been the first contact, and it would have been sometime latter half of 2023. This is 2024 now, so yes, 2023.

Q And did you -- were you -- did you have a working relationship with Ms. Cohen prior to that?

A I had never met Ms. Cohen prior to that.

Q And do you have an understanding of why they reached out to you?

MS. COHEN: I'm just going to object and caution the witness not to reveal the content of any privileged communications. You can answer at a high level.

A I have no idea.

Q Had you ever used a Neurent device prior to

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your engagement in these matters?

A I had not.

Q Have you used a Neurent device since being engaged?

A I have not.

Q Have you seen the Neuromark product?

A I have seen -- I have not seen it in person. I've seen photos and videos and various advertisement items, but I've not seen the -- I've not used the devices, or the device.

Q Looking back at the caption there, the second party that's named is Aerin Medical Incorporated, the patent owner in this matter. Were you aware of Aerin Medical before your involvement in these cases?

A Yes, I was.

Q And how were you aware of them?

A Again, they've been around for a longer period of time. I've actually used at least one of Aerin's products in the past, and actually have another one coming up, but they have -- I don't really know anyone well from the company at all.

Q Uh-huh.
A I have a rep in -- representative in my area that -- they turn over pretty quickly, but whenever I have a -- have a procedure where -- where I need to use their product, a representative will come and support the procedure.
Q Do you remember what the first Aerin Medical product was that you would have used?
A I believe the only Aerin product that I used is the VivAer --
Q Uh-huh.
A -- for the internal nasal valve.
Q And do you remember when you first used it?
A I can't tell you an exact date. Would have been in the last couple years. Probably in the last three to four years I would say.
Q So sometime sounds like maybe during the pandemic would have been the first time?
A I think -- I think that -- no, I think it would have been before the pandemic.
Q Okay.
A Yeah, I'm fairly certain, but I don't know

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a hundred percent. I can't give you a date, but I'm pretty sure it was before the pandemic.

Q And do you remember how the device came to you? How was it that you got exposure to the device?

A Oh, I was aware of the device. I attend all medical meetings in my specialty, and that's multiple meetings a year, both locally, regionally, nationally and internationally, so I'm -- I'm pretty well aware of most products that are out there. Not that I use them all, but I'm aware of them, and I get approached frequently by representatives from these companies because of my status in the society.

Q Uh-huh.

A So I would have learned through Aerin when they were -- you know, when they were on the market or maybe even before they were on the market, but I didn't do any studies with them or anything. A lot of my colleague do.

Q Uh-huh.

A So I become aware of them before they hit the market because they're involved in the research studies that are necessary to get approved, so I

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would have learned -- learned about it that way.

Q Do you remember the Aerin rep locally there in Atlanta pitching you on the VivAer product?

A I cannot remember that specifically, and like I say, you know, I run into reps from companies all the time, and honestly, I have a very bad bad memory for names and faces, and so I -- I can't remember that. I'm sure I would have talked with one or more, but I can't tell you when or who.

Q So when you -- tell me about the first time you would have used the VivAer in your practice.

A So I can't tell you when it was.

Q Yeah.

A I can tell you what it was for.

Q Sure.

A And it was for internal nasal valve collapse.

Q Okay

A And because there are multiple products. There used to be nothing on the market for internal nasal valve collapse, and I'm not sure if you know what that is, but --

Q I don't. Can you explain --
A Do you want me to explain what it is?
Q Sure.
A Sure, I'd be happy to. So the internal nasal valve is a very specific portion of the inside of the nose.
Q Uh-huh.
A So we divide the nose into thirds. So the upper third is where the nasal bones are. The middle third is where the upper lateral cartilages are. They give support to this part, the middle portion of the nose, and then the lower third is where the lower lateral cartilages is. So if you look at your nose, this area right kind of in the middle --
Q Uh-huh.
A -- off the side, it makes a little triangle. So imagine your nose as two triangles like this, right, back to back. The narrowest area in the nose is up here near that upper lateral cartilage where it meets the nasal septum. So this area up in here is the internal nasal valve, and if someone has a weak cartilage, and there could be other things

that can contribute, but a lot of times it's a weak cartilage and a narrow space.

When they breathe in, that cartilage, that upper lateral cartilage can essentially suck in and narrow that space, and you can actually have a very wide open nasal cavity but a narrow valve, and you'll feel congested because it's a very critical space for nasal breathing and the perception of nasal breathing. So that internal nasal valve is really important for the feeling of breathing freely. So there were other products on the market, and actually, I told you there might be things that I have forgotten about that I --

Q Sure.

A So I was not a consultant for a company that has a product called Latera. Latera is a dissolvable implantable support. It's a stent --

Q Uh-huh.

A -- for the internal nasal valve or internal nasal value collapse, so I was actually part of one of their -- two of their studies --

Q Uh-huh.

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A -- where I recruited patients and performed the procedure, and I did it off -- off of the -- that research protocol also. So I was actually using the Latera for patients with internal nasal valve collapse. When the Aerin product became available --

Q Uh-huh.

A -- I gave patients the option of using the Latera -- some people don't want an implant --

Q Uh-huh.

A -- which is implanted through a trocar or needle into -- through the -- under the skin, but through the tissue as opposed to just doing something on the surface. So some people chose to do the -- the VivAer procedure.

Q And how would the VivAer procedure work for internal nasal collapse?

A Variable. No procedure is -- is a hundred percent effective, and -- and the issue with nasal breathing is that nasal breathing is a very subjective -- a very subjective thing. As I said, the nose can look widely open, and we see this all the time. People can have a deviated septum, which

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is the wall between the two sides.

Q Uh-huh.

A Say someone has a deviated septum for the right side, and that side's the narrower side, they complain that the left side is their narrow side, the one they have difficulty, even though it's much wider open, and the reason is everyone has what they feel is normal to them.

Q Uh-huh.

A Person with a really deviated septum, that septum's been deviated to that side their entire life.

Q Uh-huh.

A So that's their normal.

Q Right.

A So even though it's more narrow, they're used to it. That's what they were always used to, and something happens to make the more open side a little narrower, they complain of congestion on that side. So the reason why I went into that is because again, even the results of any procedure, even though it may look one way to the person who has performed

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the procedure, the person who has the procedure done may have a different interpretation of the effectiveness.

In general, they were effective procedures. I didn't do a lot of them. Some patients had a better result.

Q Uh-huh.

A I know one patient is still complaining that it really is not a whole lot of improvement because he just saw me again.

Q Uh-huh.

A He wants something more done, so -- but it's variable.

Q So what is it the VivAer device is doing in that procedure?

A In that procedure?

Q Yeah.

A My understanding, and we're talking about internal nasal valve here --

Q Uh-huh.

A -- is that it's delivering radiofrequency to the underside of the internal nasal valve, and the

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goal is to -- the ultimate goal is to remodel the upper lateral cartilage, okay? By remodel, what I mean is change the shape --

Q Okay.

A -- by rearranging or denaturing some proteins, and then allowing them to heal in a little different shape, so instead of maybe being flat or convex, that you introduce a little concavity. That's the theory. That's the -- what you're attempting to do with it.

Q And how is it that an application of radiofrequency energy is able to do that, John?

A Well, radiofrequency energy heats the tissue. When you heat the tissue, you denature proteins. When you denature proteins, you affect the structure -- or the internal structure of -- of an anatomic structure, in this case would be the upper lateral cartilage. Upper lateral cartilage, cartilage is made of proteins, and by -- and I can't give you the exact mechanism --

Q Uh-huh.

A -- of how it denatures the proteins and how

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they reform, but that is -- essentially that's what they're doing. It's kind of causing the proteins, or the cartilage to soften a little bit and then to reshape, and then to harden again. Excuse me. That's the attempt or the -- the goal of the procedure.

Q And when you use the term "denature the protein" --

A Yeah, if you don't do something to change the protein, then the structure doesn't change, right? So in this case collagen. So collagen is a -- something that we have -- it's in all our tissue, right?

Q Uh-huh.

A It's different than bone, but -- and I'm not sure if collagen is exactly what's treated here, but basically proteins and other -- there may be other things other than proteins that are also the target of this. My understanding is it denatures the protein, it denatures the cartilage, it changes the characteristics of the cartilage by applying heat in the form of radiofrequency energy, and by doing that,

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there is also a mechanical force that's being placed. So it's not just a matter of touching it and letting the energy go through in this case. There's contact in the mucosa, but there's also lifting up and pushing into the upper lateral cartilage in multiple areas.

So you apply it in at least two or three areas across the upper lateral cartilage, but by mechanically pushing into it, the heat is softening it somehow. I'm not going to tell you exactly I know the -- hundred percent know the mechanism, but it's softening it. The pressure is allowing it to reshape a little bit, and then the healing in the postoperative, the post-treatment period is allowing that restructuring, reshaping the cartilage.

Q And is this something that you can do -- can you do many applications of this? Can you do it iteratively? It's probably a better way to say it.

A Can you be more specific? Do you mean at the same setting or do you mean multiple different times?

Q Sounds like your -- your goal with applying

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the radiofrequency energy is to denature the protein. Is that a process that you can do multiple times?

A Yeah, I can't -- I don't know that. I've never repeated that particular procedure on a patient. Doesn't mean that you can't. I'm just not aware of whether you can or can't.

Q Uh-huh.

A I'm not sure exactly -- yeah, I don't want to say either way because I don't know. I've not had to do it.

Q Okay. John, I'd like for you to turn to the -- what should be the last page of your declaration, but it won't be the last page of the packet, 122 of the one I handed you.

A Okay, we're on 190?

Q No, of the document I handed you.

A Oh, of this document.

Q Thanks.

A Okay, I'm sorry, pages what?

Q It's page 122, so it'll be the last page of your actual declaration before the appendices.

A Oh, you got -- okay, single page. Okay.

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Here, I'm going to take this off. This is annoying.

MS. COHEN: I can represent for the record that that document is the same, just a bound version.

BY MR. WARD:

Q Okay. Well, so whatever you'd prefer.

A Can I use it?

Q Yeah.

A It's just -- it's just easier --

Q Sure.

A -- to navigate, and this was '194, and this is '194, okay. 122 you say?

Q Uh-huh.

A Okay, I'm on 122.

Q So do you recognize the signature at the bottom of that page, John?

A Yes, I do. It's me.

Q That's your signature.

A Well, it's my electronic signature.

Q Yeah, and do you remember signing this January 11th, 2024?

A Well, I -- I remember the process of signing my declarations, yes.

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Q Okay. Who wrote your declaration, John?

MS. COHEN: I'm just going to caution the witness not to reveal content of privileged communications, but you can answer the question.

A I wrote my declaration.

Q Did you have any assistance in writing the declaration?

MS. COHEN: Same instruction.

A My declaration was -- was written by me with the legal team. There you go.

Q And tell me about that process.

MS. COHEN: And I'm going to -- same objection to the extent it calls for privileged information. You can answer at a high level without revealing the content of privileged communications.

A Can you repeat the question again?

Q Tell me, how did you -- how did you go about drafting your declaration?

MS. COHEN: And same objection.

A So obviously read all the materials that you -- we both have in the materials reviewed sections of the -- the declarations, excuse me,

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including what I told you, even more than what I told you I reviewed for this deposition.

Q Uh-huh.

A So reviewed the material. We discussed the material. We discussed what was available, or what was -- what information was in that -- those documents, and we collated that information, and we ended up with the -- what my opinions were, which was the final product of this declaration -- these declarations.

Q Did you create the first draft of your declaration?

MS. COHEN: And I'm going to give the same objection to the extent it calls for privileged information, and you can answer without revealing the content of privileged communications.

A Yes, I did.

Q Did you share that draft with anyone else?

A I'm not sure what you mean by that.

Q Did you share the draft of your declaration with others for comment?

A Are you referring to the legal team or --

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Q Anyone.

A -- anyone? No one has seen -- from my standpoint, no one has seen this document other than myself and the legal team and whoever they have shared the document with.

Q Did you share the draft with the legal team?

A Yes, the legal team was aware of the draft, absolutely.

Q Did they provide comments on the draft?

A Of course they did.

MS. COHEN: And I'm also -- I'm going to -- the same objection. Do not reveal the content of privileged communications.

A Correct.

Q If you would turn to page 10 of the declaration for me, John, you say in paragraph 26 there on page 10, "In preparing this declaration, I reviewed and considered the materials identified in Appendix B as well as any documents cited in this declaration."

A Okay, I assume you want me to go to

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Appendix B?

Q No, I just want to ask a question.

A Yeah.

Q I want to make sure I understand. So you're -- you're telling me in paragraph 26 that you considered everything listed in Appendix B, and in addition to the materials listed in Appendix B, any document that you otherwise cite in the declaration?

A I'm sorry, can you -- can you repeat that again?

Q Paragraph 26 says that you reviewed and considered the materials identified in Appendix B as well as any documents cited in this declaration, correct?

A Okay, so I'm just going to look at Appendix B if you don't mind.

Q Sure.

A Okay, so that is a correct statement.

Q Well, taking a look at Appendix B where you just were --

A Yeah.

Q Do you recall any materials that you

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considered that aren't on this list in Appendix B?

A I cannot recall any additional materials. I'm not saying there aren't. I cannot recall any additional materials other than those listed on Appendix B.

Q Okay, just moving back to that paragraph 26 then --

A Uh-huh.

Q You make a statement, and I thought it was in paragraph 26, but I don't see it in paragraph 26, but you made a statement that you'd have a conversation with Dr. Martin, and I can see if I can find what paragraph you make that statement in. I believe what it is, it's actually in another one of your declarations, so if we could now, I'd like to introduce to you another declaration, John, and if you prefer, you can use your copy there. It's Exhibit 1002 to the 277 case. Is that the case that you have in front of you?

A Yeah, it's the '271 case.

Q So taking a look at paragraph 26 of the '271 case, so if you go back to --

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A I'm sorry, what -- page 26 again? I'm sorry?
Q Page 10. It's paragraph 26.
A Page 10, paragraph 26.
Q So we'll see that the same sentence that we just read from your other declaration with respect to materials considered is the first sentence in paragraph 26.
A Okay.
Q It says, "I reviewed and considered the materials identified in Appendix B as well as any documents cited in this declaration." You see that?
A I do.
Q And then the next sentence is the sentence that I was remembering. It says, "I have also relied on a conversation with Dr. Gregory" --
A Yes.
Q -- "Martin, and have reviewed his declaration."
A Yes.
Q Who is Dr. Gregory Martin?
A Dr. Gregory Martin is an expert witness on

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other -- he is also I believe on the '271 patent. He's an expert witness on that patent, but on other patents that I'm not involved with.

Q So you said, "I have also relied on a conversation I had with Dr. Gregory Martin." So you had a conversation with Dr. Martin?

A I did.

Q And do you remember when that conversation was?

A I cannot tell you the exact date of the conversation. It was a teleconference.

Q Uh-huh. So it would have been in relation to this '271 patent IPR, correct?

A Correct.

Q And so it would have been obviously during your engagement on this matter, correct?

A Correct.

Q So would it have been prior to the first draft of this declaration?

A Yes, it would have.

Q And what did you talk about with Dr. Martin?

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A Well, so we can -- specifically I'd have to find what is in the declaration as far as when I discuss that I have partially relied on Dr. Martin -- my conversations with Dr. Martin that supported my opinions. So if you want me to look on there -- look in there and pick out the couple of areas, I'd be happy to do so.

Q So it sounds like you -- you had a conversation with Dr. Martin to talk to him about matters related to the '271 patent case, correct?

A Correct, correct.

Q And why is it that you needed to have a conversation with Dr. Martin?

A Well --

MS. COHEN: Objection, form.

A Okay, well, Dr. Martin is -- so I'm a physician.

Q Uh-huh.

A And I use radiofrequency and other forms of energy in the nose, so -- and I came up with my opinion based on the prior art and the literature.

Q Uh-huh.

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A But there are some technical issues that I felt it would be nice to have confirmation that I'm -- that my opinions were justified based on -- on my reading of the technical information. So Dr. Martin is an engineer. Dr. Martin is -- has been involved with patents. Dr. Martin is much more -- much more involved in the technical side of devices like this. So in order to confirm that the way I was looking at it, the way I had come to my opinions was supported in light of the more technical information.

Q And so when -- when you say the more technical information, what do you mean by that?

A Well, there's things like -- and I know that one of the references, and I'm going to -- I'm going to look at it here. Well, I know one is the Stern reference, and I'm going to pull -- I'm going to go to -- going to go to my declaration. I'm just looking for the specific -- I'm pretty sure it is in here. I thought it was going to be easier to find than this.

Q John, let me just ask you a question. Is it fair to say that you consulted with Dr. Martin on

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technical areas that are outside your proficiency?

MS. COHEN: Objection, form.

A Yeah, I wouldn't say necessarily outside my proficiency. I would say that he may have a little bit more -- he may have more knowledge on the more technical issues, as I already said, but none of my conversations with Dr. Martin changed my opinions.

Q Uh-huh.

A They just reinforced that, you know, my opinions were -- were correct, and they were unchanged after the conversation.

Q Did Dr. Martin review your declaration?

A I cannot say whether he did or didn't.

Q Did he give you any comments on your declaration?

A I did not have -- first of all, when I had a conversation with Dr. Martin, the one and only conversation I've had, my declaration had not been formulated yet.

Q Uh-huh. And did you review his declaration?

A I did review his declaration, but I do not

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-- it was some time ago, and I don't recall any details. There's a lot of technical things to --

Q Did you make any comments on his declaration?

A I did not.

Q I want to introduce to you now an exhibit. It's Exhibit 1010. It's Exhibit 1010, and this is to IPR2024-276.

A Okay.

Q Do you recognize this document?

A If -- this looks to be the Edwards document that we used to support my -- sorry, that I used to support my declaration.

Q So the top right-hand corner, it gives us the patent number. This is U.S. patent number 6,517,535, correct?

A Correct.

Q And -- and the left-hand side of the first page, it lists the inventor Stuart D. Edwards. Do you see that?

A I do.

Q Are you familiar with Mr. Edwards?

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A I do not know who Stuart Edwards is, no.
Q The assignee is listed as Gyrus ENT L.L.C. Are you familiar with that entity?
A Yeah, that's a -- well, it's a company that was in -- in our field some time ago. It no longer exists, although it may have resurfaced, but it had disappeared for a while.
Q Did they have a product in the market?
A They had many products in the market. I can't tell you exactly what they were at this point, but it was -- it was one of the -- actually one of the major players in -- in otolaryngology, especially in nasal and sinus surgery.
Q What time period?
A You know, I can't recall exactly when they -- you know, when they were at their peak, or when they -- and I don't recall whether they sold or whether they -- or how they no longer became Gyrus. I don't recall that, so I can't give you the years.
Q This patent, if you see in the center of the page, was filed on November 9, 1999.
A Okay.

Q Would you remember Gyrus being in the market in the '90s?

A I -- again, I can't tell you exactly when. I believe they were.

Q Uh-huh.

A I don't have hundred percent recollection of that. I believe they were in the market when I started my practice, which was in the mid-'90s, and they were for some time, you know, a major player in -- in otolaryngology and rhinology, but I don't recall when they no longer became a major player.

Q Did you use any of their devices?

A Oh, I'm sure I did.

Q And do you remember the trade names of any of those devices?

A Honestly, sitting here, I can't tell you because I've -- I've gone through many iterations of products that I use and the way I do things in the last almost 30 years, and so I can't tell you -- I can't tell you what particular products that I've used because I've used products from many different companies. Some of them may be as small as a pack

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that I prefer. Some may be as large as, you know, as scopes or major instruments that I use on every case, but I use products from many of these companies.

Q And you reviewed this particular patent, the '535 Edwards patent, correct?

A I did.

Q And the title of the patent is "Apparatus for Ablating Turbinates," correct?

A Yes, it is.

Q And do you recognize the Gyrus product that's disclosed in this patent?

MS. COHEN: Objection, form, relevance.

A Answer? So I can't tell you that I recognize this product, but I don't -- I don't know all the products from all the companies --

Q Uh-huh.

A -- that were in my -- in my -- that are in my field for the past 30 years. So this could well have been a product that I just wasn't aware of or didn't use, so I don't know. It may or -- may or may not have been, but I can't give you an opinion on that because I'm not aware.

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Q John, I want to show you now what's marked as Exhibit 1011, Exhibit 1011 to IPR2024-276. This is a patent, and the patent number's given at the top right. It's U.S. patent number 575 -- I'm sorry, 5,575,788 to Baker. Do you recognize this document, John?

A So I do not recognize this as much. I know I've seen it, but I'm not sure that I have reviewed it as thoroughly as the other documents. I need to -- can I -- I need to refer to something if you don't mind.

Q Let us know what you're referring to.

A I'm just referring to the -- to my declaration.

Q And which one are you looking at? Tell us the case number on the front.

A Yeah, '271 I believe this is. I have them in the wrong order. I'm sorry. '271 should be in the middle. There it goes. '271. Now, I'm just looking to where this particular document, the Edwards 78 -- I'm sorry, Baker '788 --

Q Uh-huh.

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A -- is -- of course, I'm going to look for it in my materials reviewed because -- where is it?

Q That should be it right there in appendix -- oh, no, that's -- oh, yeah, B. That's it.

A There it is. What did you call it, the exhibit number?

Q It's 1011, Baker '788.

A Baker '788. I know I've seen it and I've reviewed it, but as I said, many of these I've re-reviewed recently.

Q Yeah.

A And this is not one that I re-reviewed recently, but I know that it's used -- we use it for -- in this declaration.

Q So John, take a look at the Baker '788 patent for me.

A Uh-huh.

Q And there's a list of inventors there. The first listed inventor is James Baker. Do you see that?

A I do see that.

Q So he's listed as James Baker, Palo Alto,

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California. Do you know James Baker?

A I don't believe I know James Baker.

Q You see the second listed inventor is Stuart D. Edwards, correct?

A I see that, yes.

Q And do you understand that to be the same Stuart Edwards from the previous '535 patent we were looking at?

A I would -- I would assume that it is.

Q There's four other inventors listed, Chris Jones, Kee Lee, Phillip Sommer and Bruno Strul. Do you know any of those individuals?

A I do not.

Q So prior to this particular matter, had you ever reviewed the Baker '788 patent?

A Are you referring to prior to --

Q Prior to these IPRs.

A -- being involved in -- no, I have not.

Q And are you aware of which product is disclosed in the Baker '788 patent?

MS. COHEN: Objection, form, relevance.

A Well, it's -- I can read off what -- what

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there -- it says thin layer ablation apparatus.

Q Are you aware of this disclosure being related to any commercial product?

A Once again, I'm not aware of all the commercial products that are -- that are offered, so I can't say whether or not it was related to a commercial product.

Q Okay, I want to show you another Baker patent. This is Exhibit 1013 to IPR2024-276. Upper right corner gives you the publication number for this Baker patent. 980 are the last three digits. Do you recognize this document?

A Yes, I do.

Q And is this a document that you relied upon in your declaration?

A Yes, it is.

Q And do you see listed in the middle of the page on the left column, it lists the inventors. The first inventor that's listed is Baker, comma, Peter, correct?

A I do see that.

Q And do you understand that to be a

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different individual than the James Baker that we saw listed on the previous Baker patent?

A I would assume it is unless there was a name change.

Q There's one other inventor listed on this patent, Richard Treadwell. Is that someone that you know?

A It is not.

Q The applicant is listed as Aardvark Medical. Are you familiar with that company?

A I never heard of that company.

Q I want to turn to Appendix C of your declaration in the '271 patent case, John.

A Okay.

Q So I'm at page 178 of Appendix C.

A 178. My 178 is not Appendix C. My 178 is Appendix B.

Q Okay, so what page does Appendix C start on?

A It starts on -- the actual appendix starts on 180, and challenged claims, Appendix C, challenged claims. Is that what you're looking at?

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Q Apologies. I've got you looking at the wrong declaration again. So let's -- we're going to switch to the declaration for the '194 patent case.

A Okay. Appendix C starts on 178.

Q There you go. We're going to have a lot of fun with that today. You've got a lot of declarations here, John.

A That's all right.

Q So --

A I'm good.

Q Yeah. So you see there on page 178, Appendix C, it lists the grounds for this '194 patent IPR, correct?

A Correct.

Q And ground 1, the reference that identified -- that is identified is Baker, correct?

A Correct.

Q If you flip back a few pages to Appendix B --

A Back a few pages --

Q That's going to be page 175 --

A I got it.

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Q -- of your declaration. You see that there's two Bakers listed, Exhibit 1011 that we just looked at, and Exhibit 1013 that we also just looked at.

A Correct.

Q The abbreviation for Exhibit 1011 that's defined in Appendix B is for the '788 patent, and that is the Baker -- it's abbreviated as Baker. Do you see that?

A For the '788 patent?

Q Yeah, so Appendix B creates an abbreviation for the '788 patent --

A Yeah, no, I see that.

Q -- as Baker, correct?

A I'm -- I'm just comparing these. I've got these two Baker references here, and this is the Baker reference that we use, right, and this is -- '980 is the Baker reference that is here, so let me see, and '788 -- right, so the '788 is just -- I think there's a typo here.

Q So the -- in Appendix C where it states grounds 1, 2 and 3 all relying upon the Baker

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reference, that's not Baker Exhibit 10,011, correct?
A No.
Q So it should be Baker Exhibit 10,013?
A Yes, it should be Baker --
Q Or 1000 --
A We're using the last three numbers, '980, which is this Baker reference. That's -- is what we actually -- you know, it says Baker, but it doesn't have the -- the numbers behind it.
Q Okay, so just so that I'm --
A Yeah.
Q I'm confirming here, so the --
A Yeah.
Q -- the prior art that you relied upon, the reference that you're relying upon in the grounds for the '194 patent is Baker '980.
A Correct.
Q And that's Exhibit 1013.
A That would be Exhibit 1013.
Q Okay.
A Correct.
Q Is Exhibit 1011, the '788 Baker patent, is

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that relied upon in the grounds for this IPR?

A Okay, so can you separate into that -- that into two questions please?

Q Uh-huh. So Exhibit 1011 is the Baker '788 patent, correct?

A Correct.

Q Is that reference relied upon in the grounds for this IPR for the '194 patent?

A Okay, so it is -- if you look at the grounds, that Baker reference is not referenced in the grounds. It may be referenced in the paper -- or I'm sorry, in the declaration, but not in the grounds.

MR. WARD: Okay. Okay, why don't we take a break.

(Recessed at 1:03 p.m.)

(Reconvened at 1:12 p.m.)

BY MR. WARD:

Q So John, I'd like to turn your attention now to -- and going back to your declaration for the '271 patent, and I'd like you to turn to paragraph 13. It's on page 5.

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A Okay.

Q Paragraph 13 states, "I'm not an attorney. For purposes of this declaration, I've been informed about certain aspects of the law that are relevant to my opinion" -- "my opinions. My understanding of the law was provided to me by petitioner's attorneys." So John, what did you know about patent law before this case?

A Not very much, honestly.

Q Had you had any exposure to patents or patent law?

A I had not.

Q When you make this statement in paragraph 13 about that your understanding of the law was provided to you by petitioner's attorneys, what do you mean by that?

MS. COHEN: I'm just going to object to the extent the question calls for privileged information. You can answer without revealing the content of privileged communications.

A Okay, well, if you look at the next page, page 6 of my declaration --

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Q Uh-huh.

A -- and the subsequent pages after that, that's -- you know, and a lot of the information was related to scope of opinion, anticipation, obviousness principles, and -- and then, you know, terminology, like claim dependency. I'm still getting the terminology wrong, but I'm trying, but it's a completely different language obviously than -- than medicine or even I think other parts of law, so --

Q Uh-huh.

A A lot of it was, well, just, you know, getting me up to speed.

Q So what's set forth then in paragraphs 14 through 25 is a summary of the legal principles that were relayed to you; is that correct?

A That would be some of the legal principles that we discussed and that we utilized in -- in me formulating my opinions that are -- that are communicated in this declaration, and all three declarations actually.

Q Paragraph 15, you state, "I've been

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informed by counsel that a patent claim is anticipated, and therefore, unpatentable if each element of that claim is present in a single prior art reference." What do you mean by present?

A So since a -- you know, my understanding what a single prior art reference is is a previous patent, and if a claim says that -- or in this case, there's a violation -- I don't know the terminology, but essentially if a single prior art reference or a single previous patent has all the elements that satisfy the claim, if there are four elements or five elements, if they're all included in the single prior art reference, then that would satisfy the elements of that claim, or those claims, and therefore, would meet the criteria for the -- meet the needs of anticipation.

Q So the way you stated it is you said if each element of that claim is present in a single prior art reference. What does it have to do to be present?

A Well, it could -- it's -- it can either be described in print or in the text. It could be in

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the -- in the figures, or it could be explained in the specifications of the figures, so somewhere in the prior art reference, whether it be visual or -- or in print, that's what I would consider present.

Q If you'd go down to paragraph 21 for me, John, we were discussing anticipation with paragraph 15. Paragraph 21, you're discussing obviousness -- obviousness.

A Correct.

Q You say in paragraph 21, "I also understand that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered." So John, what was your technique that you used to ensure hindsight bias didn't apply to your analysis?

A Well, so I viewed this from a person of ordinary skill at the times --

Q Uh-huh.

A -- prior to the patent, and as, you know, all of the reference that I used and the prior art that I used predated the patent significantly by multiple years, in some cases over a decade, and I

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utilized that information and made my recommend -- or my declaration based on that information.

Q So you state, "It's important not to determine obviousness using the benefit of hindsight derived from the patent being considered," and do I understand you to say that -- how did you ensure that you didn't apply hindsight?

A Well, my understanding is -- the way I looked at it is, you know, anything that happened after that time. So you know, it's not a matter what's available now, what was available ten years ago, how practices or devices have changed. This is in consideration what we know was available prior to that, and you know, and like I said, I've been doing this since 1995, and if you go back to my training, it's 1990. So that's -- right there that's 21 years plus, a minimum of --

Q Uh-huh.

A -- 21 years of -- you know, of practice without having to use any hindsight because not considering what's been going on in the last 10 or 12 or 15 years, so that's what -- that's my

interpretation of that.

Q So you avoided hindsight by only considering what existed prior to the priority date of the patent, correct?

A Exactly.

Q And so events or updates that would have occurred after the priority date of the patent you did not consider.

A Well, things are always changing, right? Things -- new devices are always coming out, so I mean, yeah, there's been significant progress in these areas, but you know, a lot of what we're discussing today and however long we discuss this has been around for decades.

Q I want to turn to paragraph 29 of your declaration. It's on page 11.

A Still on '271?

Q Yes.

A Okay, 29, yes.

Q We were discussing priority date, and at the last sentence on page 11 there, the sentence reads, "Before June 14th, 2011, which is the claimed

priority date of the '271 patent, I would have qualified at least as a person of ordinary skill in the art under this standard." Do you see that?

A Yes, I do.

Q So is it your understanding that June 14th, 2011 is the priority date of the '271 patent?

MS. COHEN: Objection, form.

A Yeah, no, actually, what's done here is I believe it was a later date than that, but we went back to the earliest possible date where any of the previous patents, Aerin patents were available to make sure that we were -- that, you know, I'm looking at this from a person of ordinary skill at the -- the latest time.

So that would encompass, you know, all of the information that was available prior to the first patent. I may have -- I may have just not phrased that correctly, but essentially I believe the '271 patent was later, and it may have -- I don't want to give a date, but it was later. The 2011 date was a date of previous Aerin patent that was included just to make sure that we're going well -- well back and

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far enough back to not have hindsight.

Q Your statement in paragraph 29 is, "Before June 14th, 2011, which is the claimed priority date of the '271 patent," correct?

A Well, that's what it says, correct.

Q And so are you -- are you saying that there's an error in that statement?

A Well, I don't know if there's an error in that statement, but I'm explaining why that -- that date is -- why June 14th, 2021 is -- is in the declaration. I don't know what the word -- what claim priority date specifically means in legal terms.

Q Was that not explained to you?

MS. COHEN: Objection, form.

A It may have been explained to me and I just don't recall.

Q So you told me that you avoided hindsight by making sure that you weren't considering anything after the priority date of the patent, correct?

A Well, the date that we -- that -- the date of June 14th, 2020 -- 2011.

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Q So you didn't consider anything after June 14th, 2011 in your analysis.

A Not in the declarations, no.

Q And you did that because June 14th, 2011 was the priority date that was told to you, correct?

MS. COHEN: Objection, form.

A I don't recall exactly. I'm pretty sure that there was an explanation of why that date was used, was being utilized in the declaration, and I am not 100 percent sure of the conversation, exactly the details of the conversation, and my understanding is as I've already explained.

Q If you go up to paragraph 27, it states, "It's my understanding that when considering the claims of the '271 patent and the prior art, I must do so based on the perspective of one of ordinary skill in the art at the relevant effective filing date." What does the term "effective filing date" mean to you, John?

A Well, I would think that's the date that it was filed in the patent office.

Q And what's the difference in effective

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filing date and claimed priority date?

MS. COHEN: Objection, form.

A Yeah, I -- I don't know that specifically. It's legal terms that I'm not aware of.

Q So looking at your statement, "I must do so based on the perspective of one of ordinary skill in the art at the relevant effective filing date," is it your understanding that you performed that analysis based upon June 14th, 2011?

A That is correct. I don't think there would be any -- much in that -- I'm sorry, let me rephrase that. That is correct. I would have been in practice 16 years by then, so any additional years would have not made much of a difference in how I would have viewed it as a person of ordinary skill.

Q But you would agree that to avoid hindsight, you were not considering anything after that priority date, correct?

A Correct.

Q Paragraph 29 starts with the statement, "Based on these factors, as well as my experience and expertise, a person of ordinary skill in the art at

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the relevant times, 2011 to 2019, would have had," and then it provides your proposed definition for a person of skill in the art. Why does your declaration say the relevant times are 2011 to 2019?

A Well, it could have just said 2011.

Q But --

A We went back to 2011, and so -- well, I think it says 2011 to 2019 because there's -- that's the range of the patents, of all the patents, and as I said, the -- and that includes the '597, you know, the whole group of Aerin patents, the '194. So you know, 2011 is the date that was chosen for -- to make sure that we encompassed all of that, and that a person of ordinary skill in 2011 is the eyes to which I made my decisions.

Q But in paragraph 29, John, you state that, "Based on these factors as well as my experience, a person of ordinary skill in the art at relevant times, 2011 to 2019." You're indicating that 2019 was a relevant time for the consideration of a person of ordinary skill, correct?

A No, that's not --

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MS. COHEN: Object to form.

A That's not what it says. That's not what I'm saying there.

Q And so what are you saying there, John?

A Well, you can take any of those times. You can take -- you know, it says 2011 to 2019, but I wasn't considering what was available in 2019.

Q Why does your declaration say that you were considering a person of ordinary skill at that time?

A Well, as I said, we know that those dates of the patents extended to 2019, but that's not the date -- that's why the last sentence says before June 14th, 2011, I would have qualified as a person of ordinary skill in the art, okay? So we do give some more information there, but the bottom line is at the end is what we're stating. What I'm stating is that I viewed all of this through the eyes of someone, a person of ordinary skill at the time or before June 4th, 2011.

Q I'd like for you to take a look at your declaration from the '194 patent case, so Exhibit 1002 from the '194 patent IPR, paragraph 29. Similar

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to the paragraph 29 we just read from the '271 patent case, in paragraph 29 here, you state, "Based on these factors as well as my experience and expertise, a person of ordinary skill in the art at relevant times, 2011 to 2014." Why does this declaration state the time period as 2011 to 2014 when your other declaration stated it as 2011 to 2019?

A Yeah, I can't tell you exactly why, but again, the important thing is the 2011, right? And it's -- again, as it states in the last statement, before June 14th, 2011, which is the claimed priority date of the '194 patent, I would have qualified at least as a person of ordinary skill in the art under this standard, and that is the date that we used to evaluate the materials that we evaluated.

Q And you said that the reason you gave the range, so in the '271 patent, IPR declaration, you gave the range of 2011 to 2019, and you did that because there were other patents with later dates, correct?

A Well, I believe that's the case. I'm not certain.

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Q So are you aware of any other patents for these IPRs -- patents that were challenged in these IPRs that have a priority date other than June 14th, 2011?

MS. COHEN: Objection, form.

A Again, I'm not -- I'd have to check, and again, I don't understand the terms that you're referring to as far as those specific dates. What I am saying is that June 14th, 2011 is the latest date to go back that assures that evaluating what was existing now would not allow me to use hindsight, and -- you know, or to use any more -- any more recent references or materials, patents, prior art, that might overlap with any of the patents.

So 2011, June 14th, 2011, obviously anything before that is a period of time where -- you know, that's a safe period of time where anything prior to that would have been available and already in use to evaluate, you know, what was already existing at that time.

Q So John, would you agree that the level of knowledge for a person of skill in the art in 2019

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would have been different than in 2011?

MS. COHEN: Objection, form.

A I need you to clarify that question. I'm not quite sure how to interpret that question.

Q So you have opined as to the knowledge of a person of ordinary skill in the art in these matters, correct?

A Correct.

Q And you represented that you were a person of ordinary skill in the art as of 2011, correct?

A Correct.

Q And were you a person of ordinary skill in the art as of 2019?

A Given these -- so -- so what we look at -- and again, I'll answer your question the way you asked it, but I don't think it matters because everything was referred -- everything was evaluated prior to 2011. So the important date is evaluating something as a person of ordinary skill in the art as of June 14th, 2011 or before, okay? So that's -- that is the answer to the question, but in 2019, was I a person of ordinary skill in the art?

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Well, based on our -- what it takes -- the qualifications for a person of ordinary skill in the art, then yes, I would have met those qualifications in 2019 also because I would have been a Doctor of Medicine for three years. Not going to talk about the other qualifications there, and I would have had at least three years' experience in clinical use of -- of energy-delivering devices. So those are the two criteria, whether it's 2011, 2019, but the 2019's really not relevant for this because everything was evaluated, it was prior to June 2011.

Q But you would agree that the level of knowledge in 2019 is different than the level of knowledge in 2011, correct?

A Are we -- well, are we talking about the same person or are we talking about different people?

Q It's a hypothetical person of ordinary skill in the art. So imagining that individual and the knowledge available to them in 2011 is different than the knowledge that would have been available to them in 2019, correct?

MS. COHEN: Objection, form.

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A Well, it -- I'm not quite sure that's the case. Everyone has a different level of knowledge. We're talking about a person of ordinary skill would be -- I would anticipate a average practicing physician or engineer or -- so is there different knowledge available between 2011 and 2019, yes. Things progress, right? There are new devices, there are new procedures, there's new medical information. So yes, things changed between 2011 and 2019, but as I said, as far as I'm concerned, the important aspect is everything that we looked at was prior to 2011, June 14th to be specific, but there was nothing even close to 2011. So that's the answer to your question.

Q John, can I ask you about your educational background?

A Sure.

Q Tell me about your undergraduate education.

A I went to La Salle University in Philadelphia, a Bachelor of Arts, graduated in 1985.

Q And what did you do after undergrad?

A Went directly to medical -- well, I worked

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in a bank for a summer, but then I went directly to medical school, Jefferson Medical College.

Q One summer as a teller scared you -- it scared you into medical school.

A No, no, I -- I -- I was already accepted into medical school. That was my summer job. I actually got teller of the month.

Q Wow.

A I know.

Q One of your three months you were teller of the month? That's pretty good.

A I think my first month I was teller of the month.

Q Oh.

A But yeah, no, and then I went to Jefferson Medical College in Philadelphia, actually got a -- well, essentially almost a full -- full -- I got a full ride the first -- first year.

Q Wonderful.

A And got significant scholarship throughout. I ended up graduating second in my class of 229 or so. I was first in my class until the woman who was

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first in her class a year ahead of me took off a year and dropped back and she just beat me out, so -- and then I -- do you want me to keep going?

Q Yes.

A Okay. So graduated maxima cum laude from medical school. I --

Q And what year was that?

A Medical school, '89, 1989. And then I -- you know, we go through -- in medical school, we go through what's called a match to obtain our residency program. I matched in my first choice, which was what I considered the best residency program in the country, which was University of Michigan. Did my internship year in Philadelphia at a place called Lankenau Hospital, but then five years of residency at University of Michigan, and in that residency was an 18-month basic science research commitment, where I received a T32 grant, which is an NIH grant to support my research, and then when I graduated residency, I literally took off one week and then started at Emory University. At the time, we were a division of otolaryngology. Now we're a department,

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but it was in 1995, joined Emory, and I've been there since.

Q When did you begin your focus on otolaryngology?

A Well, that would have been with residency, so that would have been in 1990 when I started my residency at University of Michigan.

Q And when did you start at Emory?

A 1995, July.

Q And what was your first role at Emory?

A Well, I was an assistant professor. I was hired as an assistant professor, and I -- obviously as a clinician, but at an academic university, as Emory is, there's multiple roles that you're expected to -- to fill. So I was an assistant professor. I was doing head and neck cancer surgery mostly at the time, with some other things.

I was publishing -- started publishing papers, and obviously just continued growing a clinical practice, eventually through the last 30 years, promoted twice, been the -- been -- held many roles. So we can -- you can ask specific questions

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if you'd like, but it's all on my C.V.

Q So when did you begin your clinical practice?

A At Emory, that would have been July 1990. Sorry, 1995 --

Q 1995.

A -- when I got there.

Q So you started as an assistant professor and simultaneously started your clinical practice.

A Well, assistant professor is -- is a title, but it's a clinical title also. So everyone who is in a clinical department at Emory and at most academic institutions, medical institutions --

Q Uh-huh.

A -- are either -- start as either an instructor or an assistant professor. So we start as assistant professor, but that's -- that doesn't mean I'm in the classroom teaching and things like that. My teaching for the most part comes through medical students and residents and fellows being with me in the clinic, in the operating room. Occasionally I'll give lectures, I'll teach courses, things like that,

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but the -- my clinical practice started immediately, and that's primarily what I've done for the last almost 30 years.

Q So in 2010, you became the vice chair of the department of otolaryngology?

A Yes, if that's what it says. I don't remember the exact year, but if that's what it says on my C.V., then that's correct.

Q It also says in your C.V. 2004 to current, you were the chief of rhinology, sinus and skull-based surgery.

A Correct.

Q So you held both of those positions --

A Correct.

Q -- simultaneously during 2010 to 2021?

A Correct.

Q And why did you step down from the vice chair position?

A There was a restructuring of the department, and actually, there are four vice chairs right now, but none of them filled my role, which was clinical vice chair, but yeah, it was just a

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leadership change, and I was more than happy to give it up.

Q So what's -- is there different departments between -- so you're chief of rhinology --

A Yeah.

Q -- sinus and skull, and is that a separate department?

A It's a division. So there's divisions within the department.

Q Okay, I got you.

A So it's like the department encompasses everything. The divisions are subspecialty divisions. So we have about seven divisions, and rhinology and sinus surgery is one. Skull-based surgery is actually part of that, but then there are things like otology, neuro-otology, which is ear surgery. There's voice and laryngology, there's facial plastic surgery, there's head and neck cancer surgery. So even within those divisions, there's smaller divisions, so --

Q You say in your declaration that as a professor, the focus of my research is in the field

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of rhinology.

A Uh-huh.

Q And what do --

A Yes.

Q -- you mean by that?

A So most of what I do is clinical research. I mean, all of what I do is clinical research, so any of my publications are going to be clinical -- clinical studies or clinical data. So that's going to be similar to what we're reviewing here as far as the -- the -- the publications from Chen and Liang and Fang and -- and Kong. Those are all clinical studies. Those are studies that are based on looking at a certain problem or -- or how it was treated or results of treatment or things like that.

So that's what all of my -- for the most part, all of my publications except for some -- you know, when I was in -- in residency, some of my basic science publications, and I am involved in some basic science publications that are -- colleagues are primarily responsible for in my division that my name may be on the publications also, but for the most

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part, they are clinical studies based on my patient population, my surgical procedures and things like that.

Q John, help me understand, because you also make this statement in your declaration. You say you have three decades of experience in clinical practice as an otolaryngologist. Help me understand the distinction between the field of rhinology and otolaryngology.

A Yeah, rhinology is a field within otolaryngology, okay? So at academic institutions, we tend to -- bigger academic institutions where we have bigger programs, in my department, there's about 45 surgeons, 45 ENT surgeons.

Q Uh-huh.

A Maybe ten of them are pediatric surgeons, pediatric ENT. So rhinology is actually the -- if you take someone who's out in private practice, so you know, just someone who has a -- down -- down the street here has an office on the corner, they're --

Q Uh-huh.

A -- a general otolaryngologist. They don't

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specialize in anything. They do a little bit of everything. Well, one of the things that they're going to be doing is some nasal surgery, whether it be sinus surgery, septoplasty, that's part of rhinology if you were to divide it into divisions. So it's actually one of the most common things that a general otolaryngologist would do.

Even though I'm a -- you know, a rhinologist primarily, I do some other things, okay? I've done head and neck cancer surgery for years, I've done laryngology for many years. I don't do them now, but there's cancer surgery that goes along with rhinology. I do orbital surgery. I do a lot of different things that are encompassed within otolaryngology and rhinology and that border on other specialties like neurosurgery and ophthalmology also. So it's all part of otolaryngology. So I'm an otolaryngologist. So if you were to -- a medical board were to ask what my specialty is, I'm an otolaryngologist, but for the purpose of what is my subspecialty, I'm a rhinologist primarily.

Q Yeah, your declaration says that you treat

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sinus and nasal tumors, fluid leaks and orbital tumors, and how do you treat those conditions, John?

A Yeah, so -- well, depends on the particular condition. So every patient's different, every tumor's different, every situation is different. So most of those things that are mentioned there are treated by surgery. So nasal tumors, unless they're enormous tumors that are -- where the morbidity or the -- the negative effects of surgery are going to be too great, those will be treated nonsurgically, chemotherapy, radiation, combination of things, but I do surgery mostly through the nose with scopes, with endoscopes or telescopes to remove tumors in the nasal cavity, in the sinuses, actually tumors that are -- benign tumors that are going into the eye socket or primarily in the eye socket. I'm actually the one who does most of those at Emory. Tumors that traverse the roof of the nose into the brain we do either by ourselves or in conjunction with neurosurgeons. So that's how the tumors are treated. Spinal fluid leaks -- so the sinuses and the roof of the nose border on the brain cavity.

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Q Uh-huh.

A Okay, so the roof of the nose and the roof of the sinuses is bone that's fairly thin in some areas, and over time, there -- that bone can weaken and you can have the covering of the brain come through into the nasal cavity into the sinuses. We also see in the ears, but I don't deal with that part, and that can create a spinal fluid leak or what we call meningoencephalocele, which is actually tissue is coming through as opposed to just fluid.

Those things need to be repaired. Otherwise people are at risk for meningitis or infections in their brain, and those are fixed endoscopically through the nose, and then the third one was -- oh, orbital tumors, which I hit on already.

So those are some of the things. That's not everything I treat. I treat allergies obviously. I -- that's in there also, effects of nasal allergies, and as a matter of fact, I discovered and have been the one who has published more than anyone else on a condition that's purely related to allergy,

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and that's called central compartment atopic disease, and where it used -- used to be there were no physical findings other than some swelling that could be associated with allergy.

Well, I discovered and defined a condition that is -- happens in a percentage of allergy patients who actually develop polyps in a certain area of their nose. It's called the central compartment. It's the middle of the nose, the nasal septum, the middle turbinate, the superior turbinate. We don't see polyps on those areas, and most people have straightforward inflammatory polyp disease, but we see them in this population of allergy patients. So -- so those are just some of the things I do.

I also do a couple of things outside of rhinology that I still do because no one else in my department does, and as far as I'm concerned, we need to treat everything. We don't ever want to have to send someone to another university or another -- another practice, so someone's not doing it, I might. I used to do sleep apnea until we hired a sleep apnea person.

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Q So what conditions do you -- you treat with a radiofrequency energy delivery device, John?

A Well, it could be allergic rhinitis, non-allergic rhinitis, nasal obstruction, hypertrophy of the inferior turbinates. You can have -- you have thickening of other structures within the nose that can be treated with a radiofrequency. So a lot of -- of inflammatory nasal conditions can be treated with radiofrequency.

Q And when did you start using radiofrequency devices?

A So I've used them in the office since the late '90s to treat things like hypertrophy of the inferior turbinates is actually the most common one, but -- but other things, other obstructions in the nasal cavity.

Q And what was the first radiofrequency device that you used, John?

A So the first one I used would have been the Somnoplasty device, which is no longer available. I think it's been replaced by what I use now, which is called the Celon device, but the Somnoplasty device,

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and that was the days when I was also doing sleep apnea because I used it both in the nasal cavity and I use it on the palate, and I use it on the tongue base.

Q What's the name of the device you use today, John?

A Celon, C-E-L-O-N.

Q C-E-L-O-N?

A Yeah, it's from Olympus. It's a -- it's also a radiofrequency device.

Q And how long have you been using the Celon device?

A I can't tell you exactly when it transitioned from the Somnoplasty to -- to the Celon. It's been over a decade, but I don't remember exactly the -- when that transition was.

Q So is the Celon a later version of the Somnoplasty device?

A Honestly, I don't know if it's -- if it's exactly the same device or whether they -- frequently what they do is they retire something and then they come up with something that's, you know, new and

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improved.

Q Uh-huh.

A So -- and so it's one of those two things.

Q And why have you chosen to use the Celon device over other devices?

A I just like the effects, or the way -- I also used the Coblation. Coblation is a -- it's also radiofrequency. It's a plasma device, but I preferred the outcomes and the results that I got with Celon over Coblation. Still have a Coblation machine. I just don't -- don't use it very often.

Q So you have both the Celon device and the Coblation device in your office today?

A Yeah, and we have them in -- we have them in the operating room also, yes.

Q And do you have any other radiofrequency devices?

A Right now, no. Like I said, we don't have them. We -- when we use other radio -- for instance, like I said, I have a procedure coming up, or I've done procedures with the Aerin device. We actually don't have it. We have it brought in. Now, I may be

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wrong about that because I do have a partner who does it more frequently, but I -- I don't think we actually have the console because it involves a console and then handpieces, and the handpieces are disposable, so you buy them in bulk.

Q Uh-huh.

A Frequently they place the console, and you don't pay for the console, especially as a big institution like mine, a lot of the consoles will get placed just with the agreement of some kind of purchase agreement with -- you'll buy X number of handpieces, because the purchase of the console is a one-time thing. The purchase of the handpieces is a repeating business.

Q The razor blades are the --

A Exactly.

Q -- handpieces, and --

A What do you mean, the razor blades are the handpieces?

Q Well, the model of you give --

A Oh, exactly.

Q -- away the razor and --

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A Exactly, exactly, yeah, exactly.

Q So what's the -- you said Olympus is the name of the company that makes --

A I --

Q -- Celon?

A -- believe -- I'm not a hundred percent -- honestly, I don't -- I've been doing this so long, I don't -- plus we have a -- we have a policy of no reps in our university, so no representatives from companies in our university. So I'm not positive it's Olympus. I would have to -- I would have to check on that, but I've been using the Celon for some time.

Q And is this something that you -- you said you have a partner --

A Oh, I've got --

Q -- in your practice?

A I've got -- I'm sorry, I did not mean to speak over you, but I've got -- in rhinology, there's seven of us I think. There used to be eight. There's seven of us. There's five of us at the main hospital.

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Q And how many of them are routinely using the radiofrequency device?

A Well, I think one is routinely using it. Another one uses it occasionally, and then I've got a partner -- partners at other places, but I can't tell you what -- they're at other hospitals, so at other clinics, so I don't know what the setup they have is because I'm not -- since there are different sites and different -- different cost centers, I don't do their purchasing or I'm not involved in -- in the devices they choose.

Q John, have you ever been involved in designing a radiofrequency energy delivery device?

A No, I have not been involved in -- in developing a radiofrequency device, designing a radiofrequency --

Q Do you know if any of your Emory partners have been?

A I cannot speak on that. Many of them have many more consultantships and -- and agreements with companies than I do, so I can't speak to what their involvement is.

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Q Have you been involved in the design of a microwave device?
A No, I have not.
Q How about an ultrasound device?
A No, I have not.
Q Do you have any experience in designing medical devices that deliver energy to the body in any form?
A Well, I have some experience in -- in designing or assisting in designing medical devices, such as a microdebrider, which doesn't deliver energy, but obviously it treats tissue inside the nose.
Q But you haven't participated in designing a device that delivers energy, correct?
A No, I haven't.
Q I want to go back to paragraph 29 of the '271 patent declaration.
A '271, okay.
Q We were looking at this sentence earlier, but I want to read the portion of paragraph 29 where you provide your proposed definition of a person of

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ordinary skill in the art. You say, "A person of ordinary skill in the art at relevant times, 2011 to 2019, would have had a, number one, "Doctor of Medicine or at least a Bachelor of Science degree in engineering or a related discipline," and two, "at least three years of experience in the clinical use, design, development and/or testing of medical devices, including medical devices that deliver energy to tissue." It goes on to say, "A higher level of education may compensate for less work experience and vice versa." John, do you have three years of experience in the clinical use of medical devices that deliver energy to tissue?

A Yes, I do.

Q And I think we talked about it, but maybe you can just summarize your -- what would in your mind qualify as the three years of experience clinical use for a medical device to deliver energy to tissue?

A Okay, so as I said, I started my practice after residency in 1995.

Q Uh-huh.

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A And I don't know the exact date, but probably within two, maximum three years of starting practice, which would be either 1997 or 1998, then I would have had a Somnoplasty console in my office that would have -- that I started using to treat patients with nasal obstruction, allergic rhinitis, other symptoms, nasal cavity causing obstruction that I started using clinically to treat patients who failed medical therapy, so patients who did not get better with medication --

Q Uh-huh.

A -- and still had bothersome symptoms that I would treat with a Somnoplasty device in the office, occasionally use it in the operating room, but as I said, that -- that started in the late 1990s. So obviously by 2011, that was about 12 or 13 years of clinical use of treating patients with radiofrequency energy in the office and in the operating room, and that's just one example. I mean, in the operating room, we have other radiofrequency devices and bipolar forceps and unipolar forceps or unipolar cauteries, so --

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Q So looking at your -- the definitions, the next one that's on the list there, it says at least three years of experience, and then it gives a list of the types of experience. So at least three years of experience in the design, and you told us that you haven't been involved in the design of a medical device to deliver energy to tissue, correct?

A So the way I'm going to answer that question is first of all, you're taking this statement out of context because if you read the entire statement, it says one of the qualifications, number two, is at least three years of experience in clinical -- clinical use, design, development and/or, so don't have to meet all these criteria. Those are different criteria, right? So I don't have to have three years of design of medical devices that deliver energy to the nasal cavity. I meet the criteria of at least three years of clinical use --

Q But you would agree --

A -- of those devices.

Q -- you don't have three years of design, correct?

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A No, I do not have three years of design, but again, that is a different criteria that can be met but doesn't require to be met if another criteria's met, as I already have.

Q Would you similarly agree, you don't have three years of experience in development?

A So I've been -- so it's a matter of what you consider development. Specifically -- well, if we're talking about medical instruments in general, then I probably do meet it, but if it's for energy-delivering devices, then no. But again, same answer to that. These are not all required to meet that criteria for a person of ordinary skill in the art. I already met that criteria on both -- on both item number 1 and item number 2.

Q And as for testing, would you similarly agree you don't have three years of experience in testing of a medical device to deliver energy to tissue?

A Well, no, I would not agree with that at all because what am I doing every day in clinical practice? I'm testing these instruments, I'm testing

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the effect of these instruments, I'm testing the results of these instruments, and by finding out the answer to those questions, I'm altering my particular approach to these patients and how I'm using the devices. So you know, and that's one of the -- one of the elements of practicing medicine, is that if you're doing things the same way all the time, then you're not learning from it. You're not progressing, right? So yeah, technically I am testing.

Now, may not be the definition of testing that you're looking for, but it is testing all these instruments on a fairly regular basis.

Q Have you provided feedback to any of the manufacturers with respect to that activity?

A Sure, I've provided feedback to the representatives on multiple occasions.

Q And how do you provide that feedback, John?

A Well, usually directly, directly. I mean, you know, in -- in cases -- for instance, in cases where -- in cases where I'm using the Aerin instrument or the Aerin device, I'm directly -- you know, directly giving feedback to the representative

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after the procedure, or at some point during or after the procedure.

Q And with respect to the Aerin device, what time frame would that have been, John?

A Well, I'm saying whenever I've used the Aerin device. You know, it's not something I use frequently, and like I said, the first time I used it would have been before the pandemic, so -- and especially the first time I use it I'm going to give feedback, and they're going to give me feedback, you know, and so it's -- might be -- you know, this could be better, you know, if it was used this way, or -- or even parts -- not necessarily just of the design of the device, but also of the actual procedure using the device, the local anesthetic, the -- you know, what areas do you need to anesthetize, you know, how do you expose the area, can the device, you know, be a little different. So I can't tell you exactly what it was. I mean, we're talking five, six years ago, but I frequently -- I don't just walk out of the room and just say bye to the rep and that's done. You know, we'll have a conversation.

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Q But you've been using the Somnoplasty device in 2011?

A As I mentioned to you, I can't tell you when the Somnoplasty kind of got phased out and the Celon became the device, so I can't tell you if it's -- 2011 was Somnoplasty or Celon, but essentially there was no down time in between. I always had radiofrequency device in my office starting out with Somnoplasty, presently with Celon. That transition happened some time, and I can't -- I can't tell you exactly when that was.

MR. WARD: Let's go off the record.

(Recessed at 2:01 p.m.)

(Reconvened at 2:11 p.m.)

BY MR. WARD:

Q All right, John, let's turn now -- I think -- the '271 patent declaration in front of you there?

A Yes.

Q Okay, excellent. Right on the page you're on, paragraph 30 --

A Uh-huh.

Q -- you provide a figure there, and you say,

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"Provided below is a simplified depiction of the internal anatomy of the right side of the nose and nasopharynx. So I want to ask you, John --

A Uh-huh.

Q -- about the concha and the figure that's shown below paragraph 30, labeled superior concha, middle concha and inferior concha, if --

A Uh-huh.

Q -- I'm saying that term correctly. I may not --

A That's fine. I call them concha.

Q Concha, okay.

A Concha, like a conch shell.

Q I got you, okay.

A Or a concha shell I guess.

Q Is there a difference?

A You can use -- you can use both terms.

Q Oh, okay.

A Really, you can. I'm not -- some people say that. Most people say "concha," but you can say "conka" so --

Q Is there a difference between a turbinate

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and a concha?

A No, so concha is a older term, so there -- there are a few explanations to that. Concha is a much older term. Most people refer them as turbinates, but the inferior turbinate is -- actually comes from a different embryologic derivation than the middle and superior turbinates.

Q Okay.

A And it actually comes from the conchal bone. So -- so it's actually more appropriate -- it used to be called -- inferior turbinate used to be called a concha. They're all -- but that's the difference, the embryologic difference between the inferior and the other turbinates, and their position obviously, and their size. The inferior turbinate is the largest one.

Q And what -- what is the function of the turbinate, John?

A Yeah, so the -- the turbinates have multiple functions. The -- and really it's a matter of understanding what nasal anatomy -- all of the nasal anatomy. Now, you're looking at this on a side

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view.

Q Uh-huh.

A Those turbinates are structures that -- one function is they increase the surface area volume of the nose. The nose is not just for breathing, okay? It's actually a nasal passageway. It is for breathing, but it's also a filter. It -- so it has -- the mucosa has mucus -- mucus glands that secrete mucus onto the surface, so it's like a fly trap.

It has cilia or hairs that actually move that mucus back into your throat and you swallow it, and you make a liter to a liter -- liter to a liter and a half of mucus a day. So that's -- one function is that increased surface area helps with the filtering function. The nose actually is involved in heat and moisture exchange. So when we breathe in air --

Q Uh-huh.

A -- there's an exchange of heat and moisture between the tissue and the air. So in the winter, especially here, as you breathe in, you're breathing in cold air, you don't want that cold air hitting

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your lungs. So what happens is mainly in the front of the nose but all throughout the nose, the nose -- the mucosa, the lining adds heat to the -- to the air so that it's not cold air hitting your lungs. When you breathe out, it takes hair -- it takes heat out of it.

Same thing with moisture. Dry air coming in your nose, it moistens the air coming in. As you exhale, it actually sucks moisture out. So there's heat and moisture exchange, there's increasing the surface area. I said it's a filter. So actually, the condition I told you that I described and I published on called central compartment atopic disease, that's -- that happens as part of the filtering process where it actually is part of the immune system. It actually filters things you breathe in, and if you're allergic to them, it actually initiates an immune response that causes swelling of the tissue. So in addition to breathing, all of those functions.

Q So John, as I understand it, when you say the nose acts as a filter, and part of that

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filtration is essentially based upon a humidification of air that's breathed into the nasal cavity; is that correct?

A Well, the -- the humidification is part of -- so I'm not sure -- I don't interpret it the way you just said it. So humidification is important to keep the nose healthy. Once the nose dries out, it can't perform its functions of humidifying the air or filtering the air as well.

Q Uh-huh.

A And actually, when it dries out, it affects breathing also. So humidification -- or moisture in the nose is important because that keeps the nose healthy. The filtering and the humidification are two separate things, but they help each other.

Q You -- you identify -- on paragraph 30, there's a statement where you say, "The figure below is a simplified depiction of the internal anatomy of the right side of the nose and the nasopharynx." Can you describe to me the distinction between the nose and the nasopharynx?

A Sure. The nose refers to -- well, the nose

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has an external portion and an internal portion. So the external portion would be what's on the left side of that picture. So that'd be your external nose.

Q Uh-huh.

A And you see all the structures, multiple structures that -- that are -- that make up the external nasal -- external nose. The nasal cavity is everything that would be from the nostrils in, so from the opening of the nose to the right of the picture.

Q Uh-huh.

A So that would include the turbinates, the nasal floor, the undersides of the upper lateral cartilage. It says alar cartilage there, but that's all going to be mucosally covered, and then that extends to the back just behind the turbinates and essentially to the area of the junction of the hard and soft palate. So the palate is the floor of the nose. If you look at the bottom of that --

Q Uh-huh.

A -- picture, you see bone is above the teeth. Well, there's the teeth. Above that is the

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gums, and then above that is the palate.

Q Okay.

A So the part that's whitish is the hard palate. That's bone. Behind that, it's shaded in gray here with a thicker white covering, that's the soft palate. Once that -- essentially that transition from hard to soft palate, that starts -- goes from the nose to the nasopharynx. It's not a -- it's not like a discrete line. The nasopharynx is that structure behind the nose --

Q Uh-huh.

A -- that goes all the way to the back wall of the -- that back wall there in front of the bone. It includes -- you see it says Torus tuberis and opening of Eustachian, that's in the nasopharynx. So the nasopharynx is behind the soft palate, which is lower, goes all the way back to that bone, essentially starts -- transitions from the nasal cavity or nose to the nasopharynx, and then that'll keep going down and then transitions to what's called the oropharynx, which is continuous with the nasopharynx

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Q So I understand correctly the term "pharynx" is synonymous with the throat?

A It's -- not in medical terms, but it's part of the throat.

Q And so nasopharynx is representing, as you say, what would be in the far right-hand portion of the figure below paragraph 30?

A It would be in the far right-hand part under -- you know, except for -- doesn't include all of that because that also shows the sphenoid sinus, which is not labeled. That's that almost rectangular structure.

Q Uh-huh.

A That would be just -- that would be the roof of the nasopharynx, would be that lining on the bottom outside of that sphenoid sinus. That would be the roof of the nasopharynx.

Q And there's a sentence just after on the next page where you say, "Below, I described certain anatomical features of the nose between the nostrils at the front or anterior of the nose, and the nasopharynx at the back, or posterior of the nose."

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And so maybe can you define again for me --

A Okay, I'm sorry. You said --

Q Yeah.

A -- below I describe certain -- is that what you're talking about?

Q Yes.

A Okay, okay.

Q The statement is, "I describe certain anatomical features of the nose between the nostrils at the front, or anterior of the nose, and the nasopharynx at the back, or posterior of the nose," correct?

A Okay, so yeah, so that can be interpreted differently than I'm -- than it sounds. The nasopharynx and the nose are separate but continuous, okay? So the nose and the nasopharynx don't necessarily overlap, but it's just a continuous passageway. Like I said, the demarcation is approximately -- so how do you want me to explain this? Do you want me to explain this by showing you?

Q Better for words for the record --

A Okay.

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Q -- John, yeah.

A The nasal cavity extends, as I said, from the nostrils all the way back, everything including the turbinates, you see the tail of the turbinates, which would be on the picture the right side, that's all included in the nasal cavity. Beyond the turbinates, as you see, the turbinates, where they end on this picture, if you follow it all the way down to that palate, it's roughly in the area where the bone stops, the hard palate stops and it becomes soft palate. That is the approximate place where the nasopharynx starts.

If you're looking for an area superiorly, again, it would be behind the turbinates at the bottom of that rectangular sphenoid sinus. So everything to the right of that on this picture would be nasopharynx.

Q Essentially it's the area above what's labeled as the opening of the --

A So actually, it was -- that opening of the Eustachian tube would actually be on the side wall of the nasopharynx. We're looking at a two-dimensional

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figure.

Q Uh-huh.

A So we kind of have to fill it in. That's looking at the side wall. So just like the turbinates are on the side wall of the nose and the airway would be closer to us --

Q Uh-huh.

A The nasopharynx, Eustachian tube is on the lateral or side wall of the nasopharynx, and the remainder of the nasopharynx, the actual air passageway of the nasopharynx would be closer to us.

Q And what is it that's described as the Torus tuberis?

A That's just the cartilage that is around -- makes up a portion of the Eustachian tube in the nasopharynx, and the Eustachian tube is the tube that connects the ear cavity --

Q Uh-huh.

A -- to the nasopharynx so that you can equalize pressure in your ear, like when you're going up in altitude in a plane, you need to pop your ear, that -- that's air going through that Eustachian tube

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that allows you to pop your ear because the inner -- that's the only connection the middle ear has to the outside.

The middle ear itself, unless you have a hole in your eardrum, has no connection to the outside. Your ear canal stops at your eardrum. So that's why when people try to pop their ear by sticking their fingers in their ear, I don't know what they're doing. That's why you have to pop your ears. You have to kind of blow your cheeks out, you got to do something to increase pressure actually in the nasopharynx to force air through.

Q Good to know. Tell my kids that the next time we're flying.

A Yeah.

Q So let's move to the next paragraph, 31, and there's another figure, but before the figure, you state, "The nerve supply of the lateral wall of the right side of the nose is illustrated below." Do you see that, John?

A I'm sorry, where -- what --

Q Paragraph 31. That's at the bottom of --

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A Oh, 31. I'm sorry. Yes, I see that.

Q Thirty-one, yeah. So you introduce it -- you introduce the figure by saying, "The nerve supply of the lateral wall of the right side of the nose is illustrated below."

A Correct, or on the next page.

Q Yeah, and then you've got a figure there on page 15, and you state that the posterior inferior nasal lateral nasal nerve is a branch of the maxillary division that innervates the inferior turbinate. Can you explain to me what you mean by that, John?

A All right, so the -- okay, let me see exactly where -- hold on. Oh, okay. In the fourth sentence, for example, the illustration below depicts the posterior inferior lateral nasal nerve, which is a branch of the maxillary division that innervates the inferior turbinate, okay. So there are multiple nerves that are in -- well, anywhere has multiple nerves. There's sensory nerves, there's motor nerves, there's parasympathetic and sympathetic nerves.

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So this -- what this is describing -- and this is actually a picture from Andy Lane, who's a friend of mine who's at Johns Hopkins, in one of his publications, and this is the posterior -- on the photograph, there are multiple nerves and branches of nerves that are depicted. They're all emanating from the area called the pterygopalatine fossa, which is where a lot of nerves communicate with from the brain into the nasal cavity through the pterygopalatine fossa.

So the posterior inferior lateral nasal nerve is depicted on -- it's actually -- here it's depicted on the turbinate, but actually, it's in the turbinate, the inferior turbinate. It's a branch of the maxillary division of the -- of cranial nerve 5. So the maxillary division of cranial nerve 5, that's a trigeminal nerve. That's a nerve that gives us sensation to our entire face and a lot of the structures inside the head anteriorly. So that's what that is saying.

Q And you give there -- there's a parenthetical at the end of that sentence, you say,

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"Posterior inferior nasal branches give sensation to the mucosa of the turbinates and lateral nasal wall."

A Right.

Q So --

A So the turbinates are -- so the turbinates are on the lateral nasal wall, but there's actually -- if you look at the picture, if you look at the bottom of the turbinate, that turbinate actually -- it's like a baffle. So it -- it's not solid. The bottom part is not solid against that lateral wall. It actually -- there's an empty space under that turbinate. There's air between that lateral nasal wall and the -- what we call the lateral surface of the turbinate. So if we were looking at it from the front, that inferior turbinate, we'd be able to look underneath it and see a space. That space, the lining in that space is called the lateral nasal wall.

So this is just saying that that particular nerve innervates the lateral nasal wall in that area, and it's called the inferior meatus, and on the inferior turbinate.

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Q John, do the posterior inferior nasal branches extend both into the nose and the nasopharynx?

A Not this. Now, if you look here, there are other branches that would extend to the nasopharynx, but this -- this posterior inferior nasal branch would go into the nasal cavity, as depicted here. It goes anteriorly, as the nerves above it. There would be separate nerves that innervate the nasopharynx.

Q If you turn to the next page -- you had it there. The next figure that's associated I believe with paragraph 32 --

A Uh-huh, yes.

Q Does that figure illustrate nerves that extend into the nasopharynx?

A It does, the pharyngeal nerve.

Q What's labeled in the bottom right-hand corner as pharyngeal N?

A Pharyngeal nerve. Yeah, yes, pharyngeal N, correct.

Q So those are separate from --

A Well, so if you look at where -- so there

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are multiple nerves -- the -- it's a complex area, okay, because this pterygopalatine fossa, and if you look at the diagram on the right, it actually gives you a little bit more of an idea of some of the nerves that are contributing to the complexity of the nerve constitution of the pterygopalatine fossa, because that receives branches from the vidian nerve or the pterygopalatine nerve, and the maxillary nerve.

So it has both sensory nerves and it has parasympathetic and sympathetic nerves, and they all go to the area of the pterygopalatine fossa with that pterygopalatine or sphenopalatine ganglion, it's called both. Both names are okay, and then it gives multiple branches off, okay? That pharyngeal nerve going into the pharynx, you can see that's coming off high right off the ganglion, and then you have what's called the descending or palatine nerves, which are nerves that are going straight down.

They give you sensation to the palate, but then you have those nerves going anteriorly into the inferior turbinate, the middle turbinate, the

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superior turbinate. So it'd be the posterior inferior, posterior superior nasal nerves, they're going to have sensory nerves from the trigeminal nerve, and they're also going to have parasympathetic and sympathetic fibers from the vidian nerve or pterygopalatine nerve.

Q John, can you identify in that figure that's associated with paragraph 32 the vidian nerve?

A Yes, yes, with -- on page 16, it's actually -- so actually, it's labeled with a different name here. It says N of pterygoid canal. So it's also called the pterygoid nerve, the pterygopalatine nerve or the vidian nerve, but here it's labeled nerve of pterygoid canal, P-T-E-R-Y-G-O-I-D canal. Do you see that?

Q Uh-huh.

A Okay.

Q And how is that different than the sphenopalatine ganglion?

A So it -- so this vidian nerve actually comes out of the brain through the vidian canal or the pterygoid canal, and then it basically merges on

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to the ganglion. So what ganglions are, ganglions are a collection of cell bodies. So a nerve has axons and -- has an axon and cell body. So it has different components. The cell bodies are in the ganglion. So it contributes to the ganglion, and then it sends fibers through multiple different nerves as they exit the ganglion. So that would provide the sympathetic, parasympathetic fibers. Doesn't just go to the nose. It also goes to the lacrimal gland, so the -- the tear gland in the eye.

Q Does this figure show the sphenopalatine foramen?

A It does not. So the sphenopalatine foramen would be more medial towards us, because this is a cut-away, and it's showing the contents of the pterygopalatine fossa, which is where the ganglion is, and where that palatine, those descending palatine nerves are, if we were to keep adding layers on this, we would add the palatine bone, which would be -- it would be -- let's see, perpendicular? It would be perpendicular to the palate right here. Between the palatine foramen actually is a hole

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through that palatine bone that allows some of these -- those fibers to come out through that sphenopalatine foramen into the nasal mucosa.

Q So how does the sphenopalatine ganglion relate to the sphenopalatine foramen?

A It -- it's -- it's lateral to it. So it's in the pterygopalatine or -- the pterygopalatine fossa, so it's in that space where you see it. It's depicting this in the pterygopalatine fossa, okay? Those fibers are actually not just -- they look like they're coming forward in the --

Q Uh-huh.

A -- in the picture.

Q Yeah.

A They're not just coming forward. They're coming medial and then forward, okay? So they're actually coming out of the sphenopalatine foramen, so they have to go -- so if this -- this is the patient's right side, they have to go towards the nose first and then out. So they're coming out of the foramen and then they're making a right angle and going anteriorly, some moving posteriorly.

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Q Difficult to perceive in 2D here.

A It -- it's hard to do -- a lot of these are tough in 2D, especially if you're not familiar with -- with the area. They're hard to convert a 2D image into a 3D picture in your head.

Q John, you -- at paragraph 34, you say, "The structure and function of these and many other anatomical structures of the nose and upper airways would have been standard textbook knowledge to a person of ordinary skill in the art long before the claimed priority date of the '271 patent," correct?

A Correct.

Q The definition for a person of skill in the art that you proposed provides essentially two categories, first, someone with a Doctor of Medicine, or you say at least a Bachelor of Science degree in engineering or a related discipline. Would you understand that someone without a medical degree, only a Bachelor of Science in engineering, would have this knowledge about the anatomical structure of the nose and upper airways?

A Well, I can't -- I can't say what other

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knowledge they may have acquired. A Bachelor of Science, it could be an anatomist.

Q If they have a Bachelor of Science in engineering, would you expect them to have knowledge about the structures of the nose and the upper airways?

MS. COHEN: Objection, form.

A Yeah, again, it would depend on how much knowledge they had of anatomy. Maybe they were an engineer and worked in medical devices that treated the nose. I don't know. I can't answer that question specifically because I don't have knowledge of that hypothetical person.

Q So you don't have knowledge of an individual with a Bachelor of Science in engineering.

MS. COHEN: Objection.

A Yeah, that's not what I said. I think every case, every person will be taken individually. Does that person -- particular person have a significant background in anatomy. Have they studied the area? Even if it wasn't their major, have they studied the area, have they worked in the area, have

they worked with someone who developed products that treated the area, treated the nasal cavity, treated nerves, anything like that. So I can't answer that without more information.

Q The definition that you propose says a person of ordinary skill in the art would at relevant times have a Doctor of Medicine or at least a Bachelor of Science degree in engineering, and is it your understanding that an individual with just a Bachelor of Science degree in engineering would have knowledge about the anatomical structure of the nose?

A That's not for me to answer. This -- these criteria apply to how I am qualified as a person of ordinary skill in the art. So I have three years of -- I have an M.D. degree, I have a medical degree, and I have three years of use -- clinical use of energy-delivering devices in the nose. So for those purposes, I absolutely meet those criteria. It's not up for me -- up to me to judge if anyone else meets the other criteria to be someone who can make a judgment on this.

Q But you've proposed that a person of

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ordinary skill in the art could be someone that has only a Bachelor of Science in engineering, correct?

A That --

MS. COHEN: Objection to form.

A That is in the declaration, but again, my answer stands. I -- this is referring to whether I meet the criteria for a person of ordinary skill in the art, which as I already stated multiple times, I do. So it's not my place because I cannot -- any of these hypothetical people, I do not know what other skills they have, what other experience they have, so I can't make that judgment.

Q But you would agree that knowledge of the structure and function of the anatomy of the nose is not on the standard curriculum for a Bachelor of Science in engineering, correct?

MS. COHEN: Objection, form, relevance.

A I can't answer that question. I do not -- I've never been -- I don't have a Bachelor of Science in engineering. I don't know what's involved in obtaining a Bachelor of Science in engineering, so I can't answer that question appropriately.

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Q But in paragraph 34, you state, "The structure and function of these and many other anatomical structures would have been standard textbook knowledge to a person of skill in the art long before the claimed priority date," correct?

A Correct.

Q And would that have been knowledge known to an individual with only a Bachelor of Science in engineering?

MS. COHEN: Objection, form, foundation.

A Again, my -- my answer stands. Anyone has access to any of this information, any of these textbooks, any of these publications, but again, the POSITA definitions were -- are based on whether -- do I qualify, how do I qualify, and obviously I meet those criteria.

Q My question isn't relevant to whether or not you qualify, John. Your statement in paragraph 34 is you're stating what would have been known to those of skill in the art, correct?

A Correct.

Q And you state that the structure and

function of these anatomical structures would have been known to those of skill in the art, correct?

A I exactly say the structure and function of these and many other anatomical structures of the nose and upper airways would have been standard textbook knowledge to a person of skill in the art. It doesn't say known. It says standard textbook knowledge, which means they're in a textbook, which means you could find them, which means anyone could find them, but again, that's not my -- this hypothetical person, I can't tell you what they have access to, what their past experience is, what their past education is, how much they read. I can't tell you that, what their experience is as far as what products they've used or developed or patented.

Q So when you say standard textbook knowledge, you're saying a -- a standard textbook for someone that would have been working in this area, correct?

A Anyone. A textbook is a textbook. You know, anyone can go to a library, medical library. You don't have to be a doctor to go to a medical

library, so I'm not quite sure how --

Q But you would agree that all textbooks aren't known to any one individual, correct?

A I'm not sure what you're asking.

Q You say that -- that this knowledge, this structure and function of those and many other anatomical structures of the nose and upper airways would have been standard textbook knowledge to a person of skill in the art. You're saying that -- not that it was known, but that it was in a textbook at the time? Is that what you're saying?

MS. COHEN: Objection, form.

A If it's in a textbook, it's known.

Q So all things are known if they're in a textbook.

MS. COHEN: Object --

THE WITNESS: Well --

MS. COHEN: -- to the form.

THE WITNESS: It depends on how they're written. Things in textbooks -- I'm not saying they're fact.

BY MR. WARD:

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Q Right.
A They don't necessarily have to be fact.
Q Yeah.
A But there's a difference between opinion and anatomic structures, okay? These are anatomic structures. These are anatomic structures that are identified based on human dissections of actual human anatomy, right? And it's not just one. It's not a single -- at this -- any time in the 2000s and the late 1900s and going back way much further, these structures, these nerves have been dissected out. They've been reported. You know, the anatomy had been documented, okay?

So what I'm saying is that there are multiple references, there are multiple anatomic texts, there are multiple textbooks and articles that would discuss, and there would be figures that would show maybe not all of these. Maybe they're not all identified because that's why research continues to happen, is because sometimes they can find variations. It's not going to completely overturn someone's anatomy, but hey, maybe there are a certain

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percentages of the branches that come off late, you know, so that's why these procedures are not a hundred percent successful. These things are in textbooks. They've been in textbooks, okay?

Q So John, you understand for purposes of the obviousness inquiries, not what is known, but what is known to a person of skill in the art, correct?

A Absolutely.

Q And is it your position that knowledge of the anatomy of the nose would have been known to an individual with a Bachelor of Science in engineering?

A That's -- I'm answering this based on my qualifications. I'm not a Bachelor of Science, you know, in engineering. That's not me, okay? I'm -- it's not my role, it's not my place to determine if anyone else is a person of ordinary skill in the art, okay? Just like it's not their place to determine if I am. My declaration spells those things out to show that I'm a person of ordinary skill in the art because I'm an M.D. and I've been practicing for three years with the clinical use of energy-delivering devices in the nasal cavity.

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Q So you would agree that you haven't provided any opinions based upon what would have been known to an individual with a Bachelor of Science in engineering.

MS. COHEN: Objection, form, foundation.

A That's a question I can't answer because I am not that person, and I'm not --

Q John, the question --

A I am not looking at it through those eyes. That's not --

Q John, my question is --

A -- how I evaluated it.

Q -- have you provided any opinions based upon the knowledge of an individual with a Bachelor of Science in engineering.

A Okay, so if you phrase --

MS. COHEN: Object to form.

A -- phrase it that way, I have provided my opinions based on my qualifications, not as someone with a Bachelor of Science in engineering.

Q John, do you have an understanding of what types of engineers design products that are

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energy-delivery devices for the nasal cavity?

A I am not certain everyone who has the qualifications. I would think electrical engineers would fit that -- that qualification, but again, I'm not an engineer. I don't know the specifics of what goes into building the circuitry or any other components.

Q So John, if you don't have any knowledge about the knowledge of a engineer, why did you include an engineer in your definition for a person of skill in the art?

MS. COHEN: Objection, form.

A Well, the -- again, definitions don't have to -- there could be broad definitions, there could be narrow definitions, but again, the issue is it's not up to me to determine who meets those qualifications. These are just the qualifications based on this particular case.

Q But you testified that you believe a person of skill in the art could include an individual with just a Bachelor of Science in engineering, correct?

A Could. I guess anything could be possible.

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Q In accordance with your proposed definition in your declaration, is an individual with just a Bachelor of Science in engineering and the other qualifications about clinical use and design and development, does that individual qualify as a person of ordinary skill in the art?

A I'm sure it would qualify as a person of ordinary skill in the art in certain aspects of this case.

Q What if that engineer had no experience or knowledge with respect to medical devices for the nose, do you still think that that individual would qualify as a person of skill in the art?

MS. COHEN: Objection, form.

A I can't answer that question. Again, every person -- you know, I can't -- I don't know what all that qualification -- I know what the qualifications in the declaration are, but I don't know what that individual person's qualifications are. I don't know what the individual knowledge are -- knowledge is, I don't know what they've read, I don't know exactly what they've worked on. You're not giving me

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complete information.

Q Well, I'm asking you about your testimony, John. In your testimony, you provide a proposed definition for a person of ordinary skill in the art, and in that proposed definition, one of the categories is an individual with a Bachelor of Science in engineering, correct? Paragraph 29 if you want to go back and look at it.

A I was going to say, make sure it's exactly as you said. Bachelor of Science degree in engineering or a related discipline, yes, it does say that.

Q So an individual with a Bachelor of Science in engineering satisfies the first of your categories for a person of skill in the art, correct?

A It says it could. Would have, yes, would have satisfied. That's one -- that's -- that's not a single qualification taken out of context. They also have to have at least three years of experience in clinical use, design, development and/or testing of medical devices, including medical devices that deliver energy to tissue, okay? So -- so it's not

just three years -- because I believe -- and -- correct me if I'm wrong, but I believe the hypothetical scenario that you gave me said they have no experience with energy-delivering devices; is that correct?

Q The question I asked is would an individual that has a Bachelor of Science degree in engineering and three years of experience in the design of medical devices, but not medical devices that deliver energy to the nose, would that individual still qualify as a person of skill in the art in accordance with your proposed definition.

A Well, so --

MS. COHEN: Objection, form.

A Okay, so hypothetically, as we're speaking, they -- they could still qualify because it says including medical devices that deliver energy to tissue, and there's tissue all through the body. So it doesn't have to be the nose, and there's a lot of similarities between nasal tissues and tissues in other parts of the body, and a matter of fact, a good percentage of devices that we use in otolaryngology

and rhinology specifically are adapted from other specialties, like cardiology, like urology, and -- and ophthalmology. So tissue between different places, just because it's in a different place, for instance, for Stern, Stern is about endometrial tissue, and can -- and -- but he also talks about using it in other -- other cavities, including the nasal cavity. Well, that just is another -- it just -- it's an example of how procedures for one area can be adapted or used in other areas.

So specifically what this says is including medical devices that deliver energy to tissue. So yes, if someone hasn't used it specifically in the nose, that doesn't disqualify them. They can still meet that criteria because the information -- a lot of information could be obtained if necessary in textbooks.

Q That second category of your definition, John, at least three years of experience in the clinical use, design, development and/or testing of medical devices, including, what comes after including is just an example of the three years of

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experience, correct?

A Well, it's -- it's an example, and it's --

Q It could include additional examples, correct?

A Well, it -- that -- that covers most things. It deliver -- because this is a -- the issues that we're discussing are delivering energy to tissue.

Q So they would -- they're --

A So you would -- you know, if someone has had three years' experience with devices delivering energy to tissue, and that's the -- that's the -- the issues that we're discussing here, the issues -- the claims that are under consideration, then that should qualify according to these criteria.

Q What if they have three years of experience in the design of a medical device that has nothing to do with delivering energy to a tissue?

A Well, that's not what we state here.

Q So they have to -- the experience has to be experience --

A All --

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Q -- with a medical device delivering energy to a tissue.

A So all I can do is -- we've already -- I already have it in my declaration, even though this doesn't specifically apply to me because I meet the other criteria, but it is as is stated in the declaration.

Q And I'm trying to understand the statement in the declaration, and do you understand the statement in the declaration to require that that three years of experience be for only medical devices that deliver energy to tissue?

MS. COHEN: Objection, form.

A No, the way it's written, it does not say only, but that is an example of someone who would be qualified.

Q Would someone be qualified if they had design experience with medical devices that don't involve delivering energy to tissue?

A Well, I can't answer that, but according to the statement, that someone could possibly be qualified if they were, you know, designing devices

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even though they didn't deliver energy but were still working in the area somehow. Again, we're talking hypotheticals, and --

Q And what do you mean by working in the area, John?

A I'm just saying, doing some kind of treatment in the area. There are other treatments other than energy.

Q In the nasal area or just anywhere --

A Anywhere.

Q -- on the body?

A Well, anywhere, but here we're talking -- and again, it doesn't say -- as far as the qualification, doesn't say nasal area, okay? It says at least three years' experience in the clinical use, design, development and/or testing of the medical devices, including medical devices that deliver energy to tissue. Obviously -- I mean, that's what it states. I can't say any more than what it states.

Q And what if their medical device experience was something like a total knee replacement device?

A That's not -- that's not up to me to

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determine.

Q Does that meet your proposed definition?

A Again, that's not up to me to determine.

Q So you don't know the boundaries of your proposed definition?

A No, I don't -- I don't know what other --

MS. COHEN: Objection, form.

A I don't know what other criteria -- or I'm sorry, not criteria, but other experience that they have. Okay, you're giving me hypotheticals without a hundred percent information, so I can't -- I can't give you --

Q So --

A -- more -- more of an answer than is already in my declaration.

Q But three years of design experience on a medical device such as a total knee replacement device would not fit within your definition.

A I can't tell you whether it would or wouldn't. I'd say it's a medical device. It's an implant. I'm not sure -- you know, it could be a medical device. Again, I'm not an orthopedic

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surgeon. I don't know if they consider that a device or if they consider that an implant. So again, that's not my area, and I don't know how they would qualify that.

Q So how would you qualify it in your proposed definition of medical devices?

MS. COHEN: Objection, form.

A Well, I would -- you know, that's a -- that's an interesting question actually, but again, as I said, it says what it says, three years of experience in clinical use, design, development and/or testing of medical devices. Yeah, technically maybe a hip implant is -- I mean, there's a lot of mechanical engineering, whatever, I don't know. That could possibly -- if the person had the right knowledge, I'm sure they have other experience. Who knows? I can't answer it completely. Again, it's a hypothetical, and I don't have all the information.

Q But that could be sufficient to render that person as a person of skill in the art.

A Well, there are a lot of things that could be possible.

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Q Let's take a look now, John, at paragraph 40 of your declaration.

A Same one?

Q Yeah.

A Okay.

Q The heading that appears before paragraph 40 says, "Using Energy to Treat Medical Conditions."

A Yes, I see it.

Q And in paragraph 40, you state, "A common technique for treating medical conditions is to deliver various forms of energy, e.g., light, sound, heat, et cetera to target tissue within the body. Illustrative examples of energy-based treatment, some of which predate the '271 patent by as much as a century, include the following," and then on subsequent pages, John, you list a number of exhibits. Do you rely upon the disclosure in these listed exhibits for paragraph 40 as a basis for the challenge to the '271 patent claims?

A These are just examples. These are examples of the fact that energy delivery devices have been around for, oldest year, 1907, so that's a

hundred -- well over a hundred years from the time of the patents, and obviously others, 30, 40, 50 years. Obviously our declaration does not use these references in our -- to render the claims unpatentable. We're using them as references for examples of exactly what we said, the use of various forms of energy to treat conditions.

Q So the first reference that you identify is Exhibit 1025, De Forest, to identify as a patent issued in 1907. Are you aware of any devices such as this device described in the 1907 patent that are still in use today, John?

A I am not familiar with that. I do not know the answer to that question.

Q You're --

A I do not know whether the -- whether there are products -- there may or may not be products that have come from this patent that are still in use or have since been developed further from this use, or from this patent rather. I'm sorry.

Q The next exhibit you identify is Exhibit 1026 to Meyer, a patent issued in 1970.

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A Uh-huh.

Q Are you familiar with what device was being described by that 1970 patent?

A Well, it's discussed a transmit -- I'm sorry, let me start a little higher. "Depilation is accomplished by inserting the probe 6 into the follicle 9 of hair 10 to terminate at the papilla, in transmitting a metered amount of laser energy through the laser beam transmitting rod 11 to destroy the tissue immediately surrounding the terminal end 12." So there are multiple lasers out now. Whether they came from this patent or not I cannot tell you, but there are many products that are used for hair removal, depilation. You know, whether or not they came from Meyer I can't tell you specifically.

Q And John, in your experience, what's the typical lifetime in the marketplace of a medical device that delivers energy to tissues?

A I can't -- I don't -- all I can do is based on my experience, some products come and go very quickly. Some are around for a fair amount of time, the devices that I've been using for 30 years, like I

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said, the Celon right now and the Somnoplasty before that, the coblator's been around, assuming the Somnoplasty's no longer around, the coblator's been around longer than that, so we're talking a couple decades at least.

Q How long did you use the Somnoplasty device?

A As I told you previously, I do not remember when it essentially phased out, and then it was replaced by the Celon, but I started using the Somnoplasty device in the late 1990s.

Q You said earlier that it's common for a manufacturer to replace a medical device with an updated version, correct?

A Oh, I said that's possible. I don't know if that's the case in this -- in this situation with the Somnoplasty and the Celon, but I said that that sometimes happens.

Q And is it your understanding that that is typical in the industry, that devices are updated over time?

A Well, my understanding is that there's a

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constant goal to make products better so that if something can be improved, the company will come out with another version, and whether that be a new console or a new handpiece or -- you know, we're talking about, you know, energy-delivering devices, so smaller console that fits better into a space, is more space economic, a handpiece that's more ergonomic or, you know, something that they think that clinicians will find better, that's very common.

Most companies don't just put a product out and just, you know, just sit on it and just say well, we'll ride it for as long as we can and they we're done. I'm sure some do, but -- but I think most are trying to continue to maintain their market share and maintain their loyalty from physicians and -- you know, in using their product to treat patients.

Q And do they do that by updating the device and adding new features to the device?

A Well, it can be -- I would assume it can be done in many ways. It can be done that way. It can be done, again, making it less expensive. There's a lot of different ways that it can conceivably be

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done. I don't know all the ways. I'm not a device marketer. I know my -- from my experience that that sometimes happens. We get different, you know, devices that we use, get their power source upgraded or their handpiece -- you know, next generation handpiece or a next generation component.

Q Let's take a look at paragraph 41, John. The heading before paragraph 41, "Using Energy to Treat Conditions of the Nose and Upper Airways." In paragraph 41, you state, "It was also known to deliver energy-based treatments, such as those described in the previous section, to mucosal and submucosal tissue of the nose to treat conditions of the nose and upper airways. For example, prior to the claimed priority claim of the '271 patent, energy-based treatments had been disclosed for treating upper airway conditions, including the following," and the first example that you give, the heading is "Sinusitis," and you cite to Exhibit 1021, Makower reference. Did you review the Makower reference, John?

A I briefly looked at it, or I'd looked at it

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in the -- you know, before coming up -- before I made this declaration.

Q The next bullet point, you list rhinitis, and you cite to another exhibit, Exhibit 1019, the Gertner reference. Did you review that Gertner reference?

A I did.

Q John, can you explain to me the difference between rhinitis and sinusitis?

A Sure. I'll give you my explanation. So rhinitis -- so first of all, it's understanding anatomy, because most people think -- don't know the difference between rhinitis and sinusitis. The sinuses are actually not part of the nasal cavity, but empty into the nasal cavity. So each of the sinuses, in most people, there are four paired sinuses, the maxillary, ethmoid, sphenoid and frontal sinuses.

Three of those sinuses have a single opening that drains into the nose. Those are the maxillary, the sphenoid and the frontal sinuses. The ethmoid sinuses are kind of a labyrinth or honeycomb

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of sinuses. Each of those little sinus cells has an opening. There are two major drainage pathways, one anteriorly and one posterior.

Sinusitis is inflammation of the sinuses. Could be one sinus, could be multiple sinuses, could be one side, could be both sides. Could be any combination. There tend to be patterns, but most of sinusitis we understand now is inflammatory. Used to be thought 20 years ago, 30 years ago that it was infectious.

Q Uh-huh.

A But we know now the vast majority of sinusitis is not infectious. There is still something called acute bacterial sinusitis that we see sometimes after viral upper respiratory infections, but most, especially chronic sinusitis is inflammation of the lining, which then causes obstruction of the -- of the sinuses. You can get a backup of fluid, you can get polyp formation.

That's sinusitis, and it's acute, subacute or chronic, and then there are different kinds. There's bacterial, there is -- we break it up in --

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there's fungal sinusitis and multiple -- multiple types of fungal sinusitis, but two big groups are chronic sinusitis with polyps and chronic sinusitis without, and then this acute, subacute.

Rhinitis, all rhinitis refers to is inflammation of the nasal cavity, period. It's a general term. There are multiple subtypes of rhinitis. You can have allergic rhinitis, which obviously allergic rhinitis is related to allergy, and in this particular case, it's inhalant allergy, so things that you're breathing in that you're allergic to.

There is non-allergic rhinitis, which is still inflammation of the lining of the nose, but in a -- a much smaller percentage, the patients can identify an allergy. There's probably some overlap between the two, and some non-allergic rhinitis patients may have something called local allergy. Local allergy is where you actually can't detect the allergy with serum testing or with skin testing, but if you were to test the actual nose with research protocols, you can identify allergens or identify

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reactions to allergens. It's called specific IGE.

And then there's vasomotor rhinitis. Vasomotor rhinitis is basically a hyperactivity of the nose, hyper-reactivity of the nose where we tend to see it more as people get older. It can be debilitating. Not -- not as debilitating as other things, but people get very runny noses either for no reason or when they eat, when they have certain stimuli, and then there's rhinitis of pregnancy. There are a lot of different -- you got rhinitis from chemical exposure.

So there's a lot of different types of rhinitis, but it's un -- sinusitis, because the sinuses drain into the nose, will cause inflammation of the nose. So that's where we call it rhinosinusitis. We don't refer to it as a sinusitis -- just sinusitis anymore, because now we call it rhinosinusitis because the nose is the drainage point for the sinuses. You can have rhinitis without having sinusitis, very common. You can't have sinusitis without having rhinitis.

Q Because the -- the condition associated

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with sinusitis is drainage into the nose, which leads to rhinitis?

A Right, so it's inflammation of the sinus lining, which is contiguous with the nasal lining. So inflammation in the sinuses is going to cause inflammation in the nose because they're contiguous areas. Rhinitis is different because you can have -- rhinitis doesn't have to block off the sinuses to prevent inflammation of the nasal tissue, but not inflammation of the sinuses.

Now, there may be higher instances of rhinosinusitis in parents with certain forms of rhinitis compared to people who don't have that rhinitis, but it's not a cause -- there's no cause and effect as -- so you can have just rhinitis without sinusitis, but you can't have sinusitis without rhinitis, therefore, it's rhinosinusitis.

Q What are some of the symptoms associated with allergic rhinitis?

A So allergic rhinitis can have nasal congestion to the extreme of nasal obstruction, nasal drainage, so rhinorrhea, anterior rhinorrhea,

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sneezing, itchy nose, itchy eyes, tearing, postnasal drip, cough, those are all symptoms of allergic rhinitis, and there are more. You can have other findings, but those are the primary symptoms.

Q What are some of the others?

A Well, I mean, you can have -- some people get bags under their eyes.

Q Uh-huh.

A And then there are other signs that you can have based on how you're -- how reaction -- there are physical signs that we see. They're not symptoms, but they're signs. Because people are pushing on their nose all the time, they get something called a super tip crease, you can get dark bags under the eyes, so signs that you can see with allergic rhinitis.

Q So if a patient comes into your office, and your nurse tells you they have allergic rhinitis, does that automatically tell you certain symptoms that patient will be experiencing?

A I --

MS. COHEN: Objection, form.

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A Yeah, I would ask the patient. I wouldn't -- you know, I would ask them specifically because there's all levels of allergic rhinitis. So some people have it very mild. Some people have it very severe. Some people, as I told you, I -- I -- the central compartment atopic disease, these patients can have nasal obstruction, and to the extreme, they can have obstructive sinusitis.

You know, a typical allergic rhinitis patient with mild allergic rhinitis is not going to have that severe symptoms, whereas someone with severe central compartment atopic disease, which is essentially a souped up allergic rhinitis, will have many more symptoms, so individualized treatment, patients with allergic rhinitis, just like you individualize the treatment for any disease.

Q But specifically regarding rhinitis, do you individualize the treatment based upon the conditions, the symptoms that the patient is experiencing?

A So you can individualize it based on the severity of the symptoms. Again, now -- so right now

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we're talking about how I do it.

Q Yeah.

A Okay, because I can't tell you how -- I can kind of tell you how someone does it but I can't be a hundred percent certain.

Q Uh-huh.

A So this is how I do it, and -- and this is, you know, is -- is accepted practice. So again, there's different severity. It depends on how bad someone's symptoms are, how bothersome they are to them, so how they affect their quality of life, and what their specific allergies are. So there's a difference between seasonal allergic rhinitis --

Q Uh-huh.

A And seasonal allergic rhinitis is when people are exposed, spring or fall or other times of the year, to something they're allergic to. So it's not necessarily all year round, and those tend to be pollens, weeds, things like that. And then there's perennial allergic rhinitis, and perennial allergic rhinitis is year-round rhinitis, and those people tend to have -- they can also have seasonal allergic

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rhinitis or environmental allergies to things that bloom, but they tend to have allergies to indoor things, dust mites, pet dander, cockroaches. Those are common things.

So -- and then even with that, with each group, how bad is the seasonal allergic rhinitis, how bad is the perennial allergic rhinitis. The majority of people are just going to get treated with medical therapy and are going to do well. Even -- even a non-medical therapy is avoidance. So if you're allergic to dogs and you're constantly going to the neighbor's dog --

Q Uh-huh.

A -- you know, the first thing is stay away from the dog. If that's your only allergy, that's going to treat the allergy. You're not going to have symptoms if you're not getting exposed to what you're allergic to. If you are allergic to things that you can't get away from, like you have a dust allergy, even though you can environment your -- you can alter your environment, you can take down the curtains and take up the carpet and, you know, do your laundry all

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the time or whatever, you may not be without symptoms. So at first you go to medical therapy, medical therapy, and the first line medical therapy is what we call intranasal corticosteroids, so those are things like Flonase and Nasacort and Nasonex, so they're nasal sprays --

Q Uh-huh.

A -- that are anti-inflammatory nasal sprays. They don't just treat allergic rhinitis. They treat rhinitis in general because they're nonspecific anti-inflammatory sprays.

Q And describe to me -- allergic rhinitis and the other category, would you describe that as infectious rhinitis or --

A No, it's called non-allergic rhinitis, and it's called that because people are not identifying allergies. Now, so -- so technically vasomotor rhinitis --

Q Uh-huh.

A -- would be -- fit into non-allergic rhinitis. Anything that's not allergic is non-allergic rhinitis, but most people, when they

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talk about non-allergic rhinitis will separate vasomotor rhinitis, separate rhinitis of pregnancy, separate those things because non-allergic rhinitis are essentially people that test negative for allergies, don't tell you that, you know, when I get into this environment I get symptoms. So you can't clinically determine they have allergies, and on testing, they do not test positive for allergies, so that's just a group, non-allergic rhinitis. They're also treated with anti-inflammatory sprays, you know, to treat their symptoms.

Q And what are symptoms that are typically associated with non-allergic rhinitis?

A They can be very similar to allergic rhinitis. There's not as much association with certain exposures obviously.

Q Uh-huh.

A But they still are nasal congestion, nasal drainage. They can have anterior and posterior nasal drainage, so postnasal drip, and therefore, cough, so you know, allergic rhinitis and non-allergic rhinitis. Vasomotor rhinitis, the same thing. You

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know, most of it tends to be anterior nasal drainage, but some of it can be posterior. Those are more anterior nasal drainage patients.

Q What do you mean, those are --

A Vasomotor rhinitis. I mean, their main complaint is their nose drips. Like when they eat, their nose drips.

Q And when do you more typically see posterior nasal drip?

A So you can see -- that's a common complaint. It's a common complaint. It can be anyone with a rhinitis, allergic rhinitis, non-allergic rhinitis, occasionally -- you know, some -- any type of rhinitis can cause that. Sinusitis can cause it. So postnasal drip is caused by -- let me -- let me step back just a second.

The way I explain it to patients is your nose makes a liter to a liter and a half of mucus a day. That's what a healthy nose makes. It gets swept back by the cilia or the hairs on the -- on the surface of the mucosa into our throat and we swallow it and we never know it's there. So for us to have

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pathologic postnasal drip, so we actually sense it, then there's got to be something abnormal, so it's either making more mucus or making -- the mucus is abnormal, it's inflamed, it's -- it's infected, or -- and those are -- that's just the main thing. It's more mucus or abnormal mucus.

Q But I can have both allergic rhinitis and allergic -- non-allergic rhinitis and not have postnasal drip?

A Postnasal drip's a symptom. So some people with allergic rhinitis have postnasal drip. Some people with allergic rhinitis do not have postnasal drip. It's just one symptom. Some people will -- there are some -- there's some people that think -- that call it postnasal drip syndrome.

Q Uh-huh.

A But it's not -- it's not a syndrome like we think about syndromes. It's -- postnasal is a symptom. They also -- there's some people that refer to upper airway cough syndrome, which they associate with postnasal drip because cough is the most common symptom of postnasal drip, but if you look at those

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diagnoses, or if you consider that that condition -- there's a lot of different diagnoses that -- that fit in those categories.

So it's not a syndrome. A syndrome is -- I don't -- but some people look at it that way, is what I'm saying, but postnasal drip can be found in many conditions, and it can be found -- it's not found in everyone with allergic rhinitis. It's found in some people with allergic rhinitis because it depends on severity, it depends on where they manifest their symptoms, and same thing with allergic -- non-allergic and vasomotor rhinitis.

Q What are your treatment protocols, John, for someone with anterior nasal drip but without posterior nasal drip?

MS. COHEN: Objection, form, relevance.

A That's -- that's a long answer because it's -- you're asking me what the treatment is for a symptom.

Q Yeah.

A Not for a diagnosis. My goal is to figure out what's causing that and to come up with a

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diagnosis because it can happen from allergic rhinitis, non-allergic rhinitis, vasomotor rhinitis, sinusitis, obstruction, anything that causes obstruction so the mucus can't get back. Mucus has got to go somewhere.

It's going to come forward, and what's the differential dose for -- differential diagnosis for obstruction? Well, nasal polyps, infection, anatomic obstruction, tumor. So you're -- I don't treat a symptom. I treat a condition that causes the symptom, so we need to make appropriate diagnosis.

Q And what are the most common conditions?

A Well, the most common conditions are going to be -- and we're talking about anterior rhinorrhea here?

Q Yes.

A We're still talking about anterior rhinorrhea, or anterior drainage? Most common conditions are going to be rhinosinusitis, and again, it depends on duration. If it's a short duration, it's going to be a viral cold. It's going to be upper respiratory infection. That causes drainage

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from your nose. We all get stuffy nose and runny noses from viral upper respiratory infections. That's number one.

Then there's going to be acute sinusitis, acute bacterial sinusitis, chronic rhinosinusitis, whether it be with polyps or without polyps, allergic rhinitis, non-allergic rhinitis, vasomotor rhinitis. Those are going to be the most common ones, but all the other ones that I mentioned are also going to fit into the differential diagnosis based on whatever the patient's symptoms are. So if it's unilateral, it's on one side, well, it's not very likely to be allergic or vasomotor or non-allergic. Then you have to worry about something blocking it or nasal polyps or unilateral obstruction, dental disease, lot of different things.

Q How about chronic cough? What -- what conditions is the symptom of chronic cough typically associated with?

MS. COHEN: Objection, form.

A Yeah, a myriad of conditions can cause chronic cough, so chronic sinusitis -- well, first of

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all, start again. Viral upper respiratory infection, right, viral lower respiratory infection, any --

Q And do you -- when you say viral upper respiratory infection, so you're talking about --

A A common cold.

Q A common cold.

A That's a common cold.

Q So that doesn't -- that's not rhinitis?

A Yeah, it is. It's a viral -- it's an acute viral rhinitis, right.

Q Okay.

A But --

Q So that would be considered a non-allergic rhinitis.

A Well, if you want to be really technical, yes, but no one considers that. When we're talking about these rhinitis -- this rhinitis category, we're talking about chronic symptoms, right, because someone who has symptoms of something for seven days, you know, like a viral upper respiratory infection, we're not going to treat it the same as we are for someone who has these symptoms for six months.

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Q Uh-huh.

A Right? We're not going to give someone a diagnosis of rhinitis when they have a runny nose for seven days and they have other symptoms of a common cold, acute upper viral respiratory infection.

Q But it's still considered rhinitis.

A Oh, absolutely. Any -- any inflammation of the nose is rhinitis, absolutely. That's why I said there's pregnancy of rhinitis -- or sorry, rhinitis of pregnancy. Women get runny noses when they're pregnant. Not all of them. Some of them get very congested and get a lot of nasal drainage, and that's called rhinitis of pregnancy.

People who overuse over-the-counter decongestant sprays like Afrin and Neo-Synephrine, they get what's called rebound rhinitis or rhinitis medicamentosa. Rhinitis just means inflammation of the nasal lining. That's why you have an itis after every part of the body. It just means inflammation.

Q For you, when a patient presents, you're looking for a condition as opposed to the symptoms?

A Absolutely. The only time we treat

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symptoms as opposed to treating a diagnosed condition is when we know that they're self-limited but they're bothering someone. So someone has an acute viral infection, they have a cold. You can either just let it run its course and not put them on anything and let them just, you know, wait it out, but if they're extremely congested or their mucus is really thick, you can put them on something to thin out the mucus or a nasal decongestant or a nasal steroid or something, okay?

If someone has an untreatable disease and they have symptoms, yeah, you might treat them -- treat the symptoms without treating the disease, but for the most part, you want to treat the actual underlying problem because if you get rid of the problem, you'll get rid of the symptoms. That's always the goal.

Q Uh-huh.

A Right? But there are conditions where you try maximal therapy. So let me give you an example with chronic sinusitis, okay? We make a diagnosis of chronic sinusitis. Do we tell someone they need

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surgery? No. That's not the first thing you say. If that's the first thing you say, then you're doing a disservice to the patient.

First thing you do is you try to treat them medically. You try to get it to resolve medically because a good percentage of them are going to resolve medically. So you treat them appropriately and then you reevaluate them and determine if they still have chronic sinusitis or if they're resolved. I'm not going to say cured, but resolved, and that'll determine if you need to do something more. So you start out with medical therapy.

Q So postnasal drip is not a type of rhinitis, but a symptom of rhinitis?

A Absolutely, it's a symptom. It's a symptom of rhinitis. It can be a symptom of other things. It's -- it's a symptom.

Q And similarly, chronic cough is a symptom --

A Right.

Q -- not a type of rhinitis?

A Right, absolutely, chronic cough is a

symptom.

MS. COHEN: If now's a good breaking time, we've been going for a little over an hour.

MR. WARD: We can go off the record.

(Recessed at 3:25 p.m.)

(Reconvened at 3:36 p.m.)

BY MR. WARD:

Q Okay, John, I want you to take a look at Exhibit 1013, which I believe is right in front of you there.

A Which one is that again?

Q That would be Baker --

A Baker.

Q -- '980.

A Okay.

Q As opposed to just Baker.

A I got that.

Q Yeah, so we're taking a look at Exhibit 1013, and it's the Baker '980 reference, and I want to specifically look at page 26. Yeah, so page 26, the first full paragraph there, "Baker '980 discloses the methods and devices may be used for treating

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common colds, nasal congestion and allergic rhinitis, as well as sinusitises and other nasal conditions," and would you understand this statement from Baker to be identifying what the methods and devices disclosed in Baker '980 can be used for, John?

A This is -- I would -- my interpretation is that the devices -- the methods and devices that are being discussed have applications in those diagnoses, among -- among other diagnoses, as he says, and other nasal conditions.

Q So you use the word "diagnoses," and as we were discussing earlier, you consider a diagnosis to be different than a symptom?

A Right, diagnoses and symptoms. They're all diagnoses except for it does say nasal congestion, which is a symptom, so I misspoke about that, but yeah, it says one symptom in there, which is a symptom of all those other things actually, but -- but can be a symptom by itself also, and the rest are all diagnoses.

Q So a common cold, allergic rhinitis, sinusitis would be a diagnosis.

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A They're diagnose -- and of course, like I said, sinusitis would be -- usually you'd give it a more specific categorization than just sinusitis.

Q So if a patient comes into your office and you diagnose them with allergic rhinitis, how do you then determine how best to treat them?

A Again, as I mentioned previously, it -- there's a matter -- it's a matter of multiple different factors. It's a matter of how long they've had it, have they been treated already, because some people have tried different things already, but how long, how bad, have they been treated, how compliant have they been with their medications, and other things, like avoidance and the other things that we discussed about allergic rhinitis, how does it affect their quality of life, and those are just some of the questions, and then there will also be a physical exam. So the physical exam would look in the nose, and what we would do at this point and have been doing for many years is what's called a nasal endoscopy, so it's using a telescope to -- that's attached to a camera to look in the nose --

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Q Uh-huh.

A -- and to examine whether the nose is -- there's any abnormalities, pathology, there's any anatomic obstruction, there's any -- as I mentioned, any polyps, which could be related to severe allergy with central compartment atopic disease, is there anything else abnormal. And then you take all that information, we determine what is the best next appropriate step. So it's going to be different in everyone. The most common next appropriate step, especially if someone hasn't been treated, is to put them on pharmacologic agents, which most commonly is going to be a intranasal corticosteroid, so something like Flonase or fluticasone or --

Q Uh-huh.

A -- one of the other nasal steroids, okay? Also depending on the severity, how much it's bothered them, may have a discussion about allergy testing, and again, that would depend on duration, severity, patient's desires. So that would be the initial -- the initial assessment.

Q And when do you determine it's appropriate

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to use a nasal energy delivery device like the Celon device?

A Uh-huh, so -- so the Celon can be used for multiple things, but again, I don't use a Celon or any other radiofrequency device on anyone that hasn't had appropriate medical therapy --

Q Uh-huh.

A -- and that I feel has been compliant with appropriate medical therapy for an adequate duration of time. So a minimal amount of time is going to be a six-week course of at a minimum nasal steroid, intranasal corticosteroid sprays. So I have them use it at least once daily, maximum twice daily, come back in six weeks and then we reassess.

Q And at that point, what is a typical situation in which you will use the Celon device?

A Yeah, so if someone comes back in six weeks and they say that they've been compliant with the medication --

Q Uh-huh.

A -- and they don't feel like their symptoms have significantly improved or they haven't improved

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to the degree that they're not still bothersome.

Q But I guess my question is what is it that you're looking for in the patient that you say this patient is a good candidate for treatment by the Celon device?

A Well, again, it depends on what I'm treating. So if we're treating nasal obstruction --

Q Uh-huh.

A Let's take that as a symptom.

Q Okay.

A Okay? And I've treated them with six weeks of nasal steroids, and they come back in six weeks and they say -- and I ask them -- in this case the symptom is nasal obstruction. Has your nasal obstruction improved -- basically I'd say are you breathing better, is your breathing improved to the point where you're satisfied with it.

And then if they say no, hasn't improved much, or it's improved a little but I'm still bothered, you know, maybe left side is worse than the right, then we have a discussion. If -- assuming that their exam shows that the problem is their

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inferior turbinate, which is the most common cause of nasal obstruction, then we'd have a discussion about oh, radiofrequency treatment of the inferior turbinates, but if they come back and they say no, I'm 90 percent better, or if they say I want to be ten -- I want to be a hundred percent better, I'll say now, well, let's just keep trying the spray --

Q Uh-huh.

A -- because that's a significant improvement.

Q Right.

A All right, so -- and there are realistic expectations of what you can and can't do. So if they're better, then they're better. So in between, then you kind of have to -- sometimes you'll go more medication, sometimes you'll -- so if they have a 50 percent improvement, then you may go well, let's try another four, six weeks, go to twice a day on the medication, because the understanding is we're not getting rid of the problem that caused their symptoms. So if -- if allergic rhinitis --

Q Uh-huh.

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A -- is the cause of the turbinates getting better --

Q Uh-huh.

A -- if we make the turbinates smaller, we may help the allergic rhinitis some. We are going to help it some, but they're still going to have allergic rhinitis that needs to be treated in many cases. So it's not necessarily a replacement for medication. It just improves symptoms and may make the medication more effective.

Q Is your determination as to whether or not to use the nasal energy delivery device based upon the symptoms that are exhibited or the diagnosis?

MS. COHEN: Object to the form, evidence.

A Well, so that's -- that's -- it's both. The answer is both, right? The issue with nasal conditions is that there is tremendous overlap in symptoms. There's only so many symptoms that you can have in the nose. It's blockage --

Q Uh-huh.

A -- drainage are really the big symptoms, bleeding, and then the symptoms of sneezing and itchy

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eyes, that's specific to allergic rhinitis, right? You don't have that with sinusitis, but the other symptoms, obstruction, anterior and posterior drainage, and cough therefore, very nonspecific. So you can have them with any of those conditions.

Q Uh-huh.

A So that's why it's treating both, because a lot of the symptoms are in both -- all the diagnoses, right? So you have to take that into account, but if the diagnosis is sinusitis, and they don't respond to medication, I'm not just going to treat their inferior turbinates or do something, you know, a radiofrequency treatment in the nose because it doesn't treat the turbinate -- or the sinuses.

If it's allergic rhinitis or another form of turbinate hypertrophy, yes, then I'm going to treat the turbinates or whatever part of the nose with radiofrequency because that's going to improve their symptoms and -- and I'm still going to -- so I'm treating both a symptom and a diagnosis, right? You have to take the diagnose into consideration.

Q But if an individual -- if the individual

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presents with chronic rhinitis --

A Uh-huh.

Q -- that information alone would not be sufficient for you to determine whether or not a energy delivery device would be appropriate, right?

MS. COHEN: Objection, form, relevance.

A Again, we have to go through all these steps about medical treatment and seeing how severe their symptoms and --

Q Uh-huh.

A So just the diagnosis, because remember, you can have chronic rhinitis as part of chronic sinusitis. Chronic rhinosinusitis.

Q Uh-huh.

A So I'm not going to use a radiofrequency delivery device to treat the nasal cavity alone if their sinuses aren't going to get any better because that's just going to keep the symptoms going.

Q Uh-huh.

A Right? So that's where the diagnosis is important, right, because you're undertreating the patient. You're only treating a small part of the

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problem if you don't then treat the sinuses. So they're both important. You have to relate the symptoms to the diagnosis. So if you just treat symptoms and don't treat the diagnosis, then they're continuing to having symptoms. They may not be as bad, but they're going to continue having symptoms because the inflammatory focus is still there.

Q Let's turn to Figure 5 of this reference, the Baker '980 reference.

A Okay.

Q Are you familiar with this figure?

A Yes, I am.

Q And what does it illustrate, John?

A This -- and actually -- I can look specifically at the --

Q Yeah, if you want, you can look back at page 16.

A Page 16?

Q Yeah, page 16. Page 16, line 19 states, "Figures 3 through 5 show schematic illustrations of devices of the present invention for delivering" -- "for delivery of generally high-frequency acoustic

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energy, e.g., ultrasound energy, including high-intensity ultrasound, HIU, and high-intensity focused ultrasound, HFIU, to tissue sites such as nasal passages."

A Correct.

Q So does that refresh your recollection as to what's --

A Yes.

Q -- illustrated in Figure 5?

A Yes, it does.

Q If you turn to page 17, you'll see it states -- and it's kind of -- what is that? Line 22?

A Yes.

Q "In another embodiment, as illustrated in Figure 5, an energy delivery member may comprise a flexible deformable bladder on inflatable chamber 28 adapted for retaining an acoustically transmissive material, such as a liquid or a gel, within its interior volume." So as shown in Figure 5 and described there, this device in Figure 5 has a inflatable chamber 28, and that is associated with what it describes as wand 24. Have you used a device

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like this, John?

A Actually, I have used a device like this.

Q And what was the name of the device that you used? Do you remember?

A But that was after this. It was after this. A similar type of device.

Q Uh-huh.

A ClariFix device is similar to this.

Q And how is it similar?

A Well, it has an inflatable balloon --

Q Uh-huh.

A -- has a handle, a -- basically the same configuration there, and then inflatable balloon on the end.

Q And so just describe to me how you -- how you go about using it.

A But that -- that -- that is a more recent -- well, I can't tell you when that was, exactly when that was patented, but -- but your question was have I used a device like this.

Q Yes.

A So I have used. It delivered a different

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type of energy. It was -- it's cryo, right, so it's freezing, and I'm sorry, could you restate your question again?

Q Just if you can, describe to me your understanding of what's shown in Figure 5 as to how that works. How you do --

A Oh.

Q -- insert it into the --

A Oh, okay.

Q -- nasal cavity? How does it work?

A So this device would be inserted into the nasal cavity with the inflatable member deflated.

Q Uh-huh.

A And then -- and it would be passed under visualization of some sort, whether it be headlight or endoscopic is most common, and it would be inflated, and the energy -- the inflation can include various types of, as stated, liquid, and -- to inflate the -- the inflatable member, and then the energy is passed from the tip of element 24 to the tissue through the inflatable member.

Q And is it your understanding that the

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inflation provides a better contact with the surfaces to be treated?

MS. COHEN: Objection, form.

A Well, the inflation can perform several functions.

Q Uh-huh.

A As you stated, that -- one function, similar to what you stated, would be to obtain mucosal contact and to help to position the device, since the nose is a narrow space to begin with, narrower in some people than others. So that's one thing. The second thing, as is stated by Baker, is that it can use -- it can use various different materials or liquids within it that may have a function themselves.

He also discusses irrigations, so it may help -- it may contribute to the irrigating factor if they -- with the inflatable member having -- having perforations, it can irrigate and topically treat areas. So it is a multifunctional device, he talks about irrigation, and in his case, ultrasound energy.

Q Uh-huh.

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A But he also has embodiments that talk about radiofrequency energy.

Q So this one, if you look back at page 17, the next paragraph, it says, "The bladder or inflatable member is constructed from a material that has generally high acoustic transmisstivity properties, and when filled with an acoustically transmissive material, provides a flexible surface that's expandable and deformable to conform to contours of internal cavities or passageways, such as intranasal passages." So John, what's your understanding of an acoustically transmissive material?

A Well, it would be a material that allows sound energy, ultrasound to traverse through that material and then out through the inflatable member.

Q So the acoustic energy that is distributed from the wand 24 in Figure 5 would then continue to be transmitted through this acoustically transmittable gel? Is that your understanding?

A Correct.

Q Would it be your understanding that that

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gel in chamber 28 would diminish a radiofrequency signal?

A Well, there --

MS. COHEN: Objection to form.

A I'm sorry. So again, this -- this reference is referring to an ultrasound --

Q Uh-huh.

A -- transmission.

Q Right.

A Sound energy.

Q Yeah.

A There are other materials that are conductive for radiofrequency. So if this is -- as I mentioned already, there are embodiments where he discusses -- where Baker discusses using radiofrequency energy in place of one of the other functions, so either in place of the irrigation or in place of the sound energy, the ultrasound, in which case a different -- there's -- you know, different energy works well with different medians.

Q Right.

A So radiofrequency works very well with

saline. Saline is a conductive ionic medium.

Q Uh-huh.

A So using saline would actually benefit the transmission of the radiofrequency energy. It's something that we use all the time when I'm -- for instance, the Celon or Somnoplasty.

Q Uh-huh.

A The tissue's inflated with saline to improve the conductivity of the tissue. So again, what this is stating is related to ultrasound, but different embodiments with radiofrequency would naturally or understandably use a different conductive medium.

Q So for the radiofrequency embodiment, chamber 28 would be filled with a different medium than the acoustically transmissive medium.

A Well, if we're using -- if the energy source is radiofrequency --

Q Uh-huh.

A -- then it would be understood by anyone -- you know, a person of ordinary skill that you would choose the most appropriate medium --

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Q Uh-huh.

A -- for that particular energy source. So -- and the most appropriate medium for radiofrequency is saline, so that inflatable chamber would be filled with saline.

Q But is it the case that the acoustically transmissive material is also appropriate for radiofrequency transmission?

A Well, I can't tell you that because I -- this -- this -- this is a very vague. They're making -- I think the fact that Baker is being so vague is leaving over -- open the possibility of choosing any acoustically transmissive material to be used with ultrasound, the likelihood that there are multiple options, and leaving that up to a person of ordinary skill to decide which one to use, just as if using radiofrequency, as opposed to saying an acoustically transmitted -- transmissive material, it would be material that transmits radiofrequency well. So again, the fact that a specific material is not mentioned, the way I understand it is that a person of ordinary skill would understand that to choose the

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appropriate one.

Q So you -- you fill the chamber with a material that works well with the energy you're delivering, correct?

A In this application, yes.

Q And would you understand that an acoustically transmissive gel would work well with radiofrequency signals?

A I don't -- I cannot tell -- I cannot answer that question. I do not know because this is not naming -- this is not giving me a specific material.

Q Uh-huh.

A So there may be some materials that are acoustically -- acoustically transmissive --

Q Yeah.

A -- that also transmit radiofrequency well. Saline may, and I'm not -- you know, and -- you know, so if saline itself is acoustically transmissive, then yes, then that same material would also transmit radiofrequency well.

Q You're not aware whether or not saline is acoustically transmissive, correct?

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A I can't tell you that -- how -- how acoustically transmissive it is. It may not be as acoustically transmissive as other substances.

Q What about a laser light energy delivery device, John, would you understand that there would be devices that use a chamber like what's shown in Figure 5 for laser light?

MS. COHEN: Objection to form.

A Yeah, I -- this -- I'm not sure laser light is not discussed in this -- you know, in -- in Baker. He discusses acoustic energy and he discusses radiofrequency energy.

Q What about microwave energy?

A What about? What is your question?

Q Question is the same. Are you aware of a device in which microwave energy is delivered through a chamber similar to chamber 28 in Figure 5?

A Well, microwave energy is very similar to radiofrequency energy. They're in the same category of energy.

Q Uh-huh.

A So -- you know, am I aware of a specific

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device, no, but again, the device -- or the -- the medium can be -- can be altered or changed, as left open in this patent, in this prior art to the particular energy source.

Q And John, you mentioned that the -- this patent, the Baker '980 patent, discloses an embodiment in which radiofrequency's delivered through an inflatable chamber. Can you identify that embodiment for me?

A Let me -- I'm going to have to review --

Q Sure.

A -- to see.

Q Take your time.

A Yes, so if we look at page 9 --

Q Uh-huh.

A Hold on. Let me read this first, but I'm referring to page 9. Okay, so look to page 9, line -- it's actually the first full paragraph.

Q Uh-huh.

A It's the entire paragraph, but the -- the most pertinent sentence is the last paragraph. It says -- we'll look at the two -- last two paragraphs,

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or last two sentences, I'm sorry. "An endoscopic port may be provided for delivery of diagnostic and/or therapeutic tools, agents and the like. Systems for delivering additional diagnostic and/or treatment modalities, such as electromagnetic radiation, radiofrequency radiation, laser radiation, microwave radiation and the like may also be provided in connection with methods and symptoms of the present invention."

Q So can you point to a particular embodiment that's disclosed in this patent, John, where it talks about energy delivery -- radiofrequency energy delivery through a chamber like chamber 28?

MS. COHEN: Objection, form.

A So I'm sorry, when you talk about an embodiment, are you talking about a -- a figure?

Q A figure or description of a particular device.

A Well, as I already read, he describes that radiofrequency radiation et cetera and the like may also be provided in connection with methods and symptoms of the present. Now, the issue with Baker,

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obviously he mentions it, there can be an embodiment of radiofrequency, but we also have information from Edwards, and Edwards uses an inflatable member and delivers radiofrequency, and it can be through -- it's through an inflatable member, which can have a -- either a regular conductive fluid or cooling fluid into an inferior turbinate. So we know from Edwards that radiofrequency can be transmitted through an inflatable member.

Q The sentence that you're identifying from Baker '980 says, "Systems for delivering additional diagnostic and/or treatment modalities, such as electromagnetic radiation, radiofrequency radiation, laser radiation, microwave radiation and the like may also be provided in connection with methods and systems of the present invention." Wouldn't you understand that statement to say that these additional systems could be provided along with the system disclosed in Baker, which is an acoustic system?

MS. COHEN: Objection, form.

A No, my interpretation of this is they can

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be incorporated into the system that's already been described as additional embodiments, either within or in place of. In this case I think he's saying in -- included or in addition to, but the same system.

Q Are you familiar with a device that -- that has the capability to deliver two types of energy, say, acoustic energy and RF energy?

A Well, I'm familiar with multiple devices that can deliver multiple types of treatment, monopolar, bipolar. We use them in the operating room all the time. You have devices that both rotate in a certain direction or oscillate, and also drill.

Q Uh-huh.

A So there's multiple devices that have multiple applications that the applications in and of themselves are indifferent.

Q Are you aware of a nasal energy delivery device that delivers two different types of energy?

MS. COHEN: Objection, relevance.

A I'm just trying to think if I specifically know one, and -- and whether or not I know one doesn't -- doesn't mean it doesn't exist, which it

very well may. I have a -- you know, my practice is my practice, and my preferences are what they are, but like I said, there are multiple devices that have multiple applications, so it doesn't just have to be one form of energy delivery in a single device.

Q John, are you aware of a single device for nasal energy delivery that delivers more than one type of energy?

MS. COHEN: Objection, relevance.

A Again, just because I am not aware of one, and I am not aware of one that I've used, but again, that doesn't mean that it's not -- wouldn't be beneficial to have those devices. You know, there are devices -- even if we look at Baker here, if we were to have ultrasound and radiofrequency in the same device, then that would be beneficial to a patient because they treat by different methods and can treat different conditions.

Q Would you agree, John, that the Baker '980 patent discloses and illustrates only acoustic energy delivery devices?

MS. COHEN: Objection, form.

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A Again, the text of Baker.
Q Uh-huh.
A Even though the majority of the invention is referring to acoustic energy, also has embodiments that include radiofrequency energy.
Q Are any of those embodiments illustrated in the figures?
A No, but that's not a requirement for it being present in the prior art.
Q What is a requirement for it being present --
A It's --
Q -- in the prior art?
A It's stated in --
MS. COHEN: Objection to form.
A I'm sorry, it's stated in the prior art. It -- specifically we just read the paragraph where it is explicitly -- explicitly stated that other energy sources, and I'll reiterate, systems for delivering additional diagnostic and/or treatment modalities, and again, it says diagnostic or treatment -- and treatment because his device is not

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just an ultrasound delivery device that's -- that's originally described, but it also irrigates, so it can deliver topical medications or other things. So systems for delivering additional diagnostic and/or treatment modalities, such as electromagnetic radiation, radiofrequency radiation, laser radiation et cetera may also be provided in connection with the methods that he's already described. So in connection, so --

Q So he's --

A -- can be added.

Q -- describing two different systems, correct, John?

A No.

MS. COHEN: Objection to form.

A No, that's not -- my interpretation of this is not two different systems, but it can be in -- additionally or in place of.

Q And is there any other disclosure in Baker as to that embodiment that you're referencing?

MS. COHEN: Objection, form.

A There -- if you allow me to -- if you want

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me to go through the whole thing, I can. I can't recall the time. There may be one more, but I'd have to scour the document in order to be certain.

Q I want to hand you now Exhibit 1001 from IPR2024-276.

A Which one is this? Oh, '194?

Q Okay, John, do you recognize this document?

A I do.

Q What is it?

A It is patent number U.S. 9,415,194, what we're referring to as patent '194.

Q If you can, I'd like you to turn to the second to last page where the claims begin.

A Okay.

Q Claim number 1 states, "A method for reducing mucus secretion in an upper airway of a patient to treat at least one of postnasal drip or chronic cough, the method comprising," and then the third clause, the gerund verb "delivering" starts the clause, "Delivering a treatment from the treatment delivery portion to at least one tissue selected from the group of the mucosal tissue and other -- and

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another tissue underlying the mucosal tissue to modify a property of the at least one tissue, and thus treat at least one of postnasal drip or chronic cough in the patient." What is your understanding, John, of the statement to modify a property of the at least one tissue? What does that mean?

A So to modify a property of tissue could be modifying any property, which could be the appearance, the shape, the size, the characteristics of the in this case mucosa, mucus secretion, nerve reactivity. There also could be anatomic or physiologic properties.

Q And describe to me the distinction between anatomic and physiologic.

A Yeah, anatomy is the structures --

Q Uh-huh.

A -- and the appearance, whereas the physiology is the actual function. So -- so turbinate -- you know, the appearance of the turbinate is the anatomy. The position is the anatomy. The fact that the turbinate gets larger and smaller, that's part of what's called the nasal

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cycle, is physiology.

Q Uh-huh.

A Mucus production is physiology. So reactivity to allergens is physiology. So physiology is actual function, whereas just the -- the appearance and the position of a structure is its anatomy. The shape of the lining is its anatomy. If you change the shape of the lining or if you destroy some of the lining, you're affecting the anatomy. You also affect the physiology because you will destroy the structures that are included in that anatomic portion. So difference between anatomy and physiology.

Q Do different treatment energies result in different modifications to the properties of the tissue?

A Well, they can, as is taught in -- in Edwards and in Baker. So in Edwards teaches to use a cooling agent in the balloon, and surface electrodes can deliver the energy deeper into the tissue to create a submucosal area of tissue treatment, which could -- I'm sorry, which could reduce the size of

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the turbinate.

Also treating underneath would be expected to affect that tissue or those tissue types that are in that area, which would include mucus glands and nerves. Baker teaches that using in his case ultrasound energy, but he has an RF embodiment, treating allergic rhinitis, right? That would be treating physiology, and that would reduce mucus production by treating allergic rhinitis, reducing mucus production, reduce postnasal drip, and since postnasal drip's the most common cause of cough, would also reduce cough.

Q So if you're trying to modify a property of a tissue to treat postnasal drip, what -- what properties are you looking to modify?

A Well, you can -- there are multiple properties. There -- so you'd be trying to affect physiology, okay, so because postnasal drip is going to be from mucus production.

Q Uh-huh.

A And mucus production then results -- excess mucus production or thickened mucus can result in

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postnasal drip symptoms. So you can either reduce mucus production or -- by physically affecting the glands that produce the mucus, or you could treat the nerves that innervate the glands. So if you have reduced signals from the nerves for the glands to secrete mucus, that can reduce mucus secretion, which in effect affects postnasal drip and cough.

Q So in your opinion, is there a better type of energy to treat postnasal drip?

MS. COHEN: Objection, relevance.

A Once again, we're not -- we're treating -- postnasal drip is a symptom.

Q Uh-huh.

A In this case it's treating the tissue, treating the mucus-producing tissues, glands, nerves -- nerves innervating glands is what needs to be treated, and they're found all over the nose. The most common form of energy that's been used for the past 30 plus years, probably longer, definitely been longer than I practiced, so it's probably 40 years or longer, is radiofrequency energy.

Q Uh-huh.

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A And radiofrequency energy had the most applications in the nasal cavity. So we can use other forms of energy, but when we're trying to treat something, we're trying to strike a balance between efficacy and side effects, and considering patient comfort. So that's why there are many devices out there that can do high-temperature treating -- high-temperature treatment --

Q Uh-huh.

A -- which will actually destroy even more tissue, you get less mucus production, but then you're increasing the risk profile. Radiofrequency is low-temperature treating, which can still ablate tissue, it can still affect the functionality of tissue, but it doesn't have as much side effects because it's lower temperature heating so there's less collateral damage.

Q How would you define tissue ablation?

MS. COHEN: Objection, form.

A Ablation just means -- ablation can -- it can mean destruction, it can mean -- it's essentially remodeling -- affecting the tissue that results in a

remodeling.

Q And how does it remodel?

A Well, as we had this discussion earlier about the Aerin product and using it for internal nasal valve, so if you heat up a tissue, you're going to affect the -- the structure of the tissue.

Q Uh-huh.

A Whether it denatures proteins, whether it -- whether it has other effects on the cellular structure of the area that you're treating, it's going to create some effect. In some cases it actually causes a necrosis if you're -- and that especially happens with high-temperature heating, like monopolar cautery, in which case the tissue actually dies and then it gets reabsorbed, and if you reabsorb tissue, you're going to reduce the amount of tissue that you have.

Q Uh-huh.

A So it's a matter of what particular energy source is being used, but essentially it's creating some sort of injury and having the reparative functions of the body remodel that area that was

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injured.

Q And is that specific -- it sounds like you're talking about ablation generally.

A That's --

Q Correct?

A That is -- that is energy in general, and again, the -- the higher -- the more destructive the energy, the more damage you're going to get, so that's why I mentioned with monopolar --

Q Uh-huh.

A -- devices, which we use a lot in surgery because we can control bleeding better with monopolar.

Q Uh-huh.

A Especially with bigger vessels, but it does get -- it's a higher temperature, so it can cause more tissue injury. That's why we don't use that around certain structure like the eye socket and the brain --

Q Uh-huh.

A -- at least in the areas that I operate. Bipolar doesn't -- it doesn't heat as high, usually

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in -- you know, boiling is a hundred degrees Celsius. We're usually well below that with radiofrequency energy, so -- but it's still good enough to cause -- cause an injury, and an injury then has to be healed, right? And injured tissue does not heal identical to the tissue before it was injured.

Q Uh-huh.

A So there is an effect that's a reparative effect that is what all of these devices are intended to do.

Q So would you say that is -- that -- is ablation destroying tissue or modifying tissue?

A It's modifying tissue.

MS. COHEN: Objection to the form.

A I'm sorry. It's modifying tissue.

Q Are there any tissue cells that are destroyed as part of an ablation process?

MS. COHEN: Objection, form.

A So can you define destroyed? I'm not sure what you mean by destroyed. It's not a term that we use in medicine.

Q Are there any cells that are present in the

body that are no longer present in the body after an ablation procedure in the nose?

A Again, as I've already mentioned, the higher the energy --

Q Uh-huh.

A -- the more likely that there is to be some necrosis of tissue, so basically tissue death.

Q Uh-huh.

A So we try to avoid that, but even devices that are meant to preserve tissue will sometimes create tissue damage that is not intended. The higher the temperature, the more of that you'll get. The lower the temperature, again, radiofrequency is lower temperature, the less of that you'll get, but it can't be -- it's not completely avoided in any device. The only way to avoid the possibility of doing that is just to not do it at all.

Q Right. What happens to the tissue that undergoes necrosis?

A It's reabsorbed by the body. Now, sometimes -- and again, depends on where it is. So if you had necrosis on the surface --

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Q Uh-huh.

A So say, an example, some mucosal surface inside the nose underwent necrosis, it's going to form a scab if there's no bone exposed, because bone heals differently. Bone has a different blood supply. If there's no bone exposed, then it may just crust, gets kind of like a scab, and then that scab may heal and fall off, and that area underneath won't look the same as the surrounding tissue. It'll look more -- there'll be a change in that tissue. Now, whether it's scar tissue, whether it's an area where the lining has to regrow, which sometimes happens in the nose, but it's going to look different. It's going to be a reparative area, so it's going to be an area that has been modified.

If there is severe damage, so if, say, we use a monopolar, and there's exposed bone, that area may require additional steps to get it to completely heal because bone doesn't have a good blood supply. So if you expose bone and it gets infected or it just never -- the lining doesn't grow, it could cause chronic symptoms like crusting and, you know, mucus

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sticking to that area, and that may have to be cleaned up, but that's why lower temperature radiofrequency is used in these outpatient settings especially, because it's safer, it delivers energy, but it does not cause as much tissue injury compared to what's been around a lot longer, which is monopolar, but that's what we use a lot in the -- both in the operating room, and the more we're getting towards critical structures, the less we're using monopolar, the more we're using bipolar radiofrequency.

Q Uh-huh. What other types of -- you have experience with radiofrequency energy delivery devices used for the nose. What other energy delivery devices do you personally have experience with, John?

A Yeah, I've used laser energy, I've used that. I've used it a little bit in the nose, but I've used it a lot in the larynx, in the throat, in the mouth for various lesions. I personally haven't used ultrasound energy. I've used it -- there's one application for ultrasound energy that we have used

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in the nose, and that's a -- it's -- it's an application that disrupts the tissue.

Q Uh-huh.

A And actually, it's for nasal congestion, so -- so there's laser, radiofrequency, monopolar, acoustic, you know, or applications for light energy. I haven't personally used them. There are, and they have been used for premalignant lesions. They're used even more commonly in the oral cavity in dental offices and my colleagues who do head and neck surgery, so they use light-emitting energy sources both for diagnosis and for treatment.

Q Uh-huh.

A They're used a lot in dermatology also and in cosmetics. So I've used several different sources other than radiofrequency, but -- and they're -- you know, like I said, as I said, there are a lot of applications. Radiofrequency's the most applicable, and especially in the outpatient setting, which is where most of these devices are being utilized.

Q Uh-huh. Let's take a look at claim 12 on that same page there, John.

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A Twelve, okay.

Q Claim 12 reads, "The method of claim 1 wherein delivering the treatment comprises injuring the at least one tissue." What's your understanding of injuring the at least one tissue?

A As the discussion we've been having is that any time you do a treatment with energy in the nose or anywhere else, you want -- you're trying to change something. You're trying to get the tissue to remodel.

Q Uh-huh.

A And so as I said, these treatments create an injury, which then gets repaired. It's a reparative process by the body, which then leads to an alteration in at least one characteristic of the tissue, whether it be the anatomic or physiologic or both.

Q Is there any tissue modification that wouldn't be considered an injury?

MS. COHEN: Objection, form.

A The only -- so I'm sorry, can you rephrase your question so I answer it appropriately?

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Q Uh-huh. Is there any tissue modification that wouldn't be considered an energy -- I'm sorry, an injury?

MS. COHEN: Same objection.

A Well, any tissue modification, unless you're talking about just putting pressure on the tissue and then releasing it, which will temporally deform, but then it will no longer be deformed, but that's not a treatment. If you are -- because there are some treatments that do that, use mechanical energy in the nose, balloons, and there's balloons that open up the sinuses and there's balloons that -- that are used to open up -- there's one that's used to open up the nasal cavity, essentially a balloon septoplasty or balloon deviated septum surgery.

So even though they're doing minimal amount, they're still creating an injury because in the case of a balloon sinuplasty, which is a balloon that goes up, as I mentioned, the openings of the sinusitis, three of the sinuses have a single opening into the nose, balloon can be -- a deflated balloon over a catheter with a guide wire can be placed up

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into one of those openings, a balloon inflated that will create microfractures. Doesn't look like a big change, but it dilates that bony outflow tract. It's not much, but it's -- causes microfractures, but then they have to heal, and ideally heal with the sinus more open, okay?

If you're delivering maybe topical therapy to a nose, nothing more, topical antibiotics, topical steroids, you're not injuring the tissue, but that's not delivering energy.

Q Would you consider that modifying the properties of the tissue?

A Well, that could be modifying the properties because if you're treating something --

Q Uh-huh.

A -- any disease process, which includes any form of rhinitis, affects the tissue. So it may be inflamed --

Q Uh-huh.

A -- which symptoms of inflammation include edema or swelling and other inflammatory changes, so changes in the mucus. So if you -- we use a lot of

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topical steroids. Again, it's not an energy source, but if you deliver topical steroids, then yeah, you can have -- over time, you're going to alter -- you're definitely going to alter the characteristics of the tissue. Otherwise you're not -- your treatment's ineffective. It's going to reduce the swelling. It's going to make the mucus production more healthy, healthier, rather.

Q Are all types of tissue ablation -- do they all result in an injury?

A By definition, it does.

Q Let's take a look at claim 16. It reads, "The method of claim 1 wherein delivering the treatment comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue." Does ablating tissue decrease the volumetric rate of mucus production?

A It absolutely can, as I mentioned before. So mucus-producing glands are found throughout the nasal cavity, and nerves that innervate the mucus-producing glands are found throughout the nasal

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cavity. Essentially every -- every gland has to have a nerve ending going to it. The glands are right below the mucosa, and they have a duct or a drainage canal --

Q Uh-huh.

A -- that deposits -- deposits the mucus directly on the lining. All these treatments either are treatments on the lining or below the lining, and those are the areas that encompass both the mucus-producing glands, the ducts that drain the mucus-producing glands, and the nerves that innervate the mucus-producing glands.

So injuring any of those tissues is going to injure what is in those tissues, which are the nerves, the glands and the ducts. If you injure them, you're reducing the volume of any or all of those, and that by definition will reduce mucus production. So if you destroy ten percent, five percent of glands, you should have five percent less mucus production.

Now, over time, the body heals itself well, so over time, the brain could tell the body

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theoretically to make more mucus, you know, but the more mucus-producing glands you -- you destroy, more nerves you destroy, then the less mucus, so the volume of the mucus is decreased.

Q Is there a way to measure the volumetric rate of mucus production? Is that something that you -- is that a metric that you can give to a patient?

A No, that's not something that we can clinically do. You know, we go based on symptoms. There may be research tools, but they're not tools that are clinically relevant. The only research tool I know is really not about measuring mucus production, but it's about measuring mucus clearance. It's called mucociliary clearance test, but that's more about the function of the mucosa and the sweeping the mucus, but as far as measuring the mucus production, no, I'm not aware of any clinical or research tools to do that, but there may be, but -- but they're not clinically relevant.

Q Okay. John, let's turn back to your declaration from the '271 patent case.

A Okay.

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Q Turn to page -- page 4, it's paragraph 10, it's the bottom of page 4.

A Yes.

Q You make -- yeah, you make this statement. You say, "As part of my practice, I have frequently used radiofrequency RF energy for the treatment of nasal conditions, such as inferior turbinate hypertrophy, rhinitis, and to treat the tongue and palate for sleep apnea and snoring."

A Correct.

Q Can you give me an idea of what you mean by frequently, so how often, how many times a week or a month are you using --

A Sure. So that's something that is not consistent.

Q Uh-huh.

A So you know, you treat patients as necessary. So I will tell you I -- I just did one last week. I used radiofrequency last week, and I'm using it twice this -- I'm not here this week.

Q Yeah.

A But Friday I just did one in the office,

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and this coming Friday, next week --

Q Yeah.

A -- I'll be doing two in the office, okay? I'm not in the office every day.

Q Yeah.

A I'm in the office maximum one and a half days a week.

Q Uh-huh.

A So that'll be both weekends. Now -- or both weeks. If you look back here, remember, I mentioned earlier that I've gone through multiple stages of my career. I used to treat sleep apnea --

Q Uh-huh.

A -- when we didn't have a -- a dedicated sleep position, so I did a lot -- when I was also doing sleep apnea, then I did a lot of radiofrequency because I was using it -- this is the days before some of the technology that we have now to treat sleep apnea, which is what are called hypoglossal nerve stimulators, and at the time, what we had in our arsenal were procedures to reposition or reduce the size of structures, and one of the big things,

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because the tongue and, you know, the nose, the palate and the tongue are all parts of sleep apnea, all those things were treated with radiofrequency because that's something that we can do in the office.

Snoring, you know, I probably did it -- at least a snoring procedure a month or every two months.

Q Uh-huh.

A Tongue, I probably did a dozen or two dozen. The nose, all the time. I mean, almost on a weekly basis for a while. I do it a little less frequently now, but that's only because my practice patterns have changed. I've become more senior, I have more junior partners, I do a lot more advanced surgery. I still do it in the office, as I told you, but I'm not as frequently as I used to, but I have done hundreds of these radiofrequency treatments in the nose.

Q Uh-huh.

A Minimum, hundreds.

Q And have the majority of those been with

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the Somnoplasty or the Celon device?

A Majority, and some with the Aerin device.

Q And so your -- you say --

A And I'm sorry, and -- sorry to interrupt, and the coblator.

Q So maybe if you could kind of identify which procedures you're using the Somnoplasty or Celon device and which procedures are you using the coblator?

A Oh, as I've already mentioned, we've discussed this, I went through a period of time where I was using the coblator or the Celon, but I'm much happier with the results of the Celon --

Q Uh-huh.

A -- than the coblator, and the reason for that is because you can program more and it's more controllable.

Q Uh-huh.

A Or at least the -- and that might have changed because I haven't used the coblator for that -- for intranasal purposes for some time, so they may have come out with the next -- next best version or

two next best versions, but as far as I was concerned, to create less collateral tissue damage, less what's called -- less mucosal injury, and I was happier with the results, so I transitioned to exclusively losing -- using the Celon.

Q John, if you go down to paragraph 93 in the same declaration, the very last sentence of the paragraph on page 62 there, you say -- well, let me read the previous sentence to give you the context. You say, "A person of ordinary skill in the art would have found the use of bipolar electrodes in the arrangement taught by Stern to be reasonably likely to successfully ablate the nasal tissues targeted using the combined method. This is consistent with my experience treating patients using RF treatment elements with bipolar electrodes, which by 2011 were widely available to clinicians and came in a variety of different configurations." When you're -- you say bipolar electrodes, which device are you referencing --

A Well --

Q -- as part of that?

A We have bipolar electrodes in the -- in the operating room, but we also -- there's something called a dentist bipolar, which is specifically designed for the nasal cavity, and it's actually just by chance -- and it's been out for 30, 40 years. It was out when I was a resident at Michigan, and it just happens that the person who invented, his name is Don Dennis, and Don Dennis is in practice in Atlanta at Piedmont Hospital.

That's all I'm going to say about Don Dennis, but that is specifically a bipolar forcep that's used to treat the nasal cavity, and most common application is to treat the inferior turbinate, and it's -- it is treated -- it treats it in a submucosal fashion, and that has been available for years, and as I said, there's been multiple radiofrequency -- radiofrequency devices that have been available, the ones that we've already discussed. So that's -- they've been out for a very long time.

Q So that device, the Dennis device --

A Dennis bipolar, yeah.

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Q Completely separate from the Celon device.
A Completely separate. Completely separate, but it's been around for a very long time. I can't tell you exactly what year. All I know is it was available when I was a resident in Michigan because we had it there, and that was from 1990 to 1995, and honestly, when these other devices became available, I stopped using that.
Q Uh-huh.
A It's -- again, I didn't think it was as predictable as some of the devices that became available because of the ability to titrate the dosage of the energy that you were delivering, or I was delivering, rather.
Q John, what is a bipolar electrode pair?
A A bipolar electrode pair is two electrodes where energy moves across from one to another, a positive and negative typically, but pair of electrodes that act in unison. I don't know if it's in unison. Basically energy goes between the electrodes.
Q And how is that different than a unipolar

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electrode pair?

MS. COHEN: Objection, form.

A I'm sorry, I -- I don't understand what --

Q Are you familiar with a unipolar device?

A Yeah, a unipolar cautery, yes.

Q And how is that different than a bipolar device?

A Well, I'm not sure about the specifics, but the -- it doesn't require the electrode pair. The energy doesn't go between the two electrodes, so that's why -- and the fact that a unipolar -- a unipolar device is at a much higher temperature than a bipolar device. As I mentioned, we use both in the operating room. I don't use a unipolar device in the clinic because it -- you know, it -- it has very little application in the clinic, but it has significant applications in the operating room, but --

Q And why is that, John?

A Because it's -- the higher temperature helps to destroy tissue better, and when we're dealing with larger blood vessels, especially if

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they're not near the eye or the brain, then the unipolar is much more effective in controlling that bleeding than the bipolar, although we use both because I work around the eye and the brain a lot, and the nose is close to both structures, but --

Q So unipolar is essentially a more effective tool, or --

A No.

Q -- or has a bigger impact, I should say.

MS. COHEN: Objection, form.

A No, I wouldn't -- I wouldn't categorize it either way. It's a different tool. It's a different tool that has different applications.

Q And that's primarily based upon you say the heat that's associated with the unipolar device?

A Well, there are multiple factors. The heat is one.

Q Uh-huh.

A The conductivity is another because the unipolar cautery, if we were to use it near the eye, the current can go through the eye and create damage, whereas if we use a bipolar cautery, the heat or the

device is only going between the electrodes, or between the -- if we're using a -- what's called bayonet forceps, only going between the tips of the bayonet, so anything outside of that is not getting affected.

Q Uh-huh.

A So it's more controllable, and it creates less collateral damage.

Q With the bipolar, you're able to more precisely direct the energy that's applied, correct?

A No, you could precisely direct it with a unipolar also, but you can't control if it goes through tissue that -- that's close by.

Q Uh-huh.

A Right, the higher temperature creates a bigger area of treatment, which sometimes is what you want.

Q Uh-huh.

A I mean, we use -- so there are different types of unipolar cautery. We have -- and we can use them on different modes. So we can cut skin with unipolar cautery. We don't have bipolar -- many

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bipolar knives. We have similar things, but we can cut with a unipolar cautery. So it has different functions. I wouldn't say one's better than the other. I wouldn't say one's more dangerous than the other. They have different applications.

Q Uh-huh.

A They're better in different cases.

Q All right, John, let's turn to page 108 of your declaration. Right above paragraph 166, there's a heading that states, "Stern teaches wherein the treatment element comprises two rows of bipolar electrode pairs, and it would have been obvious to combine Edwards '535 and Stern," and in paragraph 166, you state, "As I explained above, in my analysis of limitation 1A in ground 1, based on my discussion with Dr. Martin and my review of his declaration, I understand that Stern discloses two rows of bipolar RF electrodes, and that the combination of Edwards '535 and Stern would have been obvious." John, did you rely upon your conversation with Dr. Martin for your understanding of Stern's disclosure regarding the bipolar electrode pairs?

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A No, I came up to this -- I came to this determination by myself with -- by reviewing the prior art of Stern and the -- I'm blanking on the word. I call it -- having correct -- I call it a legend, but it's basically the descriptor, the -- what describes the photos, the figures.

Q Uh-huh.

A But basically by reviewing the text and the figures and the descriptor of the figures, I used Dr. Martin to confirm that what -- the way I was interpreting it, you know, if that was correct. So Dr. Martin confirmed that my interpretation of the teachings of Stern were correct, so that was my consultation with Dr. Martin regarding Stern.

Q So did you rely upon Dr. Martin's understanding to supplement your own?

A No, it confirmed that what I was thinking, so it reinforced the fact that my -- that -- that the way I was thinking about it and interpreting it was correct. So it didn't influence -- it didn't alter my interpretation of Stern or of the combination of Stern and Edwards.

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Q But you relied upon Dr. Martin to confirm your own understandings.

A Well, I asked his opinion --

Q Uh-huh.

A -- if my way of thinking of it -- thinking of this arrangement was correct and -- or did he agree with it. Not if it was correct because I wasn't asking for him to anoint it or whatever, but to get his opinion and is this -- am I interpreting these correctly, because it looks like this is what I am -- what Stern is teaching.

Q So you would agree that you relied upon Dr. Martin to confirm your understanding.

A Oh, I did --

MS. COHEN: Objection.

A -- not rely on him, no. I had a --

Q So you didn't rely upon Dr. Martin.

A I had a conversation with Dr. Martin, okay, and -- but I did not rely on Dr. Martin.

Q What was the point in having a conversation with him if you didn't rely on him?

A Well, maybe if my interpretation of it was

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wrong, then I may have relied on him, but my interpretation was not wrong, so it was to get confirmation that I was thinking about it correctly, but I was not relying on him for my opinion.

Q So you independently assessed the Stern reference and its disclosures?

A Yes, I reviewed the Stern reference completely.

Q And you presented your understanding --

A Oh, I'm sorry, could you rephrase that, because I thought I heard something wrong at the end. You said in his disclosure?

Q No.

A Oh, okay, okay, I misheard.

Q You reviewed Stern, correct, John?

A Correct.

Q And you developed your own determinations as to what Stern disclosed, correct?

A Correct.

Q And you spoke with Dr. Martin to confirm your interpretations of Stern, correct?

A I -- in my conversation with Dr. Martin, we

discussed what my interpretation was and my opinion on what Stern was teaching, and Dr. Martin was in agreement.

Q And had Dr. Martin not been in agreement, would you have modified your own understanding?

A Well, that's a hypothetical. So Dr. Martin was in agreement, so I can't tell you what I would have done in a case that didn't happen.

Q Did you have discussions with Dr. Martin about points other than this particular disclosure from Stern?

A I did, and I think there are other -- one or two other instances, and I believe one -- would you like me to try to find it?

Q Well, let's take a look, paragraph 124.

A Paragraph 124?

Q Uh-huh, paragraph 124. It's on page 82.

A Okay.

Q Paragraph 124, you state, "In addition, I've spoken with Dr. Gregory Martin and reviewed his declaration. Dr. Martin's analysis confirms and supports my conclusions" --

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A Uh-huh.

Q -- "that in the combined method of Edwards '535 and Kong, radiofrequency energy is produced by a radiofrequency energy source configured to run between one watt and a hundred watts."

A Right, so as you see, I think there are three instances maybe where I disclose that I had a conversation with Dr. Martin, and they're all related to some of the technical -- technical issues, so this -- obviously, the number of watts, and what we just discussed as far as the Stern reference, but they're technical just to confirm since I'm not an engineer --

Q Uh-huh.

A -- and there are some aspects of this that are -- are technical, to make sure that I was interpreting things, or that the way I was interpreting things were correct.

Q So you feel qualified to evaluate a disclosure -- for instance, a disclosure with respect to a radiofrequency energy source configured to run between one watt and a hundred watts?

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A So I think I'm qualified to see what's in the prior art --

Q Uh-huh.

A -- and in the previous references. The issue is that not all of them disclose the particular range. So the question is -- you know, it's disclosed in these references but not in these references, so am I safe to assume or to interpret that as meaning this is the correct range even though these particular references don't disclose their particular range.

Q And how is it that Dr. Martin was able to make that determination in a way that you were not?

A I can't tell you. I can't speak for Dr. Martin.

Q But you relied upon his determination for your own understanding?

A I didn't rely. I -- so I presented my opinion and, you know, there was no disagreement that that opinion was correct.

Q Did you ask Dr. Martin any questions about what a particular reference may or may not have

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disclosed?

A I can't tell you exactly what I asked Dr. Martin. The conversation was ten months ago or longer.

Q Paragraph 127, you state, "In addition, I've spoken with Dr. Gregory Martin and reviewed his declaration. Dr. Martin's analysis confirms and supports my conclusion that the combination of Edwards '535, Kong and Stern discloses that applying radiofrequency energy includes heating the target tissue to a temperature between 50 degrees Celsius and 70 degrees Celsius." Why did you feel the need to talk to Dr. Martin about this particular limitation?

A Well, so this -- so I'm going to -- my answer to that is I didn't feel the need to, but this -- the fact that Dr. Martin had the same opinion further reinforces my opinion. This -- all of this information is in the text and the prior art and the references, the combination of the two that we have -- that I have disclosed in the declaration, but adding that someone with an engineering background

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and a product design background, that I had a conversation with him and he was in agreement just further reinforces the point, but I did not rely on him. He did not change my opinion.

Q But you said you spoke with Dr. Martin with respect to technical issues, correct?

A Yeah. Well, this is a technical issue. It's the temperature range. Now, the temperature range in some of the references goes up to -- I actually see in -- in 126, in some, they say all the way up to 90, but the -- most of the publications and things that we're referring to are in a narrower range, anywhere from above 40, which I believe was Edwards says, and then 55 to 65 or 50 to 70, but some go all the way up to 90, but that range that is in the claim is -- is -- you know, we found -- I found in multiple of the references.

Q So you wanted to confirm with Dr. Martin technical issues that are outside your daily practice?

A Well, since -- although I came up to these -- came to these conclusions on my own, it never

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hurts to get the opinion of someone who is more seasoned in an area. I do it at work. Most people do.

Q Let's take a look at paragraph 151 as well, John. Paragraph 151 states, "In addition, I've spoken with Dr. Gregory Martin and reviewed his declaration. Dr. Martin's analysis confirms and supports my conclusions that the combination of Edwards '535, Kong, Stern and Edwards '886 teaches that the radiofrequency energy is applied in the form of a 460 kilohertz sinusoid wave." Do you have experience in evaluating 460 kilohertz sinusoid waves, John?

A So I do not, but I -- in the references that we -- since I'm -- I'm sorry, I do not, since I'm not an engineer. I'm sure I -- I encountered it in physics class at one point, but it's not my area of expertise, but it is in some of the references, but there was some discrepancy in some of the references, so that's where the conversation with Dr. Martin occurred, and that's the entire reason for including that in this statement, because otherwise

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it's spelled out in some of the references.

Q So if it's spelled out in the references, why did you need to have a conversation with Dr. Martin?

A Well, because --

MS. COHEN: Objection to form.

THE WITNESS: I'm sorry, I didn't hear.

MS. COHEN: I just said objection to form.

THE WITNESS: Okay, the reason is because one reference states it differently, and actually, instead of kilohertz, it says megahertz, so there was some question on whether that was a -- was correct or incorrect --

BY MR. WARD:

Q Uh-huh.

A -- which most likely was -- since it was the only reference, period, that did not include 460 or a range around 460, it's the only one that said megahertz, I just wanted confirmation that -- that why is that outlier there, this must be a mistake, and it was agreed upon that this is not -- it's likely not correct, that one reference, and that 460

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kilohertz is correct, the range around 460, but specifically 460 is the most common -- most common measurement, and that the other one was -- whether it be a typographical error or just a mistake somehow in -- by the authors --

Q Do you --

A -- or by the publishers or whatever.

Q Do you remember which reference it was that had the megahertz disclosed?

A I believe I do. I believe it was -- it was the Edwards '535. So it's actually the same Edwards that misstates it in one.

Q And you're basing your conversation with Dr. Martin, who came to the conclusion that that was a typographical error in Edwards?

A Well, I didn't come to a conclusion that it was a typographical error or what type of error it was, but that it was inconsistent with all the other publications, all the other references, and it was even inconsistent with a reference from the same person, who, as you've pointed out, is on many of these patents. So whether it was a mistake or why it

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was a mistake we don't know. It could be many things, but it's not us -- not up to me to determine why is a mistake, but to make sure that I'm correct in just assuming that that's an outlier and that's not -- it's an outlier for a reason that's not significant.

MR. WARD: Let's go off the record.

(Recessed at 4:57 p.m.)

(Reconvened at 5:09 p.m.)

BY MR. WARD:

Q All right, John, I want to go back to paragraph 166.

A '271 still?

Q Yeah, '271, paragraph 166, and the heading above paragraph 166 states, "Stern teaches wherein the treatment element comprises two rows of bipolar electrode pairs, and it would have been obvious to combine Edwards '535 and Stern." What I'd like to do, I want to hand you a copy of the Stern reference, John. It's Exhibit 1033. Do you recognize this document, John?

A I -- let me look completely.

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Q Uh-huh.
A Yes, yes.
Q So you made the statement, John, that Stern teaches two rows of bipolar RF electrodes, and so I'd like for you to identify for me Stern's disclosure of two rows of bipolar RF electrodes.
A So figure 19.
Q Yes.
A The device in figure 19 shows two rows of bipolar electrode pairs. 322 is an electrode, so each of those -- well, they're different shapes obviously.
Q Uh-huh.
A But the squares and then the -- what is that? A trapezoid underneath it, they're all electrodes, so that shows two rows of electrode pairs.
Q So just so we have it on the record, you're pointing to figure 19, and you identify what's labeled as reference numeral 322?
A Correct.
Q And what -- what is 322?

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A Well, it's an electrode, and it's -- if we look at the -- we said figure 19, right?
Q Uh-huh.
A Yeah, figure 19, 322, where is it? But Stern marks 322 as an electrode, 321.
Q Yeah, if you take a look at column 14 --
A Fourteen, I'm on 14.
Q Line 26.
A Twenty-six, bladder 3 -- oh, I was missing 322, right. So a plurality of electrodes 322 are formed on the surface of the bladder 320, correct.
Q What's your understanding of the bladder 320?
A That's the -- that's the -- the body of that treatment element, so that would be the entire surface would be the bladder.
Q So going back to figure 19 --
A Uh-huh.
Q You would understand that each of the four boxes shown inside 320 illustrate an electrode?
A Correct.
Q And are you considering the first two

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squares at the top of figure 19 to be the first row?

A That would be the first row, and that would be a bipolar electrode pair.

Q So the -- the two squares at the top of figure 19 would be the two electrodes of a single pair, correct?

A Correct, right, that's a -- that's a bipolar electrode pair.

Q A single bipolar electrode pair.

A It's a bipolar electrode pair.

Q And that would be in the first row of the device shown in figure 19, correct?

A Correct.

Q And are you identifying the two polygons in the middle of figure 19 as the other two electrodes?

A Correct.

Q And would you identify that as a second row?

A Yes, I would.

Q And so you would identify the two polygons as the two electrodes of a single pair?

A That is the bipolar electrode pair.

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Q So is it your understanding then that Stern discloses two rows of a bipolar electrode pair?
A No, two rows of bipolar electrode pairs.
Q Okay, so let's look at row 1. How many pairs are in row 1?
A So it's a bipolar electrode pair.
Q One of them.
A One pair.
Q One pair, a single pair?
A Bipolar electrode pair.
Q A single pair is in row 1, correct?
A Row 1 is a bipolar electrode pair.
Q And row 2 has a --
A Another bipolar electrode pair.
Q Row 2 has a single bipolar electrode pair, correct?
A It has a bipolar electrode pair.
Q So only one pair in each row.
A There's a bipolar electrode pair in each row.
Q And no more disclosed.
MS. COHEN: Objection, form.

A What do you mean, no more disclosed?
Q Does Stern disclose additional pairs in those rows?
MS. COHEN: Objection, form.
A I don't -- I'd have to review the document that the -- let me -- I think he -- let me go back to -- he describes a plurality of electrodes 322 are formed on the surface of the bladder 320.
Q Does he disclose more than one electrode pair in a single row?
MS. COHEN: Objection, form.
A He refers to it as a plurality of electrodes, but from looking at it, someone of ordinary skill would recognize this as two bipolar pairs, two rows of bipolar pairs.
Q Someone of ordinary skill would recognize what's shown in figure 19 as two rows of a single pair in each row of electrodes.
A Two --
MS. COHEN: Objection, form.
A -- rows of bipolar pairs.
Q Two rows of bipolar pairs?

MS. COHEN: Objection, form.

A Two rows of bipolar pairs.

Q Okay. Well, show me the additional pair in any of the rows.

A Well, it's grammatically incorrect to say two rows of bipolar pair, correct? So it's two rows of bipolar pairs. That's the correct grammatical statement.

Q Does Stern disclose any additional electrodes other than what's shown in figure 19?

MS. COHEN: Objection to form.

A Are you referring to in figure 19?

Q Uh-huh.

A Well, there's one other shape. I do not interpret it as a bipolar electrode because it's a single shape, unless he does describe that the circuitry can be altered to use different combinations of electrodes --

Q Uh-huh.

A -- in which case that could be a single electrode that can then be combined with one of the electrodes above it.

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Q And can you identify a disclosure in Stern to that effect?

A I cannot because he does not -- the -- the photograph -- he describes the ability to combine various electrodes, to alter which electrodes can be used in which pair, so in different directions or above and below or side to side or diagonally. So it's possible. I do not think it's disclosed, but it's possible that that structure on the bottom could be an additional electrode that could be conceivably paired with one of the ones above it by altering the circuitry, but regardless, above it is two rows of bipolar pairs.

Q I want to go back to your declaration, John, same one from the '271 patent.

A Okay.

Q Paragraph 145 that's on page 94. Paragraph 145, you state, "Edwards '535 does not provide details about when or how the bend shown in figure 3B was formed, which is consistent with the fact that forming bends in catheter shafts has long been routinely performed in the context of delivering

treatment to the nasal passages. By way of example, the following references disclose further details of forming bends in catheter shafts when treating upper airway conditions," and you cite a number of references in paragraph 145. The first one is Exhibit 1013, the Baker reference, then Exhibit 1019, the Gertner reference.

A Uh-huh.

Q Exhibit 1021, Makower.

A Uh-huh.

Q And then at the end, it's on the bottom of page 95, you state, "Examples of apparatus and construction that may be used to render these devices steerable or volitionally bendable include but are not limited to those described in" -- you give a list of patents, and it looks like just as a rough guess there, you list around eight or nine patents and two patent publications. John, did you rely upon these references for teaching the -- the disclosures that you talk about?

MS. COHEN: Objection, form.

A I'm sorry, could you rephrase that? I

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didn't quite understand the question.

Q Your declaration identifies --

A Right.

Q -- a number of references in paragraph 145. Are you relying upon those references for their teachings?

A So these references are just additional examples of -- of prior art that -- and publications that show that it's very common to put a bend in the shaft, as we see in figure 3B of Edwards, and as a matter of fact, even though Edwards doesn't describe putting a bend in the shaft, there is a bend in the shaft on the photo, and in addition, as someone who performs nasal procedures on patients, that -- if that bend wasn't -- first of all, if that bend was already in the shaft, there's no way to get that device comfortably in that patient. That device has to be modified somehow to -- to get into that position. So someone who -- a person of ordinary skill would understand looking at this diagram that -- this figure 3B, that a bend in this shaft would have been created as part of the procedure.

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Q And you rely upon these references to teach that bend.

A No, I do not rely upon those references. Those references are additional examples that it's very common -- in my practice, I put bend in instruments almost on a daily basis. I mean, this is something that is frequently done. The nasal cavity is not a straight shot from anteriorly to posteriorly, and you know, most people don't realize the anatomy of the nasal cavity. That's why you tell someone you're going to look in their nose, they stick their head back. They tilt their head back, which the nose, if you look here, is a -- almost a triangle, right? So it goes very high, it goes very low.

Frequently not one device with a fixed structure is going to access all different parts of the nose. So it needs to be a device in many instances that can be malleable. You know, some part of it needs to be malleable. Sometimes it's a shaft, sometimes it's the tip, but frequently a device needs to be malleable. Fixed devices don't work well for

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procedures on the nose, with the exception of the scope, but the scope, we're not getting around corners and going into crevices. And so those are just examples. I did not rely on them.

Q Uh-huh.

A As you see, we -- I was relying on Edwards and Baker. Those are just additional examples. Just like anything else, more examples just reinforce the point that it's very common to require putting bends in a shaft or a treatment element to access the tissue that you're trying to treat.

Q So these additional references that you cite that aren't exhibits in the case at the end of the paragraph, you say they are examples of apparatus and construction that may be used to render these devices steerable or volitionally bendable. So what is it that's disclosed in these references that's not disclosed in the previous references?

MS. COHEN: Objection, form, foundation.

A I can't with -- sitting right here now --

Q Uh-huh.

A -- without reviewing each one of those --

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Q Yeah.
A -- I cannot answer that question completely. I would have to review -- re-review --
Q Uh-huh.
A -- each of these references to see exactly what point, if anything, is not covered in the previous references, in the main references.
Q Do you remember what was your intent in including this --
A Well --
Q -- list?
A As I mention, the intent is to show how -- we're not -- that the references that we have, Gertner, Makower, Baker, Edwards, are not the only references --
Q Uh-huh.
A -- that point to a common need to alter the shape of a device, to bend the shaft or some other form of modification that helps with treatment.
Q Back up on just one page, 90 -- page 95 where you're citing to Exhibit 1021, Makower, do you know Makower?

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A I do not know him personally. I know of him. I have seen him. I've never had a conversation with him.

Q Where have you seen him, John?

A It would have been at a meeting. So there's -- there's a lot of history behind that, not with me, but with his device and -- and how it was handled in our specialty. So he is -- and I don't know what his position, whether it was president, CEO, whatever, of Acclarent, which is the balloon sinuplasty company. So that is a steerable device that uses a balloon to remodel tissue. So I do not know him personally. I know some of the story.

Q And what was -- what's the name of the commercial product?

A So the company was called Acclarent.

Q Acclarent.

A Acclarent was the company. The balloons had individual names, so -- but --

Q And what procedures were they used for generally?

A It was called balloon sinuplasty, so it's a

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balloon dilation procedure for the sinuses, for sinusitis.

Q Uh-huh.

A And it's -- it was subsequently bought by Johnson & Johnson. It's still a product. I'm not sure if it's still called Acclarent, but Acclarent was purchased by Johnson & Johnson, but that was ten, 15 years after the product became available.

Q Did you ever use the product?

A I have used the product. I've used it -- not very often, but I've used it. I was actually one of the first people to use it in Atlanta, but I don't use it very frequently because it doesn't have a big place in my practice because of my patient population. It's really for mild to minimal sinus disease, and that's a very rare patient that I see.

MR. WARD: That's all the questions I have. We can go off the record.

MS. COHEN: I think we're good. We have no questions.

(Off the record at 5:29 p.m.)

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ACKNOWLEDGMENT OF DEPONENT

I, John Michael Delgaudio, M.D., do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me, and any corrections appear on the attached errata sheet signed by me.

_____ _____

(DATE) (SIGNATURE)

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CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Karen Young, Court Reporter and Notary Public within and for the District of Columbia, do hereby certify:

That John Michael Delgaudio, M.D., 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, Neurent Medical, Inc. and Neurent Medical, Ltd., was represented by counsel at the deposition.

I further certify that the deposition of John Michael Delgaudio, M.D. occurred at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 2100 Pennsylvania Avenue, Northwest, Washington, D.C., on Thursday, October 10, 2024, commencing at 12:02 p.m. to 5:29 p.m.

I further certify that I am not related to any of the parties to this action, and that I am in no way interested, financially or otherwise, in the

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outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 14th day of October, 2024.

My commission expires:

September 14, 2029



Karen Young

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