

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4
5 NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,

6 Petitioner,

7 v.

8 AERIN MEDICAL, INC.,

9 Patent Owner.

10
11 IPR2024-00277

12 U.S. Patent No. 11,241,271

13
14 Deposition of JOHN MICHAEL DELGAUDIO, M.D.

15 Washington, D.C.

16 Friday, February 7, 2025

17 9:34 a.m.

18
19
20 Job No. 570092

21 Pages 1 - 189

22 Reported by: Karen Young

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2 held at the offices of:
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11 Pursuant to notice, before Karen Young,
12 Notary Public of the District of Columbia.

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1 A P P E A R A N C E S
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C O N T E N T S

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EXHIBITS REFERRED TO

(Retained by Counsel)

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

2 (Exhibits were marked prior to the deposition.)

3 JOHN MICHAEL DELGAUDIO, M.D.,

4 having been duly sworn, was examined as follows:

5 - - -

6 EXAMINATION BY COUNSEL FOR AERIN MEDICAL, INC.

7 BY MR. WARD:

8 Q Good morning, Dr. DelGaudio. Can you state
9 your full name for the record?

10 A John Michael DelGaudio.

11 Q Can I call you John?

12 A Sure.

13 Q My name's Trenton Ward. I'm a patent
14 attorney with Greenberg Traurig. I represent patent
15 owner, Aerin Medical and the Foundry, and John, you
16 understand that you're here for a deposition in
17 connection with proceedings before the PTAB --
18 actually, one proceeding today before the PTAB, and
19 it is IPR2024-277; is that correct?

20 A That's correct, that's patent number '271,
21 correct.

22 Q Yes.

1 A Okay.

2 Q Now, John, do you understand that you're
3 under oath today?

4 A I do.

5 Q And do you understand that that means you
6 swore to tell the truth and the whole truth?

7 A Absolutely.

8 Q Any reason you would not be able to testify
9 truthfully today, John?

10 A Not at all.

11 Q Well, you'll remember from our -- our last
12 meeting in this exact location --

13 A Round 1.

14 Q I'm sorry?

15 A Round 1.

16 Q Round 1, yes, and here we are for round 2,
17 but you'll remember the rules for deposition from
18 last time, John, but I'm just going to go over them
19 again just to refresh everyone. I'm going to ask you
20 about some documents involved in the IPR, including
21 your -- your reply declaration, the second
22 declaration. I'll provide you copies of those,

1 although it looks like you came with your own there.
2 The court reporter, Karen's going to transcribe
3 everything that you say, everything that I say, and
4 we'll try not to talk over each other. I'm sure I'll
5 do it at some point during the day. You'll probably
6 do it as well. We'll try and make our conversations
7 separate so that Karen can accurately document
8 everything, and I'll do my best to wait until you
9 finish answering my question, and I'll ask that you
10 do the same to not interrupt me when I'm asking a
11 question. Does that sound good?

12 A Absolutely.

13 Q Great. John, when I ask a question, can
14 you please tell me if you don't understand the
15 question?

16 A I will.

17 Q And do you understand that to mean if you
18 answer my question, I can understand you to have
19 understood the question?

20 A I do.

21 Q And if your counsel objects to the
22 question, you understand that you are to answer the

1 question unless instructed by your counsel not to
2 answer the question, correct?

3 A Correct.

4 Q We'll have to remember to keep our
5 responses verbal, so no ums or ahs today. Take a
6 break any time you need it, John. Kind of like last
7 time, I usually try and break on, you know, the hour,
8 but let me know if you need a break. Happy to take
9 one at any time. The only thing I'll ask is that if
10 you do need a break, I'll ask for you to finish
11 answering my question before --

12 A Sure.

13 Q -- we take a break, and do you recall that
14 you're not able to discuss the substance of your
15 testimony during a break?

16 A Absolutely.

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

19 MS. COHEN: And I will just instruct the
20 witness not to reveal any privileged communications
21 with counsel.

22 A So I reviewed some documents. Would you

1 like to know which ones?

2 Q I would.

3 A So my reply declaration.

4 Q Okay.

5 A My -- some of my original declaration, the
6 Stern patent prior art, the --

7 Q Uh-huh.

8 A -- '271 patent. There was -- we had a Zoom
9 meeting, myself and counsel, approximately a week
10 ago, and we had a preparation session yesterday.

11 Q Okay, and who was involved in those
12 preparation sessions?

13 A Alexis Cohen and Brian Lambson and myself.

14 Q Nobody else involved?

15 A No one else was involved. You're talking
16 -- you said yesterday, correct?

17 Q Yesterday.

18 A Yes.

19 Q And what about any previous preparation
20 sessions, any additional --

21 A That one we did a week ago, Alex Nemtsov
22 was also involved.

1 Q Okay. Well, like to share with you a copy
2 of your reply declaration. It looks like you have
3 one there.

4 A Do you want to check and make sure?

5 Q Yeah, can I just take a --

6 A Absolutely.

7 Q -- look and see? So this is a copy of
8 Exhibit 1083 to IPR2024-277. It's the reply
9 declaration for Dr. John DelGaudio. That's a copy
10 for you, Karen. Okay, John, do you recognize this
11 document?

12 A I do.

13 Q What is it?

14 A It is my reply declaration.

15 Q And could you turn to the last page, which
16 is actually kind of the middle of the declaration,
17 page 42, it's right before the appendix starts.

18 A Okay.

19 Q And is that your signature there on page
20 42, John?

21 A Yeah, that's my electronic signature, yes.

22 Q Okay, dated January 17, 2025?

1 A Correct.

2 Q Who wrote this declaration, John?

3 A I wrote this declaration.

4 Q Did you work with anyone?

5 A I worked with counsel.

6 Q And did counsel draft portions of the
7 declaration?

8 A We worked in conjunction to come up with
9 the final declaration.

10 Q And what do you mean by worked in
11 conjunction?

12 MS. COHEN: And I would just caution the
13 witness not to reveal the content of any privileged
14 communications.

15 A So we -- we had discussions --

16 Q Uh-huh.

17 A -- about the -- the content, and came to
18 mutual agreement on the content of the final
19 declaration.

20 Q Did they provide red lines to the
21 declaration for you?

22 MS. COHEN: I'm going to object to that. I

1 think that's calling for -- I think that's calling
2 for privileged information.

3 BY MR. WARD:

4 Q Did they comment on the declaration, John?

5 A Well, we both -- everyone commented on the
6 declaration. We worked in conjunction.

7 Q And how were those comments provided?

8 A I don't know. Well, as I said, we had Zoom
9 meetings, so they were -- there was back and forth
10 verbally. There was an original -- or drafts of the
11 declaration that were then edited.

12 MS. COHEN: Yeah, I'm just going to caution
13 like the -- where we're going, I think it's getting a
14 little bit too into privileged information.

15 MR. WARD: Alexis, I'll just remind you,
16 speaking objections are not allowed on the record.

17 MS. COHEN: They are for privileged
18 objections.

19 BY MR. WARD:

20 Q They're not allowed for privileged
21 objections, but a more general question for you,
22 John, were there written comments provided in

1 addition to verbal comments?

2 MS. COHEN: I think that this is getting
3 into privileged information. Drafts are not
4 discoverable.

5 MR. WARD: I'm not asking for the draft.
6 I'm asking to the extent were written comments
7 provided.

8 MS. COHEN: I think you can answer at a
9 high level about the preparation, but I think -- I
10 don't want us getting into details.

11 THE WITNESS: Written comments were not
12 provided.

13 BY MR. WARD:

14 Q Okay. John, have any of your opinions
15 changed since this draft, or since the declaration
16 that's dated January 17, 2025?

17 A No, they have not.

18 Q So are there any errors that you'd like to
19 correct in the declaration?

20 A There were only some typographical things
21 that are inconsequential.

22 Q Okay. I want to turn just to the next page

1 there. Page 43 is the start of Appendix A, and then
2 you can turn, I guess page 44 -- well, yeah, it looks
3 like you're on it.

4 A Yeah.

5 Q The start of Appendix A, it's labeled
6 "Materials Considered," and so do I understand
7 correctly that you're indicating that all of the
8 exhibits listed in Appendix A are materials that you
9 considered for this reply declaration?

10 A All of these materials were considered in a
11 combination of -- well, for this, but because this
12 also refers back to the original declaration in some
13 areas.

14 Q I'm sorry, I didn't follow that. So --

15 A So there's some references in this
16 declaration --

17 Q Uh-huh.

18 A -- to my original '271 declaration.

19 Q Yes.

20 A So some of those materials would have also
21 been referenced, excuse me, in that '271 declaration.

22 Q So you didn't review all of these materials

1 for purposes of this reply declaration, is what
2 you're saying.

3 A I didn't completely review all of these --
4 all of these references, no, for this particular --
5 for this declaration.

6 Q But for either the -- your original
7 declaration or the reply declaration, you considered
8 all the materials listed in Appendix A, correct?

9 A Correct.

10 Q Okay, flip back to page 1 of the
11 declaration for me. I just want to take a look at
12 paragraph 2 of your declaration.

13 A I'm sorry, not this page.

14 Q I'm sorry, yeah.

15 A Not this Roman number 1.

16 Q Yeah, yeah, the start of the declaration.

17 A Okay, I'm there.

18 Q So your -- your paragraph 2, you state,
19 "Since preparing my first declaration, I have
20 reviewed patent owner's preliminary response, the
21 board's institution decision, the patent owner
22 response, and the Bikson declaration. I've also

1 reviewed and considered the documents cited by
2 Dr. Bikson in his declaration, and the transcript of
3 Dr. Bikson's deposition" --

4 A Uh-huh.

5 Q -- "held on January 7th, 2005."

6 A Correct.

7 Q So you're indicating there that -- in
8 paragraph 2, those are the particular documents that
9 you reviewed with respect to this reply declaration;
10 is that correct?

11 MS. COHEN: Objection, form.

12 A Well, I reviewed -- when I received this --
13 this -- obviously this is information that wasn't
14 available during my original declaration, and in
15 order to -- obviously the proceedings that have
16 happened between then and now --

17 Q Uh-huh.

18 A -- included all of these things, so I have
19 reviewed those documents.

20 Q And did you review any additional
21 documents?

22 MS. COHEN: Objection, form.

1 A Yes, they're listed in the -- the ones that
2 I'd mentioned, correct, when you asked me what I did
3 to prepare for the --

4 Q Uh-huh.

5 A -- deposition, and many of the documents
6 that are in the appendix that we just referenced.

7 Q Okay. Turning to paragraph 6 of the
8 declaration, Exhibit 1083 --

9 A Yes.

10 Q Paragraph 6, you state, "Dr. Bikson
11 proposes the following definition of a person of
12 ordinary skill in the art, which unlike my
13 definition, requires a person of ordinary skill in
14 the art to have three years of design and development
15 experience irrespective of any clinical use or
16 testing experience."

17 A Correct.

18 Q And I believe you've reproduced a table
19 there in paragraph 6 that compares your definition of
20 a person of ordinary skill in the art and
21 Dr. Bikson's definition, correct?

22 A Correct.

1 Q And do you understand the difference
2 between those proposed definitions is that
3 Dr. Bikson's definition does not include experience
4 in clinical use or testing of medical devices,
5 correct?

6 A Correct.

7 Q So in the next paragraph, paragraph 7, you
8 state, "I disagreed three years of development and
9 design experience is necessary to qualify as a person
10 of ordinary skill in the art, as Dr. Bikson's
11 definition requires. Nevertheless, I qualify as a
12 person of ordinary skill in the art under both
13 definitions." So John, you believe that you do
14 qualify as a person of ordinary skill in the art
15 under Dr. Bikson's proposed definition?

16 A I do, as I -- as I said in what you just
17 read, I think I qualify as a POSITA in both -- under
18 both definitions.

19 Q So what medical devices have you designed,
20 John?

21 A So I have -- and it's in my deposition --
22 my declaration, I'm sorry -- and I also actually

1 discussed it in my previous deposition, although that
2 really wasn't referenced very much, or whether it was
3 lost, I don't know. So I have experience, as we
4 mentioned here -- let me look exactly where I have it
5 in the declaration. It's right here. Let's see.
6 Where it starts is on 9, paragraph 9, I have
7 extensive experience developing, designing medical
8 devices throughout my decades-long career.

9 For example, I routinely consult with and
10 deliver feedback on device manufacturers to improve
11 the features and performance of the devices, and then
12 I go on to describe an example, and actually, I think
13 we discussed this example in my previous deposition,
14 and this is -- I have a long -- basically a
15 career-long relationship with Medtronic. At times
16 I'm a consultant, at times I'm not. We discussed
17 that at the previous deposition also, but in this
18 particular one, as we discussed previously, products
19 are constantly upgraded, improved.

20 Q Uh-huh.

21 A Unfortunately, sometimes the products --
22 the new product is actually not better than the

1 previous product, and we had that experience with
2 Medtronic and their image-guided system or computer
3 navigation system, which the present one is called
4 the Stealth. I've been using it actually longer than
5 they actually owned it. I -- I started using it when
6 the previous company called Sofamor Danek developed
7 it and then Medtronic bought it, so I actually have
8 more experience with that than the company actually
9 does.

10 But they came up with a new system, and
11 that system was not functioning well, so if you -- if
12 your GPS system was sending you two blocks away from
13 where you actually were, and it looked like -- it had
14 your little blue dot on the map and you weren't
15 actually there, that'd be a problem. Well, that's
16 the equivalent of what these systems do. The tip of
17 the instrument is a dot on the screen or crosshairs,
18 and I actually had over a period of many months
19 representatives, engineers come into my O.R. to show
20 them how the system was not accurate, and that was
21 the beginning of a very long months to year and a
22 half -- and this is one example, where -- process

1 where they were trying to work with me first in the
2 O.R. to alter various things on the computer system,
3 the software, to try to improve the accuracy,
4 registration techniques, whatever. That was not
5 effective. They were in the O.R. with me, so they
6 witnessed it.

7 They then invited me down to Jacksonville,
8 where their headquarters is. I met with their actual
9 engineers that came up with the software and the
10 system who were stationed in -- some of them in
11 Colorado, some of them in Minneapolis, because the
12 neurosurgical part of their company's in -- in
13 Minneapolis. There were, I can't remember, four or
14 five engineers.

15 We tested the system in the -- in the
16 facility. We used cadaver heads. I went through my
17 whole technique. They were -- didn't realize since
18 this was a primary neurosurgical system adapted to
19 otolaryngology, that our registration techniques are
20 different, our imaging is different. So basically we
21 were not having enough surface area on the specimen
22 head, the patient's head, to allow the registration

1 that they developed to be accurate.

2 We were not providing enough points because
3 they were expecting the entire head to be available
4 on the imaging, which is not typically the case with
5 sinus films. So it led to them -- it led to them
6 having to rework the software for otolaryngology. We
7 had to make some concessions too and tried to include
8 more of the patient's head on our CT imaging,
9 although that's not always possible because a lot of
10 times patients come in with CT imaging from outside
11 facilities, and so that we don't blow up the health
12 care costs, we're not going to repeat those imaging
13 for -- just for that reason. So -- so there were
14 concessions on both sides to try to make the system
15 more effective.

16 That was only one thing I actually did at
17 that visit. I also worked with them on their powered
18 instrumentation, their microdebrider, which also has
19 drill attachments, and we looked at the efficacy of a
20 new system that they were coming out. It's actually
21 -- that was several years ago, and the system is
22 still not out yet, but it should be in the next one

1 year, and it's a new console.

2 It's a new -- new drill bits because we do
3 a lot of drilling in the -- in the roof of the nose
4 and the sinuses and the skull base. That included a
5 recommendation that they have some bigger drill bits
6 that could be more aggressive. So that's one
7 example, and that was just over a period of
8 approximately a year and a half or so.

9 Q So John, when you say registration is
10 different for otolaryngology, what do you mean?
11 Different than what?

12 A Than neurosurgery because --

13 Q So the device was originally designed for
14 neurosurgery?

15 A Correct, it's a -- it's -- well, the
16 engineers designed it with neurosurgery in mind, not
17 knowing that there would be significant differences
18 between what's available to the neurosurgeon to
19 register the device and what's available to the
20 otolaryngologist. By registration -- just to clarify
21 what registration means, these systems take images
22 like a CT scan or an MRI that's on the computer --

1 Q Uh-huh.

2 A -- and then you have the patient on the
3 operating room table, so there has to be a way to let
4 the system know where the patient is and to be able
5 to -- just like your GPS system has to know where
6 your car is, right? Has to know where the patient is
7 within one to two millimeters so that it can actually
8 track these instruments.

9 So there is -- there is various
10 technologies. Some is line of sight, and some's
11 electromagnetic fields that allow you to basically
12 trace the patient's face and head. It takes that
13 basically mask that you make with your tracing and
14 superimposes on the patient's imaging, and that
15 allows the computer program to essentially register,
16 to correlate patient in real space to the imaging on
17 the computer, and then it also tracks the instruments
18 that allow you to stick them in the nose, tell you
19 where the tip of your instrument is. The closer that
20 is to real life obviously the more accurate. When
21 it's three millimeters or a centimeter away, it's
22 dangerous. You can think you're one place and be

1 somewhere else. So that's what registration is.

2 It's correlating the patient to the system.

3 Q So John, in your role as a consultant, are
4 you often helping a company modify a device that's
5 intended for another type of procedure for
6 otolaryngology?

7 A Could you clarify that question? Okay, I
8 think you mean because that was a neurosurgical
9 system.

10 Q Yes.

11 A Well, it wasn't -- it's not just a
12 neurosurgical system. It's an otolaryngology system,
13 but because the engineers didn't realize the
14 difference between neurosurgical and otolaryngology
15 as far as some of these intricacies on what's
16 available to us during surgery. So it's not adapting
17 the system, but it was helping them realize the
18 differences that allow -- because there's -- these
19 systems actually have -- it's a big unit, but you can
20 have a kind of scaled-down unit. We use the scaled-
21 down unit most of the time. Same software, but the
22 scaled-down unit, because we can use it in our

1 outpatient surgery centers, where we do a lot of our
2 surgery, whereas the neurosurgery do everything
3 inpatient so they can use a bigger unit.

4 Q So John, the problem there of the device
5 not working appropriately with otolaryngology --

6 A Correct.

7 Q Is that something you've encountered in
8 other projects?

9 A So in -- I've worked -- this is just one
10 example. I have consulted with them on their
11 previous systems also, but not to this effect,
12 because their previous systems were much more
13 accurate, and unfortunately, you know, all these
14 systems have a shelf life, right? They only have so
15 many years where they can make money off these
16 systems, and then if everyone has systems, then
17 they're not selling any more.

18 So what they have to do is they have to
19 upgrade, right, so that people want the new systems.
20 That's what happens, and unfortunately, this upgrade
21 was not functionally a better system. So that's just
22 -- that's just one example of consulting, and I put

1 another example in here where I -- me and a
2 colleague, also a rhinologist, sinus surgeon, worked
3 with a company to actually develop de novo a
4 disposable microdebrider.

5 Q I want to ask about that one, but I want to
6 ask just a few more questions --

7 A Sure.

8 Q -- about this particular one. So you --
9 the statements you make -- it's at the top of page 4
10 of your declaration, you say, "I've helped to develop
11 and improve an image-guided computer navigation
12 system used for tracking the tip of an instrument
13 inside a patient during sinus surgery." John, did
14 you say the -- the commercial name for the product is
15 Stealth?

16 A The latest one -- latest one is Stealth.
17 It's gone through multiple different names. The one
18 before, it was called the Landmarx, L-A-N-D-M-A-R-X.
19 Before that, it was -- it actually previously when it
20 first started was called the Stealth also, and then
21 there was one other name, but Landmarx and Stealth.

22 Q So you say specifically, John, that you've

1 helped to develop and improve the image-guided
2 computer navigation system. Do you agree that you
3 did not design the system?

4 A I did not design the system.

5 Q And when you say that you helped to
6 develop, what do you mean by that?

7 A Well, just what I just described to you.
8 So obviously modify or work with our engineers to
9 modify the system, yeah, so changing the direction
10 that they were going to develop the improvements in
11 the system because the existing system was -- and I
12 was not the only one in the country who was -- who
13 was having issues with the system. I guess I was
14 just the most vocal, but the -- you know, working
15 with them on seeing the direction that it needed to
16 be redesigned.

17 Q So in your mind, John, developing includes
18 providing feedback?

19 A Developing -- developing pathways for
20 improvements, developing plans for progress and
21 improving the system, absolutely.

22 Q And both of those, developing pathways and

1 developing progress, that's -- your role was to
2 provide feedback, correct?

3 A To provide feedback, to educate, to educate
4 their engineers, obviously to use the system and
5 demonstrate the flaws of the system, in addition to
6 the good parts of it obviously. It wasn't a
7 completely bad system. It just wasn't accurate
8 enough.

9 Q John, I understand your testimony then
10 regarding developing a system. Have you designed a
11 medical device?

12 MS. COHEN: Objection, form.

13 A Well, yes, I have designed a medical
14 device, and that's what I just mentioned, de novo,
15 worked for the company, excuse me, to develop a
16 disposable microdebrider, and I don't know if you
17 recall what a microdebrider is.

18 Q I don't know what it is.

19 A We discussed that in the last -- it's in
20 the -- it's in the reply declaration, but we
21 discussed it in the last deposition a few months ago.
22 A microdebrider is essentially -- it's a device that

1 was developed in the orthopedic field for basically
2 kind of shaving joints. It's a device that has --
3 it's a powered device that shaves -- or suctions and
4 cuts at the same time. It can have multiple -- it
5 can -- it can -- and actually, microdebridors for the
6 last decade and a half at least also have drill
7 components.

8 We weren't working on the drill component.
9 We were working on an office-based or primarily
10 office-utilized disposable microdebrider. There's
11 been a huge shift in our specialty, go to more
12 office-based procedures, and I've been kind of at the
13 forefront of that for the last one to two decades.
14 So I was approached by a company, me and one of my
15 colleagues, to develop a office-based disposable
16 microdebrider system, and worked with the company de
17 novo to develop strategy, initial device, particular
18 work with them on particular factors that need to be
19 considered as far as the ergonomics of the handpiece,
20 the -- the power source, the -- how malleable the
21 blades need to be, because these were malleable
22 blades, so these were not -- each of these

1 microdebrider blades, the blade is the functional
2 part that plugs into the handpiece.

3 In order to avoid having to have multiple
4 blades, which the ones that we use in the O.R. are
5 multiple because they have straight ones, they have
6 40 degree, they have 60 degree, they have 90 degree,
7 they have 110 degree, so they're all separate pieces.
8 This system was designed -- being designed to have a
9 single blade that was malleable that could be bent,
10 so we needed to decide for the office-based
11 utilization how far do we want it to be able to bend
12 and did we want to be able to have a material that
13 would bend back somewhat.

14 So you know, we worked with the engineers
15 on that, and I -- it went to the phase of I did a
16 couple of cadaver sessions looking at the -- you
17 know, the prototypes, some of the different
18 materials, some of the different degrees of -- of
19 tensile strength of the blades to see if they need to
20 be more or less malleable. So this, you know, was
21 over a period of at least a couple of years that we
22 went through this process.

1 Unfortunately, Olympus beat them to the --
2 getting a product out, and then there was some
3 problems with the -- or I don't know what the
4 internal problems were with the company so they
5 scrapped the project so it never came to fruition.

6 Q What was the commercial name for the
7 microdebrider?

8 A There wasn't a name yet. The company was
9 called -- was named Prodex, and it's not even an
10 otolaryngology company. P-R-O-D-E-X. It was not
11 even a, like I said, a otolaryngology company, so
12 this would have been the first foray definitely into
13 rhinology, but --

14 Q Were you an employee of Prodex, John?

15 A No, I was not. I was a consultant.

16 Q Did you sign a consulting agreement with
17 Prodex?

18 A I probably did. I would think that I did,
19 but I don't have that -- I could have it somewhere.
20 I don't know, but obviously I think I would have most
21 likely. I can't tell you for sure. I don't
22 remember. It was several years ago.

1 Q Did you have a duty to assign any of your
2 intellectual property creations to Prodex?

3 MS. COHEN: Objection, form.

4 A I don't recall exactly what's in the
5 contract, but we were working on one specific
6 project, so this was purely related to this one
7 project, no other -- no other designs or product
8 ideas.

9 Q Were you listed on any patents filed by
10 Prodex?

11 A No. No, I was not.

12 Q Is the purpose of the microdebrider to
13 deliver energy to tissue?

14 A So by suctioning and cutting, it would be
15 -- I would consider it mechanical energy. You know,
16 we're altering tissue, and frequently it's by either
17 removing tissue, most commonly polyps, but it can
18 also be removing bone, opening up sinuses by removing
19 thin areas of bone, actually reducing turbinates. So
20 it -- it works by actually cutting and suctioning the
21 tissue, so I would consider that mechanical energy.

22 Q And how is that mechanical energy received

1 by the tissue?

2 A Well, it's putting pressure -- you have to
3 put pressure on the tissue to engage the tissue, and
4 then the -- you know, because it's by contact, and
5 then there's an open -- the tip of the blade, refer
6 to the active part of the blade as two sheaths, so it
7 -- the inner sheath has an opening, a fixed opening
8 that doesn't move. The outer sheath has a rotating
9 surface that also has an opening so that -- and it
10 has serrated edges, so those serrated edges -- first
11 of all, the inner -- when the two openings are
12 aligned, the device is connected to suction, so it
13 suctions the tissue in, and by engaging the foot
14 pedal, allows the outer blade to rotate over the
15 inner blade, and those serrated edges will cut off
16 anything that is sucked into the -- the open port, so
17 pressure of contacting the tissue and then the
18 mechanical energy of rotating and -- and basically
19 slicing the tissue.

20 Q So John, you stated earlier that you did
21 not design the image-guided computer navigation
22 system, but you consider yourself to have designed

1 this microdebrider.

2 A I worked with -- sure, I worked with the
3 company of Prodex, as I mentioned, and their
4 engineers and their -- I don't even know the guy who
5 was -- whether he was in marketing or whether he was
6 in development, our primary contact, but it was -- he
7 kind of spearheaded it but put us in contact with the
8 engineers, and he oversaw the project, so yes, but
9 absolutely designed from the beginning.

10 Now, obviously there -- there are
11 microdebridors that are in -- have been for a very
12 long time that have been in use, so obviously -- and
13 we've used many different -- I myself and my partner,
14 who I -- who I worked with on this project, used
15 multiple different types of microdebridors, different
16 companies, including there had been a disposable
17 microdebrider available that we had used for a period
18 of time, but for some reason, that -- that company
19 sold to a Canadian company, who then shut it down, so
20 we no longer -- so the market had a void in that
21 particular product, so that was the impetus in
22 starting the development.

1 Q So what's the difference between your role
2 for the microdebrider and your role for the
3 navigation system that makes you a designer for the
4 microdebrider but not a designer for the navigation
5 system?

6 A Well --

7 MS. COHEN: Objection, form.

8 A Yeah, so I would say because I did not
9 develop the micro -- sorry, the navigation system.
10 Like I said, I've -- I have more experience with it
11 than the company actually in years because I used it
12 before they bought it, so I've gone through -- I've
13 utilized that system since its -- very close to its
14 origination, so when it first became available, but I
15 didn't design it.

16 I have worked with the company. I've made
17 suggestions about things that could be -- should be
18 included, things that I didn't think should be
19 included because of safety issues because it's not
20 just academic, you know, specialists who are using
21 this. This is in very common use for people who
22 really may rely on it too much, you know, which could

1 be dangerous, but -- so because I did not design it
2 de novo, I would not consider myself designing the
3 system.

4 I would consider myself having significant
5 input over the last 30 years in how the system has
6 been improved and how it's utilized and, you know,
7 some of the changes that have been made in the
8 system, but I didn't design it. The microdebrider, I
9 was integral, me and my partner, my colleague were
10 integral in every step of that development.

11 Q So for the navigation system, you consider
12 yourself as developing that system because you
13 provided feedback on the system.

14 A I consider --

15 MS. COHEN: Objection to form.

16 A I don't consider myself developing. I
17 consider myself involved in the development of the
18 system, right, because I helped to direct some of the
19 software updates based on my interactions with the
20 personnel of the company in my O.R. over a period of
21 several months, and then in their research and
22 development facilities.

1 Q So in your mind, John, what's the
2 difference between developing and being involved in
3 the development?

4 A I don't understand your question.

5 Q You -- you just stated that you didn't
6 develop the navigation system.

7 A I said I didn't design it.

8 Q I can read back the --

9 A Okay.

10 Q -- your earlier --

11 A I didn't design it. I've been instrumental
12 in developing software or working with the engineers
13 in the development of software upgrades and the
14 things that I've already mentioned that --

15 Q So John, you testified, "I don't consider
16 myself developing. I consider myself involved in the
17 development of the system."

18 A Right, so I didn't develop -- when I say
19 developing, I consider that de novo. Coming up with
20 the idea -- when I say involved in the development or
21 contributing to development, I have input, okay?
22 It's not my system, okay? I know that may be

1 semantics. In my -- in my head, it's clear. So I'm
2 not the one who developed or designed the system, who
3 came up with the idea of the system who then worked
4 with others to -- to put the system together.

5 The system was already an existing system.
6 It was an inadequate system. It was an inaccurate
7 system. I helped in developing the progress in the
8 software, so -- I didn't develop the software, but
9 had ideas that were input to help improve the system.
10 So I would consider that contributing to the
11 development of the system, not the design of the
12 system, okay, but developing improvements. That may
13 be not be the best word to use, but that's how I
14 envision it.

15 Q So in your mind, if you're providing
16 feedback, you're involved in the development of the
17 system.

18 MS. COHEN: Objection, form.

19 A If you're providing feedback that leads to
20 changes in the system, yeah, you're contributing to
21 the development of the system. So you may be
22 contributing to the development of the next

1 generation of the system, right? If it was my idea
2 to do these things and they incorporate those things
3 into either the next generation of the system or the
4 upgraded system, then I absolutely would consider
5 myself involved in the development of that aspect of
6 the system. I wouldn't say I designed it. I would
7 say I contributed to the development, the
8 improvement, to the improved accuracy of the system,
9 which was the entire goal of doing this, you know?
10 We needed a system that was more accurate than --
11 than what they were providing.

12 Q So John, if a -- if a ultrasound tech is
13 using an ultrasound machine to examine babies, would
14 you consider that person to be involved in the
15 development of the ultrasound machine?

16 A No.

17 MS. COHEN: Objection, form.

18 A They're utilizing the system. That's
19 completely different than what we just discussed.

20 Q And how is it different?

21 A Because they're just utilizing a system.
22 The system is produced for people to use it for a

1 certain purpose, okay?

2 Q So --

3 A Now, if that person -- now, that's clinical
4 experience, right? So -- now, say if that ultrasound
5 tech was finding that they were doing ultrasound for
6 fetal ultrasound, and obviously fetal ultrasound,
7 pretty good for detecting the sex of the baby, the
8 gender of the baby, and say that ultrasound system
9 was really not very accurate in determining the sex
10 of the baby, and there were a lot of boys born when
11 they were expecting girls and vice versa, but what if
12 that ultrasound tech then said well, here's what I
13 think the problem is, you know, and maybe we should
14 look at this, maybe -- maybe the ultrasound is doing
15 this or this and that's why it's not accurate, and
16 the ultrasound company then says okay, well, let's
17 look -- we'll look at that, right, and they look and
18 they -- and that ultrasound tech was asked to work
19 with that company, and they said well, yeah, there is
20 -- there's a software problem or there's a -- a
21 problem with the -- I don't know, the ultrasound
22 sensor, whatever, and you know, we're losing clarity,

1 we're losing resolution. Wouldn't you consider that
2 ultrasound tech to have been contributing to the
3 improvement of that system? That's what I'm
4 describing.

5 That's different than if the ultrasound
6 tech's like just using the system and doing their job
7 and nothing more. There's a lot of things that I
8 don't -- you know, that I use, I don't -- in a
9 clinical use that I don't provide feedback --

10 Q Uh-huh.

11 A -- that helps to make it better. Then I'm
12 just using the product.

13 Q So in the ultrasound tech example, what if
14 the -- let's say the tech is providing feedback.
15 What if the company doesn't implement the feedback,
16 are they still involved in the development?

17 MS. COHEN: Object to the form.

18 A So that -- in that particular case, they're
19 giving their feedback, but if -- if -- if the product
20 isn't changing at all, then they're not involved in
21 the development. They're involved in the clinical
22 use and they're making their own assessments of the

1 accuracy of the system, and in that case, I would
2 hope that that ultrasound tech would be talking to
3 their superiors and looking for alternatives because
4 they're not being appreciated by parents who are
5 having -- you know, who have nice big pink nurseries
6 and they have a boy.

7 Q I told my wife, I said I'm not repainting
8 the nursery, so if they're wrong, they're staying
9 pink. So for the navigation system, do you remember
10 providing feedback that wasn't followed?

11 A Well, I don't -- I can't remember every --
12 you know, every particular suggestion I made, but I
13 would be surprised if a hundred percent of my
14 feedback was -- was incorporated, but I will tell you
15 that there -- obviously because we saw after that --
16 you know, first of all, it opened the eyes of the --
17 the engineers and how there were a significant
18 difference between how rhinologists or
19 otolaryngologists, sinus surgeon uses the system
20 compared to what they -- in their lab, you know, with
21 no patient care, no patient contact, what they
22 thought was how it was being used.

1 Q For the navigation system, were you an
2 employee of that company?

3 A Never.

4 Q What was your relationship with them?

5 A I'm considered -- well, at times -- you
6 know, the navigation system is owned by Medtronic, so
7 at times, I've been a consultant for Medtronic, and
8 they consider me a -- what's the word? A key thought
9 leader because of my national position as a -- as a
10 president of the American Rhinologic Society, and you
11 know, just national, internationally known in my
12 field.

13 Q And do you have a consulting agreement
14 signed with Medtronic?

15 A I presently do not know if there's an
16 active agreement or not. The last -- the last -- and
17 we discussed this during -- during the last
18 deposition actually. I try to avoid being a
19 consultant for anyone. I will do it selectively if
20 necessary. So I spoke at a meeting last June in
21 Kuala Lumpur, Malaysia, where I was on -- I was doing
22 a talk on office sinus surgery, so I signed a

1 consultant agreement specifically for that talk so
2 that I could be compensated for my time since this
3 was a sponsored talk. So it was me and three other
4 physicians from around the world, but I haven't had
5 any contact with them in a consultant capacity since
6 that time.

7 Q Are you listed as an inventor on any
8 Medtronic patents?

9 A I am not.

10 Q In any of your consulting work, have you
11 been listed as an inventor on a patent?

12 A I have not.

13 Q John, have you provided feedback on the
14 development of a RF energy delivery device?

15 A I've provided feedback. I wouldn't
16 necessarily consider it on the development of the
17 device. I've provided feedback on procedural aspects
18 of -- of devices, you know, and that would be as far
19 as how I thought the procedure could be improved. I
20 haven't, to my recollection -- again, I've been doing
21 this 30 years, so there could be something in there
22 that I'm not recalling, but I -- not in the design or

1 development of a radiofrequency device. I've given
2 feedback, like I said, of even the Aerin device or
3 the procedure to use the Aerin device on internal
4 nasal valve.

5 Q And what sort of feedback have you
6 provided?

7 A Feedback on the procedure as far as parts
8 of the preparation of getting the patient more
9 comfortable from an anesthesia standpoint, as far as
10 -- and I can't remember the specifics of that. I
11 absolutely remember that, you know, maybe for a
12 second -- second or third time or maybe even all of
13 those times I've used it because the first time
14 you're using a device, obviously it's -- frequently
15 we'll have the rep there. You know about it, you've
16 read it, but usually have the representative there
17 who's been involved in dozens to hundreds of them to
18 -- to also be there for question, whatever. So I
19 would give feedback to the representative, you know,
20 on what I think makes it, you know, more comfortable
21 for the patient as far as local anesthetic injections
22 or positioning of the device or things like that.

1 Q And why is it that you don't consider that
2 feedback to be development, but you consider your
3 feedback for the navigation system to be development?

4 MS. COHEN: Objection, form.

5 A Yeah, well, it's -- it's feedback -- like I
6 said, if it's for developing the device, and that's
7 what we're talking about, the difference of
8 developing a device or just -- or even changing a
9 procedure, but the feedback that I'm giving is -- a
10 lot of it is for my -- you know, what I think makes
11 it easier for people to do the procedure. I'm not
12 necessarily changing the device, right? I'm not
13 changing the -- I'm not saying well, you know, this
14 device is inadequate because of this. What we talked
15 about the microdebrider, we're changing, we're
16 improving the device, we're changing the software,
17 we're improving the accuracy, right? So they're all
18 different ways that you can give feedback, some of
19 which is -- may just be your thoughts on the
20 procedure that don't necessarily lead to any changes.
21 Others are thoughts on improving the efficacy of a
22 procedure for a device or both, so there's all

1 different degrees of what feedback, or all different
2 directions that feedback can lead to, and not
3 necessarily -- not necessarily every one of them is
4 going to be in developing, or further developing a
5 device.

6 Q So just to confirm, you haven't been
7 involved in the development of a RF energy delivery
8 device.

9 A I have not. Now, there's going to be one
10 caveat, and it's not a caveat, but it's just -- just
11 for completion sake. That device, the microdebrider,
12 the disposable office-based microdebrider that we
13 were developing over a period of a few years, when we
14 considered what all to include in the device, there
15 had been a previous iteration of an office -- I'm
16 sorry, of an O.R. microdebrider that came from -- and
17 I don't -- it was from a company called Gyrus.

18 I don't remember if it was Gyrus at the
19 time because these companies get bought and sold and
20 -- but they had a microdebrider called a Diego, and
21 the Diego had radiofrequency included on the device
22 on the tip. So in addition to having mechanical

1 energy, it had radiofrequency energy.

2 So we considered in the beginning and for
3 the first iteration, even though it wasn't included
4 in the disposable microdebrider, considered whether
5 radiofrequency needed to be used on the device, but
6 we didn't get to the point of including it.

7 Q You had mentioned earlier that you
8 considered the microdebrider to be a device that
9 delivers energy to tissue, correct?

10 A Correct.

11 Q Did you work in the development of any
12 other devices that generally deliver energy to
13 tissue, although maybe not RF energy?

14 MS. COHEN: Objection, form.

15 A Not that I can recall at this point.

16 Q So the microdebrider would be the only
17 device that delivered some sort of energy to tissue
18 that you developed.

19 A Correct.

20 Q Let's take a look at paragraph 12 of your
21 declaration, John.

22 A Okay.

1 Q You state, "The fact that I'm a person of
2 ordinary skill in the art is not inconsistent with
3 the fact that in the course of preparing my first
4 declaration, I had a discussion with Dr. Martin, an
5 engineer with experience designing the underlying
6 circuitry used to implement energy devices." Do you
7 recall, John, that in your previous deposition, you
8 testified that you'd had a discussion with
9 Dr. Martin?

10 A Yes, I do.

11 Q Have you spoken to Dr. Martin since that
12 discussion?

13 A I have not. I've ever only spoken with him
14 that one time.

15 Q Did Dr. Martin provide any input or comment
16 on your reply declaration, John?

17 A No, he has not. I've had -- like I said,
18 in addition to not speaking to him since that one
19 time, I've had zero communication with him.

20 Q Did you review his reply declaration?

21 A I have not.

22 Q Did he review your reply declaration?

1 MS. COHEN: Objection, form.

2 A I have no idea whether he did or didn't.

3 Q In paragraph 12, you go on to state, "Based
4 on my knowledge" -- sorry, "Based on my own knowledge
5 and experience, I was qualified and did offer
6 opinions on the teachings of Stern regarding
7 configurations of bipolar electrodes and their
8 applicability to the challenged claims. However,
9 Stern goes further than the '271 patent in disclosing
10 implementation details about the circuitry used to
11 operate the bipolar electrodes, the physics of
12 delivering energy to tissue, among other things. For
13 these aspects of Stern that go beyond what the '271
14 patent itself teaches into how the energy delivery
15 devices work, my discussion with Dr. Martin helped
16 support and confirm my understanding of the prior art
17 teachings." So John, do I understand from that
18 statement, that you needed Dr. Martin's help with the
19 details about the circuitry used to operate the
20 bipolar electrodes?

21 MS. COHEN: Objection to form.

22 A No, that's not an appropriate assumption,

1 and the other thing is that, just to -- along those
2 same lines, is that in the -- the response from
3 Aerin, it repeatedly says that I relied on Dr. Martin
4 for my opinions, which is not the case, as it says
5 here, and it said in my first declaration that I had
6 discussions, and I -- and those discussions were just
7 to ask questions about my own assessment of Stern,
8 Edwards and other prior art, and those discussions
9 confirmed my already-existing opinions from my own
10 analysis.

11 Now, when we're looking at '271, patent
12 '271, patent '271, the reason why it says that Stern
13 goes into much more detail is the '271 patent is --
14 essentially states it's a method for treating nasal
15 tissue, and it really doesn't talk about the
16 circuitry very much if at all. Makes some very kind
17 of rudimentary surface comments about the details of
18 the electrical configuration, whereas Stern is
19 actually not just a method. It's a method for
20 designing the system and a method for treating the
21 tissue.

22 So Stern obviously goes into much more

1 detail about how the electrodes are configured, how
2 they are -- how they are charged, how they're
3 powered, how they can be manipulated or, I'm sorry,
4 configured from monopolar, bipolar or multiple
5 bipolar pairs. So there was a lot more detail in
6 Stern, a lot more circuitry compared to the '271
7 patent.

8 Q So --

9 A So that was some of the questions I would
10 have -- and I can't tell you exactly what the
11 questions were because that meeting was well over a
12 year ago, but those are kind of some of the things
13 that were discussed with Dr. Martin.

14 Q So you didn't need help in understanding
15 the details about the circuitry used to operate the
16 bipolar electrodes?

17 A No, I didn't need help. I just needed
18 confirmation, or I was looking for confirmation to --
19 that my assessment was the correct assessment, which
20 it was.

21 Q In your first deposition, John, you stated,
22 and I'm quoting here, "Dr. Martin is much more

1 involved in the technical side of devices." What did
2 you mean by that?

3 A Oh, absolutely. He's a -- Dr. Martin's an
4 engineer. I'm not an engineer, but as -- so he --
5 so, you know, if we needed to take a -- if someone
6 needed to take apart a device and analyze the
7 circuitry, that would be Dr. Martin. That wouldn't
8 be me, but when I use a device, which I use devices
9 every day in my practice --

10 Q Uh-huh.

11 A -- many different devices, I know what the
12 device can do, I know what the safety profile of the
13 device is. I know how the device delivers energy,
14 how I can manipulate the device to deliver energy,
15 how to set up the console, put in the parameters that
16 I am trying to deliver. Can I take apart the device
17 and tell you exactly what every piece is? No,
18 absolutely not. I'm a physician, not an engineer,
19 but these medical devices are configured so that they
20 are easy to use for a physician. They have profiles
21 that you pick a profile, you pick, you know, a
22 certain -- a certain configuration that works for

1 what you're using it for.

2 Q So you comment in paragraph 12 about the
3 physics of delivering energy to tissue, so you didn't
4 have any problem understanding the physics of
5 delivering energy to tissue.

6 MS. COHEN: Objection.

7 A Rudimentary. I can't go back to my physics
8 in undergrad, you know, to have a hundred percent
9 understanding, but I understand enough of it to be
10 able to -- to safely and effectively use these
11 instrument -- this instrumentation, or to assess what
12 the applications in this case, to be able to assess
13 what Stern is teaching and how it can be applied.

14 Q So John, you didn't need any help from
15 Dr. Martin with respect to this case; is that
16 correct?

17 MS. COHEN: Objection, form.

18 A Honestly -- yeah, honestly, I wouldn't have
19 changed anything -- anything that I believed or
20 included in my primary declaration or this
21 declaration, and as I said, I haven't consulted with
22 Dr. -- or even spoken with Dr. Martin since prior to

1 that -- my initial declaration.

2 Q So why did they need Dr. Martin? Why not
3 just rely upon you?

4 MS. COHEN: Objection, form.

5 THE WITNESS: That would be a question that
6 you may have to ask counsel.

7 MR. WARD: Okay, we can take a break.

8 (Recessed at 10:29 a.m.)

9 (Reconvened at 10:36 a.m.)

10 BY MR. WARD:

11 Q John, I want to turn to paragraph 18 of
12 your declaration, Exhibit 1083.

13 A Reply declaration, correct?

14 Q Yes.

15 A Okay, okay.

16 Q You state in paragraph 18, "Dr. Bikson
17 opines that the claimed method steps of challenged
18 claim 1 must be performed in the written order. I
19 also understand that the patent owner has proposed
20 construing claim 1 to require claim steps to be
21 carried out in order. In my first declaration, I
22 explained that the prior art references disclose the

1 claimed steps in the specific order in which they are
2 claimed. First, the treatment element of Edwards
3 '535 in view of Kong or Liang and Stern contacts the
4 mucosa as recited by limitation 1A. Next,
5 radiofrequency energy is applied as recited by
6 limitation 1B. Finally, the treatment element is
7 removed from the nasal array as recited by limitation
8 1C."

9 And then you go on to state in the next
10 paragraph, paragraph 19, that, "If the board adopts
11 the patent owner's construction requiring the steps
12 of claim 1 to be carried out in that order, that
13 would not change my opinion that the claims are
14 unpatentable." Do you agree, John, that contacting
15 the mucosa, delivering energy and removing the
16 treatment device is the common sequence of steps for
17 nasal treatment?

18 MS. COHEN: Objection, form.

19 A Could you say that again?

20 Q Sure. Do you agree that contacting the
21 mucosa, delivering energy, and then removing the
22 treatment element is the common sequence of steps?

1 MS. COHEN: Objection, form.

2 A Well, in this claim, I believe that that's
3 -- that's what's stated here, the first -- the first
4 step is -- first of all, it's inserting -- inserting
5 the device. Secondly would be contacting the mucosa,
6 applying the radiofrequency and then removing the
7 device would be the steps.

8 Q Is it possible to rearrange those steps and
9 still have effective delivery?

10 MS. COHEN: Objection to form.

11 A Could you give me an example?

12 Q That's my question to you, John. Is there
13 another way you could arrange those steps and still
14 have effective delivery?

15 MS. COHEN: Objection, form.

16 A Well, I don't see how you could -- as I sit
17 here now -- now, I can't tell you if I -- it would
18 change if I had a lot of time to think about it, but
19 in order to deliver the energy, you need to contact
20 the tissue that you want to deliver the energy to.
21 Before you do that, you have to insert the device.
22 After you deliver the energy -- you can't deliver the

1 energy without contacting the surface.

2 Now, are there devices that may be able to
3 -- there are things like lasers. A laser doesn't
4 have to contact the device. A laser can actually
5 project the energy. So if we're talking about
6 something other than radiofrequency, that could be
7 possible, but that's not what we're talking about
8 here. So I'm not aware of any radiofrequency devices
9 that don't have to contact the tissue in order to
10 deliver the energy, so the contact with the tissue,
11 the mucosa, would need to precede the delivering of
12 the energy, and then the device is removed. Does
13 that answer your question?

14 Q It does. Thank you.

15 A Okay.

16 Q John, what is an electrode?

17 A What is an electrode? It's an electrical
18 component that can deliver energy.

19 Q And what is the electrical component made
20 of?

21 MS. COHEN: Objection, form.

22 A Well, I'm not -- I can't tell you exactly.

1 I would think that there are multiple things that an
2 electrode can be made of, various types of metal, but
3 -- but I can't tell you specifically what an
4 electrode is going to be -- or what all the possible
5 types of materials that an electrode can be composed
6 of.

7 Q Do you know of a common material that
8 electrode is composed of?

9 MS. COHEN: Objection, form.

10 A I'm not an engineer. I'm not an
11 electrician, so I would leave that up to the people
12 who design and develop -- or develop devices or
13 design electrodes.

14 Q So you said that an electrode delivers
15 energy; is that correct?

16 A It can, yes, it can deliver energy. It can
17 be involved, it can be a portion of an energy-
18 delivering device. For instance, there are monopolar
19 electrodes and bipolar electrodes, and a monopolar
20 electrode is -- can be a single electrode, and
21 bipolar is a pair of electrodes that work together.

22 Q And what types of energy can a electrode

1 deliver?

2 MS. COHEN: Objection to form.

3 A Well, one is, you know, bipolar -- bipolar
4 energy, and that's what we're discussing in this
5 case.

6 Q What is bipolar energy?

7 A Energy -- it's a electrical energy that
8 gets delivered between two poles, between two
9 electrodes.

10 Q And what does that energy consist of?

11 MS. COHEN: Objection, form.

12 A I think that can go to a very fundamental
13 level, and I'll leave that up to the physics -- or
14 you know, the -- or I'm sorry, the engineers. You
15 know, I use this type of energy all the time as a
16 clinician. You know, they -- I'm not -- my ability
17 to use this technology is determined on the efficacy
18 and the safety profile of the device, not necessarily
19 what the electrodes are made of and other -- the
20 other factors.

21 Q So you don't know what type of energy's
22 delivered by the bipolar electrode?

1 MS. COHEN: Objection.

2 A It's electrical energy. It's bipolar
3 electrical energy. As far as whether we're talking
4 the details of exactly what -- what is in the
5 current, I'm not -- you know, that's not something
6 that I've reviewed to -- or it's not something that's
7 even essentially for clinical use is important.

8 Q And does an electrode have a power source?

9 A Well, any electrical energy has a power
10 source.

11 Q And for RF bipolar electrode, what is the
12 power source?

13 MS. COHEN: Objection, form.

14 A I don't understand what the power source
15 is. What do you mean, what the power source is?

16 Q So you said --

17 A I can say simply you plug it into the wall.

18 Q So the power is a -- a power coming from
19 AC?

20 A As a current, yes.

21 MS. COHEN: Objection, form.

22 A That would be my understanding. I mean,

1 you know, again, as a clinician -- and remember, so
2 in evaluating the '271 patent, this is a patent that
3 we're talking about that is a method of treating
4 nasal tissue, right? It doesn't talk very much about
5 any of the details of the circuitry, and really it is
6 about a clinical application of bipolar energy. So
7 from a standpoint of evaluating this claim, that is
8 the primary focus of this patent and of the claim
9 that I'm evaluating.

10 So as we said, Stern gives much more
11 information about the circuitry and various factors
12 that -- that provide the charge for their bipolar
13 electrodes, whereas Stern -- I mean, sorry, the '271
14 patent doesn't go into any of that detail.

15 Q Is it your understanding that the bipolar
16 energy includes RF energy?

17 A Yes.

18 Q Can it include other types of energy?

19 A I believe it can. I can't tell you what
20 those particular types of energy are, as I'm, as I
21 said, not an -- not an engineer.

22 Q But your understanding is that RF energy is

1 exchanged between the two electrodes of a bipolar
2 electrode?

3 A Well, bipolar -- in a bipolar,
4 radiofrequency energy flows between the two bipolar
5 electrodes.

6 Q How does a monopolar electrode differ?

7 A Monopolar, it can be a single electrode,
8 and it doesn't have a paired electrode with it, and
9 actually, it requires grounding, so it requires that
10 there be some kind of grounding unit. In the
11 operating room, it's a grounding pad because the
12 energy has to exit somewhere, right? It has to flow
13 to somewhere, and that grounding pad is where it
14 flows to, and there's -- there's many other
15 differences between monopolar and bipolar energy.

16 Monopolar energy is -- is a higher
17 temperature than bipolar energy. Monopolar energy
18 can -- is less controllable because obviously it's
19 not flowing directly to a second electrode. It's
20 flowing to a grounding pad. It tends to cause more
21 collateral damage, so you get a bigger area of
22 treatment than bipolar area.

1 Q So with a bipolar electrode, the RF energy
2 passes between the two terminals of the electrode,
3 correct?

4 A Correct, between --

5 MS. COHEN: Objection.

6 A It passes between the bipolar electrodes.

7 Q And in a monopolar electrode, the energy
8 passes between the monopolar electrode and a
9 grounding pad, correct?

10 A Some sort of grounding pad or source or --
11 yes, some sort of ground.

12 Q So you would agree that in both, there's a
13 flow of energy between two terminals?

14 A Between two points, correct.

15 Q And with a monopolar electrode, what
16 dictates the current path?

17 MS. COHEN: Objection, form.

18 A So I can't tell you exactly I know how a
19 monopolar works because we use monopolar electrodes
20 very frequently in the operating room.

21 Q Uh-huh.

22 A So I mean, they work by direct contact, you

1 know, the -- and I can speak specifically to the
2 monopolar devices that I use and I've used for over
3 30 years, 35 years actually, and they -- actually,
4 it's 36 years if you -- and that would be that it --
5 the -- the monopolar electricity, monopolar is
6 directly where you contact it, right, and there -- it
7 can spread around the edges there, and then they --
8 the current dissipates to the point of the grounding
9 pad. That's why if your grounding pad's on the leg
10 and you're treating the nose, you don't get treatment
11 effect between where you're touching in the nasal
12 cavity and -- and the thigh or wherever the -- the
13 grounding pad is.

14 Now, how that dissipates, why it doesn't
15 happen, I can't tell you all -- or why -- why it
16 doesn't cause any further treatment effect I can't
17 tell you. I'm not a -- you know, I don't -- I don't
18 know the details of the dissipation.

19 Q So you're saying that if I put the
20 grounding pad on a patient's leg for a nasal
21 procedure, it will not work for a monopolar
22 electrode?

1 A Well, no, it does.

2 Q It does.

3 A No, it does, absolutely. You have to have
4 -- anywhere on the patient it'll work.

5 Q Anywhere on the patient.

6 A Anywhere on the patient it'll work.

7 Q And where -- where's the common location
8 that you put it?

9 A On the leg.

10 Q On the leg?

11 A Yeah.

12 Q And --

13 A And if we don't -- if we don't put one on,
14 the device doesn't work at all. It has to have that
15 grounding -- that ground so the current can actually
16 travel somewhere. So I can put the -- if I don't put
17 the grounding pad, or someone doesn't put the
18 grounding pad on the patient and I put a monopolar
19 and I either push the button or step on the pedal,
20 whatever, there are different ways you can do it,
21 nothing will happen.

22 Q And --

1 A It has to have a grounding pad.

2 Q What is your understanding of the current
3 path? Current is flowing between --

4 A In that --

5 MS. COHEN: Objection, form.

6 A I'm sorry, and I didn't mean to cut you
7 off. I'm sorry. And that's what I'm saying. I --
8 the current is obviously going to dissipate between
9 the site of application, so in my case, in the nasal
10 cavity or oral cavity or wherever it may be, and the
11 grounding pad, so the point where there is no
12 treatment effect beyond the depth of the treatment in
13 the nasal cavity and the grounding pad. So there is
14 no treatment effect that's going to go in between
15 those. The physics of that I'm not familiar with,
16 but I absolutely know that there's no treatment
17 effect beyond the area of contact so that you don't
18 get any kind of burn anywhere else.

19 Q Is the RF energy applied by a monopolar
20 electrode the same as the RF energy applied by a
21 bipolar electrode?

22 MS. COHEN: Objection, form.

1 A I don't understand the question.

2 Q What type of energy does the monopolar
3 electrode provide?

4 A Well, so as I already mentioned, energy
5 provided by a monopolar is going to be a much higher
6 temperature. Radiofrequency energy tends to be in a
7 certain range. Monopolar energy is usually a much
8 higher temperature than radio -- than bipolar energy.
9 So bipolar energy -- we use bipolar energy -- that's
10 why we use it so much in the nasal cavity, because it
11 has a much more -- it's much safer profile, and it
12 only flows between the two bipolar electrodes, so we
13 can avoid -- as we have in monopolar energy, there is
14 a little less controllability, so if you use a three
15 millimeter monopolar electrode cannula, you're going
16 to -- you could end up with bigger than three
17 millimeter area of treatment, whereas if you have a
18 bipolar, you're only going to get treatment between
19 the bipolar electrodes, and it's going to be a much
20 lower temperature. You get much less collateral
21 damage so working near vital structures is going to
22 be much safer.

1 Q So it's your understanding that the energy
2 output from the monopolar electrode is different than
3 the energy output from the bipolar electrode.

4 MS. COHEN: Objection, form.

5 A In my -- in the -- the devices that I
6 typically use, that is absolutely the case. Now, you
7 can adjust the temperature of all of these things.
8 So it's not just a standard, you know, you turn it on
9 and off and there's nothing than can be adjusted.
10 Both monopolar and bipolar energy are adjustable, so
11 you can have settings from zero to a hundred for both
12 of them, right, and it may vary based on power
13 console, but typically the ones we use are zero to a
14 hundred, and so you can turn up the settings on both
15 monopolar and bipolar to provide a greater amount of
16 energy, but what's different is the controllability
17 especially of bipolar compared to monopolar because
18 the bipolar is only traveling between the bipolar
19 electrodes, whereas the monopolar has to travel
20 throughout.

21 Q John, do you do procedures where you'll use
22 both --

1 A Absolutely.

2 Q -- monopolar and bipolar?

3 A I'm sorry. Yes, absolutely.

4 Q Is that the majority of your procedures --

5 A No.

6 Q -- you use both?

7 MS. COHEN: Objection, form.

8 A No, not the majority of procedures. Every
9 procedure is different, and again, monopolar and
10 bipolar have different -- in my practice and a lot of
11 otolaryngology practices, but especially in rhinology
12 and nasal sinus surgery, there are roles for both
13 monopolar and bipolar energy, and the reason is there
14 -- the nose is a very vascular structure, so that's
15 why people get nose bleeds. Your nose is full of
16 blood vessels. There are some -- there are a lot of
17 small blood vessels, but there are also some
18 significant blood vessels, arteries in the nasal
19 cavity.

20 So when we do a lot of sinus surgery and
21 other advanced nasal surgery, some of these larger
22 arteries that we might get into are better treated

1 with monopolar energy because we can control them
2 much quicker, but when we start getting near the eye
3 or the orbit, the eye socket, we start getting near
4 the brain, you get near the skull base, and so there
5 are some arteries, the anterior and posterior ethmoid
6 artery that travel from the eye socket across the
7 roof of the nose into the brain, and if we get
8 bleeding from those vessels, we do not want to treat
9 them with monopolar cautery if they're in the bone
10 that separates the brain from the sinus, so we're
11 going to use bipolar cautery in those situations.

12 Also if we're -- if we've taken down the
13 bone between the sinus and the brain and we're
14 looking at the covering of the brain, we're
15 definitely not going to use monopolar because
16 monopolar can conduct straight through the brain. It
17 can cause collateral damage. Bipolar is only going
18 to be treated -- it's only going to treat where we
19 touch it, so we routinely use bipolar cautery in that
20 area.

21 Q And John, do you use an instrument, a
22 device that provides a -- that can provide both

1 monopolar and bipolar from the same treatment
2 element?

3 A Our -- our monopolar and bipolar devices
4 are separate. I do not have a -- I'm not sure if
5 there is one that is available. I just have not used
6 it because that would be -- it's just we use -- some
7 cases we only use monopolar. Some cases we only use
8 bipolar, but we use them separately, so I do not --
9 I'm not aware of a device that I've used at least
10 that has monopolar and bipolar. Be great to have
11 one. Honestly, you know, one of the problems though
12 is that -- so we do have consoles. All of our
13 consoles do monopolar and bipolar.

14 Q Uh-huh.

15 A So our energy source does both. We don't
16 have separate consoles for monopolar and bipolar.
17 They're all the same console, so the energy source is
18 the same. What's different is the handpieces, and
19 the handpieces need to be different because the
20 energy is -- you can't use a bipolar -- you wouldn't
21 use a bipolar forcep to deliver monopolar energy
22 because -- well, you want different forceps to apply

1 it to different areas.

2 Q I want to show you now, John, a copy of
3 Exhibit 1033 from IPR2024-277.

4 A Oh, okay.

5 Q And that is a copy of the patent number
6 5,562,720. Do you see that at the top right of the
7 document?

8 A Yeah, 5,562,720, yes.

9 Q And do you recognize this document, John?

10 A Yes, this is Stern.

11 Q Okay. I'd like for you to turn to page 13

12 --

13 A Of Stern or --

14 Q Thirteen of Stern, yes.

15 A Okay.

16 Q It's figure 16, which might make it easier
17 to find.

18 A Okay, okay.

19 Q Yeah, 16 at the bottom --

20 A Uh-huh.

21 Q -- of the page. Do you see it, John?

22 A Yeah.

1 Q Okay. I'm going to read you the --

2 A Okay.

3 Q -- description from Stern while you're
4 taking a look at figure 16.

5 A Okay.

6 Q Stern states at column 13 line 5, "The
7 figure 16 shows a structure or a balloon 250 having
8 two electrodes 252 and 254 which operate in the
9 monopolar condition. It can be seen that the
10 electrical field lines proceed between each one of
11 the electrodes 252 and 253 and return electrode not
12 shown comprising a ground plate or patch, such as the
13 return electrode 230 of figure 15 placed on the
14 outside of the patient."

15 A You were -- you were just reading figure
16 16, correct?

17 Q I was reading figure 16, yes.

18 A Okay, because you said 252 and 254.

19 Q Yeah, I believe they're --

20 A And of course, there's no 254.

21 Q Yeah, I believe there are some typos --

22 A Yeah.

1 Q -- in Stern.

2 A And there's no -- yeah, 254 in the picture.

3 Q Right, so I think Stern has some
4 typographical errors, but would you understand the
5 two boxes at the top of figure 16, which are labeled
6 252 and 256, to be the electrodes?

7 A Yes, in this -- in this configuration
8 embodiment, then what you just described is two
9 electrodes. I believe you just said two monopolar
10 electrodes.

11 Q Okay, so even though there's -- there are
12 two electrodes shown here, your understanding is that
13 this is an illustration of a monopolar electrode,
14 correct?

15 A Didn't you just -- I believe you just read
16 monopolar, yes.

17 Q Yes.

18 A Because Stern has configurations where they
19 -- has embodiments where they can be configured as
20 monopolar or bipolar, and he described -- just
21 described this one, as you read, as being monopolar.

22 Q Right, yeah, Stern says figure 16 shows a

1 structure or a balloon 250, which I think is --

2 A Right.

3 Q -- generally 250 --

4 A The whole thing, yeah.

5 Q -- having two electrodes --

6 A Right.

7 Q -- which operate in monopolar condition.

8 A Correct.

9 Q So is it your understanding that the -- the
10 lines shown in figure 16 are the electrical field
11 lines?

12 A Yes, that's how I would interpret that, and
13 they're flowing away from the electrodes, and as you
14 read, to a ground, or to a return, which is a ground.
15 Same thing.

16 Q And do you have an understanding of what
17 dictates the path of those electrical field lines?

18 A Yeah, I don't -- I don't understand or
19 fully -- I don't know what he is depicting of them,
20 whether they're actually --

21 Q Uh-huh.

22 A -- going in a direction or they're just

1 depictions of an energy field, or energy flow,
2 rather.

3 Q Turn over to page -- the next page and take
4 a look at figure 17.

5 A Correct.

6 Q And I'll read to you what Stern --

7 A Uh-huh.

8 Q -- states about figure 17. It says, "In
9 contrast, a bipolar operation is shown in figure 17.
10 The balloon 256 includes electrodes 258 and 260
11 labeled" --

12 A Got it right there.

13 Q "The electrical field lines proceed between
14 the two electrodes. With a bipolar electrode, the
15 current paths are more easily controllable by
16 appropriate placement and activation of the
17 electrodes, whereas the field lines in figure 16 in
18 monopolar operation depend upon the placement not
19 only of the electrodes 252, 254, but also the
20 placement of the grounding pad 230 on the physical
21 structure of the individual patients.

22 A Right.

1 Q So in taking a look at figure 17, do you
2 have an understanding of what controls the electrical
3 field in figure 17?

4 A Sure, that's the --

5 MS. COHEN: Objection, form.

6 A Sorry, that's the bipolar nature of the --
7 the electrodes, so it's flowing between the bipolar
8 electrodes, whereas in -- that's in 17. Whereas in
9 16, it's unipolar, so it's flowing away from the
10 electrodes towards the ground or towards the return,
11 and that's exactly what he describes.

12 Q And figure 17, the electrical field lines
13 are shown in a semicircle, correct?

14 A They're -- that's how they're depicted
15 here.

16 Q And is that your understanding of how the
17 electrical field lines flow between the two
18 electrodes of a bipolar electrode?

19 A Well, the bottom line is they flow between
20 -- whether they flow semicircular or linearly I can't
21 tell you. They're -- this is the depiction on how
22 they're flowing, and basically what it's saying is

1 they're flowing between the two electrodes.

2 Give you an example where we use bipolar
3 electrodes all the time or bipolar devices all the
4 time in the operating room which have different
5 configurations than this. Those configurations are
6 more like paddles that come together. Those paddles
7 are likely not going to be flowing in an arc as much
8 as they are going to be from one paddle to the other.
9 So I think this is just a depiction so that it shows
10 you the surface of the device and the fact that it's
11 going just between one electrode and another.

12 Q Take a look at paragraph 21 of your
13 declaration. Sorry, not Stern.

14 A Oh, my declaration.

15 Q Yeah.

16 A Paragraph 21, okay.

17 Q You'll see that you reproduce figure 17 --

18 A Uh-huh.

19 Q -- from Stern, correct?

20 A Yes.

21 Q And just before the figure, you state,
22 "When bipolar energy is applied, the electrical field

1 lines proceed between the two electrodes," correct?

2 A Correct.

3 Q And so this is what you're talking about,
4 that the electrical fields are more concise and
5 controllable with the bipolar electrode?

6 A Correct.

7 Q The next sentence, you state, "A person of
8 ordinary skill in the art would have further
9 understood the S in bipolar electrode pairs to simply
10 mean that there are multiple pairs of electrodes,
11 like those shown in figure 17." What are you
12 referring to, John, when you say the S in bipolar
13 electrode pair?

14 A Well, in Stern in multiple areas refers to
15 bipolar electrode pairs, and what that's referring to
16 is that the device, and -- and there are multiple
17 devices in Stern that are depicted, or multiple
18 embodiments, figure 19 being one of them, that has
19 multiple electrodes depicted. In that case, there
20 are five electrodes. There are two rows of bipolar
21 electrode pairs, and it says pairs, not pair. So
22 it's not referring to a single bipolar electrode

1 pair. It is referring to multiple bipolar electrode
2 pairs. That's what the S is -- is noting.

3 Q I'd like to provide to you now, John, a
4 copy of your first declaration.

5 A Uh-huh.

6 MS. COHEN: We have a bound copy of --
7 BY MR. WARD:

8 Q You have one, okay. Anybody else want one?

9 A Thank you. Do you want to check this or
10 are you okay?

11 Q No.

12 A Okay.

13 Q You're fine. So what you're looking at
14 now, John, is Exhibit 1002 from IPR2024-277, correct?

15 A Yes.

16 Q And do you recognize this document?

17 A I do. It's my original declaration.

18 Q And so, John, can you identify for me where
19 in this original declaration you refer to figure 17
20 of Stern?

21 MS. COHEN: Objection, form.

22 A I'm looking still. I don't remember

1 whether or not that particular diagram was included
2 in Stern. And we're looking for figure 17, correct?

3 Q Figure 17 of Stern, yes.

4 A You know, I don't see that particular
5 figure in my original declaration unless you can
6 point me to it.

7 Q John, are you familiar with the guidelines
8 for patent claim construction?

9 MS. COHEN: Objection, form.

10 A I know -- I can't tell you that I'm
11 completely familiar with them, but I know some
12 aspects.

13 Q And how do you know those aspects?

14 A Just what I've been taught from
15 conversations with counsel.

16 Q John, is prior art to be considered to
17 determine the meaning of a claim term?

18 MS. COHEN: Object to the form.

19 A Could you -- could you repeat that
20 question, clarify for me?

21 Q Uh-huh. Is prior art to be considered in
22 determining claim construction?

1 MS. COHEN: Objection, form.

2 A I believe so.

3 Q Let's look back at paragraph 22.

4 A Of --

5 Q Of your declaration, the reply declaration.

6 A Okay.

7 Q We're going to go back to Exhibit 1083,
8 paragraph 22.

9 A Twenty-two. I'm sorry, paragraph 22?

10 Q Paragraph 22.

11 A Oh, okay.

12 Q And actually, I'm going to read from the
13 next page, 12, where it starts, "In my experience."

14 A Okay.

15 Q So you state, "In my experience, using such
16 devices, the terminology used to describe the bipolar
17 electrode pairs does not depend on whether the pairs
18 are active or not. For example, when the device is
19 turned off, a clinician would not cease to refer to
20 the electrodes on the device as a bipolar electrode
21 pair." John, is it proper to rely upon one's own
22 personal experience for claim construction of a term?

1 MS. COHEN: Objection, form.

2 A I'm not -- I am giving my assessment of
3 this. I'm not relying on it completely. There are
4 other examples that we use, but -- I mean, this is --
5 this is not the -- not the entirety of our -- my
6 opinion.

7 Q But is it okay to rely upon personal
8 experience for claim construction?

9 MS. COHEN: Objection, form.

10 A Well, I think we're mostly -- we're not
11 just relying on personal opinion. We're relying on
12 the prior art, and the prior art of Stern shows
13 multiple pairs of bipolar forceps and actually
14 describes multiple pairs of active bipolar -- I'm
15 sorry. Bipolar electrodes, not forceps. I'm sorry,
16 I misquoted there, but actually this describes
17 various configurations of single bipolar electrode
18 pairs that can be activated and multiple bipolar
19 electrode pairs that can be activated simultaneously,
20 but what this is describing is that when the device
21 is not turned on --

22 Q Uh-huh.

1 A -- what do we refer to those as? Are they
2 not bipolar pairs anymore, especially if it's a
3 purely bipolar device. For instance, if it's just --
4 or no monopolar, it's just bipolar, and there are two
5 pairs of electrodes, before they're turned on, are
6 they nonexistent or are they still two pairs of
7 bipolar electrodes? That's what this is referring
8 to. It's just -- it's just more theoretical than it
9 is practical.

10 Q If the statement is applying radiofrequency
11 energy with the bipolar electrode pairs, would you
12 agree that this would require the pairs to be turned
13 on?

14 A If it is applying -- actively applying
15 radiofrequency energy with multiple bipolar pairs,
16 then they would need to be turned on, correct, and
17 Stern meets that.

18 Q John, do you agree that the claims at issue
19 here used the term "pairs" in plural?

20 A Pairs can only be plural, so yes.

21 Q So the word "pairs" can't be singular?

22 MS. COHEN: Objection, form.

1 A No, that would be pair I would think, not
2 pairs. Pairs is plural. Pair is singular.

3 Q And --

4 A Now, a singular pair is still two things,
5 whereas pairs is multiple.

6 Q And do you agree that the claims at issue
7 here use the term "pairs" plural?

8 MS. COHEN: Objection, form.

9 A The -- I would have to look at the claim,
10 but I believe it does say pairs. It does say pairs,
11 okay.

12 Q You agree it says pairs.

13 A It says pairs.

14 Q Okay.

15 A I'll agree to that.

16 Q Well, let's look at the patent anyway.

17 A Let's look at the patent again.

18 Q I'm going to share with you a copy of
19 Exhibit 1001.

20 A Yeah, I know where to find it too.

21 Q Do you have a copy?

22 A No, no, I -- no, no, no. I mean on the

1 document, on the document.

2 Q Here it is. So I'm sharing with you a copy
3 of Exhibit 1001, IPR2024-277. Do you recognize this
4 document, John?

5 A Yes, this is the -- this is '271.

6 Q Okay. Let's turn to column 23, 64.

7 A Twenty-three -- this document's a lot
8 bigger than it was when I accessed it.

9 Q Yes, unfortunately, my folks printed these
10 single -- not double-sided yesterday.

11 A All right, 23, line 64? Okay.

12 Q It says, "In some embodiments of treatment
13 devices comprising an array or multiple pairs of
14 electrodes, each pair of electrodes, bipolar, or each
15 electrode, monopolar, may have a separate controlled
16 electrical channel to allow for different regions of
17 the treatment element to be actively" -- "to be
18 activated separately." John, do you agree that this
19 quote from the specification uses the term "pair" and
20 "pairs" in proper grammatical form?

21 MS. COHEN: Objection to the form.

22 A Yeah, I would agree.

1 Q So it talks about multiple pairs of
2 electrodes, each pair of electrodes --

3 A Correct.

4 Q So you would agree that the specification
5 identifies the term "pair" in the singular form,
6 correct?

7 A Correct.

8 MS. COHEN: Objection, form.

9 A Correct.

10 Q And just to turn to claim 1, which is at
11 the back of the patent, claim 1, the first clause,
12 contacting a treatment element of nasal airway
13 treatment device directly with nasal mucosa of the
14 nasal airway wherein the treatment element comprises
15 two rows of bipolar electrode pairs. As we
16 identified earlier, you would agree that the claim as
17 in claim 1 provides the term "pairs" in plural form,
18 right?

19 A Okay.

20 Q You agree?

21 A Yeah.

22 Q Okay. Now let's turn back to your reply

1 declaration.

2 A Uh-huh.

3 Q Paragraph 26.

4 A Okay.

5 Q In paragraph 26, you state, "I further note
6 that Stern uses the term 'pairs' nine separate times
7 to refer to its arrangement of bipolar electrode
8 pairs," and I just want to take a look at some of the
9 citations that you provide there, John. So we'll
10 look at Exhibit 1033.

11 A Okay. That's Stern?

12 Q That's Stern, Exhibit 1033.

13 A Do I have Stern -- I have Stern right here,
14 okay, and we're looking at --

15 Q So we'll start with Exhibit 1033, yes, at
16 column 2, line 36.

17 A Yeah.

18 Q I'll read it for us.

19 A Okay.

20 Q It says, "It's a further object of the
21 present invention to provide a system of selective
22 delivery of either monopolar RF energy to a single

1 electrode or bipolar RF energy to chosen pairs of an
2 array of separate electrodes, which are used to bring
3 the endometrial temperature to a desired level."

4 John, when Stern discusses selective delivery of
5 energy to chosen pairs, do you understand Stern to be
6 disclosing the delivery of energy to a chosen pair
7 from multiple pairs?

8 MS. COHEN: Objection, form.

9 A No, I do not understand it that -- to
10 indicate that.

11 Q What do you understand it to indicate?

12 A Well, first of all, this is a single
13 sentence from the entire document, and in other
14 places -- and I -- I could still understand this as
15 or bipolar RF energy to chosen pairs of an array of
16 separate electrodes which are used to bring
17 endometrial temperature. That could indicate
18 multiple -- activating multiple electrode pairs
19 simultaneously, but there are other -- in addition,
20 there are other areas in Stern that he talks about
21 various configurations that allow activation of
22 multiple electrode pairs at the same time, single

1 electrode pairs or multiple electrode pairs.

2 Q So when Stern says in this paragraph
3 selective delivery to a bipolar RF energy to chosen
4 pairs of an array of separate electrodes --

5 A Chosen pairs, right, so -- so that can have
6 a lot of different -- there can be a lot of different
7 configurations included in that statement of chosen
8 pairs, right? It could be -- I would think that he
9 would say a chosen pair if it was single, right?

10 Q Uh-huh.

11 A And that would be a single bipolar
12 electrode pair.

13 Q Right.

14 A But he says chosen pairs. Chosen pairs
15 would indicate multiple, just as you indicated pairs
16 means multiple, and since he actually mentions chosen
17 bipolar pairs rather than the chosen bipolar pair,
18 he's indicating multiple activated at the same time.

19 Q And with your understanding that Stern
20 discloses delivery of energy to certain selected
21 pairs versus certain unselected pairs, correct?

22 MS. COHEN: Objection to the form.

1 A No, I wouldn't -- I wouldn't say that at
2 all. It doesn't say it. It says selected pairs. It
3 doesn't say unselected pairs. Now, I will say,
4 because this, again, is one statement out of the
5 entire document, and there are other places where he
6 describes a multitude of arrangements that can be
7 configured, right?

8 So it can be monopolar, it can be bipolar,
9 it can be a single bipolar electrode pair, it can be
10 multiple bipolar electrode pairs. They can be
11 oriented differently. They can be oriented
12 horizontally or they can be oriented vertically. So
13 various bipolar pair -- or I'm sorry, various bipolar
14 electrodes can be oriented differently to select
15 different orientations or different configurations of
16 Stern's treatment element.

17 Q So let's look at another example. Your
18 next citation is column --

19 A Sure.

20 Q -- 3, line 37. It says, "The step of
21 controlling said radiofrequency energy can include
22 selectively providing bipolar energy to selective

1 pairs of said plurality of electrodes." So would you
2 agree that selective pairs means that you choose to
3 deliver energy to certain pairs among a group?

4 A Okay, so can I -- can I -- here's how I'm
5 going to respond, because I -- that's not a yes or no
6 answer. What it is, because Stern chose five
7 electrodes in figure 19, right? Even if we ignore
8 the last one, the fifth one on the bottom for -- for
9 -- for right now, he is describing here, again,
10 saying pairs, right? Not a pair, right? You can
11 activate a pair and have the other pair not
12 activated, but that's not -- even here,
13 grammatically, a step controlling said radiofrequency
14 energy can include selectively providing bipolar
15 energy to selective pairs, right? Not a selective
16 pair. A selective pair would be one. Selective
17 pairs is multiple.

18 So he's talking about -- and of said
19 plurality of electrodes because there's five
20 electrodes on this particular -- on 19. There's
21 actually eight electrodes on another one of his
22 embodiments, which is figure 4A. So there are

1 multiple combinations, and that is what this
2 statement reflects, is multiple possible
3 combinations, and multiple electrode pairs can be
4 activated simultaneously.

5 Q Because if there was only one pair, you
6 wouldn't need to choose a pair, correct?

7 MS. COHEN: Objection, form.

8 A No, that's incorrect also because this is a
9 programmable device, right? There's not just two
10 electrodes. So if there was only two electrode
11 bipolar electrodes or a single bipolar electrode
12 pair, then you can either choose it's on or off. I
13 mean, there's no choice there, but that's not what
14 Stern is describing or --

15 Q Right.

16 A -- showing as prior art. There is not a
17 single electrode pair. There's multiple electrode
18 pairs. There's the capability of activating a single
19 electrode pair, just as there is in patent '271, but
20 there is also the capability of activating multiple
21 bipolar electrode pairs simultaneously and various
22 configuration of those -- those pairs of bipolar

1 electrode pairs.

2 Q Let's look at column 13, line 27.

3 A Okay. Are we on --

4 Q Sorry, yeah, Exhibit 1033, Stern.

5 A Okay.

6 Q Column 13, line 27. It's one of your
7 citations.

8 A Just because I was on paragraph 27 here, so
9 you confused me.

10 Q Yeah, sorry.

11 A Okay, 13.

12 Q Uh-huh.

13 A Twenty-seven.

14 Q Line 27, Stern states, "The bipolar
15 arrangement allows various pairs of electrodes to be
16 picked in order to heat uneven or rather,
17 asymmetrical areas" -- sorry -- "within individual
18 patients in which the balloons are inserted or within
19 special needs for certain tissue destruction. That
20 is, any unusual features within an area to be heated
21 may be taken into account in a bipolar operation by
22 selection of different pairs of electrodes for

1 energization utilizing the circuitry of figure 15."

2 So John, do you understand various pairs of
3 electrodes to be picked to mean that they're selected
4 from a group of pairs?

5 A As I've already stated in the previous
6 answers, I take that to mean that various
7 configurations are possible where multiple electrode
8 pairs can be -- can be activated simultaneously, and
9 what this is describing is -- is the reason for being
10 able to pick multiple electrode pairs or various
11 electrode pairs is because of contour differences in
12 the target tissue.

13 Q Let's go back to your reply declaration.

14 A Uh-huh.

15 Q Exhibit 1083, and we'll go back to where we
16 were in paragraph 26.

17 A Okay.

18 Q And flip to the next page, 15.

19 A Uh-huh.

20 Q You state, "That is, the only support
21 Dr. Bikson offers for his interpretation is the
22 pluralization of the term 'pairs.'" You cite Exhibit

1 2001, Bikson declaration, paragraph 69, "And Stern
2 uses the same plural term, so consistency dictates
3 that a person of ordinary skill in the art would have
4 understood them to refer to the same thing." So
5 John, is it your understanding that the term "pairs"
6 refers to more than one pair?

7 A Correct.

8 Q If you go back one page, back to page 14 of
9 your declaration --

10 A Uh-huh.

11 Q -- you've reproduced an annotated version
12 of figure 19 of Stern there, correct?

13 A Correct.

14 Q And what is illustrated by your
15 annotations?

16 A So in this -- you mean what's colored?

17 Q In what's --

18 A Yeah.

19 Q -- colored in purple, yes.

20 A Okay. So what's colored in purple are the
21 -- the electrodes on inflatable bladder of the
22 treatment element in this figure 19 of Stern, and

1 what is in purple are four electrodes. There's
2 actually five on this bladder, but the fifth one is
3 not -- is not shaded in for this purpose, and what is
4 depicting row 1 and row 2, and row 1 shows a bipolar
5 electrode pair, and row 2 shows a second bipolar
6 electrode pair.

7 Q So how many pairs exist in row 1 of figure
8 19?

9 A So there's one in -- one pair in row 1, and
10 one pair in row 2.

11 Q And what would happen if all four
12 electrodes annotated in figure 19 were active at the
13 same time?

14 MS. COHEN: Objection, form.

15 A Then we would have two pairs of bipolar --
16 two rows of bipolar electrode pairs.

17 Q And between which electrodes would energy
18 flow?

19 A Well, in this -- as -- as I mention and
20 Stern teaches, there is programmability in his
21 design, so here, because we have it labeled row 1,
22 that would be row 1. Those two electrodes on the top

1 would be one bipolar electrode pair. Row 2 on the
2 bottom, the bottom purple would be a second bipolar
3 electrode pair, can also be configured that the two
4 on the left are a bipolar electrode pair and the two
5 on the right are a bipolar electrode pair, but the
6 way it's labeled here, we're using top and bottom as
7 two separate pairs.

8 Q So if all four annotated electrodes were
9 active, would current bleed from row 2 into row 1?

10 MS. COHEN: Objection to form.

11 A Would it -- it would flow between --
12 between the paired bipolar electrodes. For instance,
13 if the two on the left were both positive and the two
14 on the left are both negative, you're going to have
15 flow from -- between the positive and the negative,
16 correct? I mean, because it has to be a positive and
17 a negative.

18 Q Uh-huh.

19 A Right?

20 Q So do you agree that your annotations of
21 figure 19 from Stern don't show a row with multiple
22 pairs of bipolar electrodes?

1 MS. COHEN: Object to the form.

2 A Could you clarify what you mean?

3 Q In looking at your annotations to figure 19
4 of Stern on page 14 of your declaration, do you agree
5 that figure 19 does not illustrate a row that has
6 multiple bipolar electrode pairs?

7 A So --

8 MS. COHEN: Objection, form.

9 A You're asking whether figure 19 depicts a
10 single row with multiple bipolar electrode pairs?

11 Q Yes.

12 A Okay, so this particular embodiment depicts
13 rows of multiple bipolar electrode pairs, but not a
14 single row of multiple bipolar electrode pairs, but
15 this is only one embodiment of Stern. Stern has
16 another embodiment, figure 4A, that shows more
17 electrodes on the surface, and that is on page 21 of
18 my reply declaration, and in this embodiment, Stern
19 indeed shows a treatment element that's configured to
20 show multiple pairs of bipolar electrodes in a single
21 row, and the top row has four electrodes. That can
22 be similar to how figure 19 can be configured. It

1 can be configured to have multiple bipolar electrodes
2 pairs in a single row with four electrodes in row 1,
3 as is labeled on figure A on page 21 of my reply
4 declaration, and three electrodes in row 2, which can
5 be paired, and it can be oriented vertically also
6 where multiple electrodes can be -- electrode pairs
7 can be vertical.

8 Q John, can you identify for me where in your
9 original declaration, Exhibit 1002, you refer to
10 figure 4A of Stern?

11 A So it is not in my original declaration as
12 far as specifically referring to figure 4A, and we
13 refer to figure 19 because the patent describes rows,
14 multiple rows of bipolar pairs. It does not describe
15 multiple bipolar pairs in a single row, so figure 19
16 satisfies the claim of multiple rows of bipolar
17 pairs, so that's why if the claim was multiple
18 bipolar pairs in a row, that is also taught by Stern,
19 but that is not what the claim states. So that's why
20 figure 4A is not included in my original declaration.

21 Q So you did not refer to figure 4A of Stern
22 in your original declaration, correct?

1 MS. COHEN: Objection to the form.

2 A I'd have to completely review my original
3 declaration to be 100 percent sure, but as I already
4 mentioned, because figure 19, which is replicated in
5 my -- or mentioned in page 14 of my reply
6 declaration, figure 19 meets the criteria of -- meets
7 the claim, I'm sorry, of multiple rows of bipolar
8 pairs in claim 270 -- or in the patent '271.

9 Q Let's take a look at your original
10 declaration, Exhibit 1002, John.

11 A Sure.

12 Q We'll look at paragraph 61.

13 A Paragraph 61, okay.

14 Q So paragraph 61, this is where you provided
15 the annotation to figure 19 of Stern, correct?

16 A Correct.

17 Q You also provided an annotation to figure
18 15 of Stern, correct?

19 A Correct.

20 Q Does figure 15 of Stern disclose two rows
21 of bipolar electrodes, each having two bipolar
22 electrode pairs?

1 MS. COHEN: Objection, form.

2 A Figure 15 you're asking?

3 Q Figure 15.

4 A Okay, so figure 15 is actually what is
5 described in Stern as an example of activating a
6 single pair of bipolar electrodes, okay?

7 Q Uh-huh.

8 A So this is a depiction -- and again, it's
9 only one configuration in Stern, and it's showing
10 which -- the configuration that is required to
11 activate 220 and 222 alone, but that's just, as I
12 said, one configuration of Stern. This is one --
13 this is the configuration to activate a single
14 electrode pair.

15 Q And in figure -- your annotations to figure
16 15, what would you consider to be a row?

17 MS. COHEN: Objection, form.

18 A I'm not sure what your question is.

19 Q Which of the electrodes in figure 15 are in
20 a row?

21 A So in this depiction, the activated -- or
22 the -- okay, so in a row, if we are equating figure

1 19, 15 so that 220, 222 are the top row of electrode
2 -- the top row is the electrode pair on top, and 224
3 and 226 are the bottom row, row 2 would be the -- the
4 orientation, so 220 and 222 would be a row.

5 Q Do you agree that neither of those rows has
6 two bipolar electrode pairs?

7 MS. COHEN: Object to the form.

8 A Each one has a single bipolar electrode
9 pairs, which means multiple rows of bipolar electrode
10 pairs, but there's not multiple pairs within a single
11 row in this depiction.

12 Q Okay, let's turn back to Exhibit 1033,
13 Stern.

14 A Uh-huh.

15 Q We're going to look at column 12, line 44.

16 A Okay. I'm sorry, what did you say?
17 Forty-four?

18 Q Yes, 44. It's --

19 A It's the last line of the paragraph?

20 Q Yeah, the last line of the paragraph, it's
21 the description of figure 15, and I'll read it for
22 us. It states, "Figure 15 illustrates the use of

1 four electrodes 220, 222, 224 and 226, a voltage
2 source 228 with the same patient grounding pad or
3 patch or return electrode 230 as in, for example, the
4 Figure 5 unipolar arrangement."

5 A Okay, hold on.

6 Q Are you following me, John?

7 A What page? What --

8 Q Yeah, sorry. So we're -- if you're looking
9 at Stern, column --

10 A You said 12, right?

11 Q Uh-huh.

12 A Twelve, 44.

13 Q And line 44, or 46 I guess.

14 A Okay, 46, okay.

15 Q Yeah, yeah.

16 A All right, all right. There you go.

17 Q The description --

18 A Okay.

19 Q -- of figure 15 --

20 A Right, exactly.

21 Q And you're -- you've got a copy of --

22 A Yeah.

1 Q -- figure 15.

2 A I'm familiar with it.

3 Q Okay. So continuing on --

4 A Uh-huh.

5 Q It says, "The essence of figure 15,
6 monopolar," slash, "bipolar switching arrangement, is
7 that the physician or operator has the ability to
8 provide either monopolar or bipolar operation. When
9 the switch 232 is" -- "is closed, and the switches
10 234, 236, 238 and 240 remain open, the device
11 functions essentially the same as the Figure 5
12 embodiment, that is, it provides monopolar operation.
13 On the other hand, if switch 232 is opened, and if
14 pairs of switches with one of the pair being selected
15 from the switches 242, 244, 246 and 248, and the
16 other being selected from switches 234, 236, 238 and
17 240 are operated in proper conjunction, the
18 electrodes 220, 222, 224 and 226 will provide a
19 bipolar operation." So John, is it your
20 understanding that based on this disclosure, that
21 Stern is disclosing a device that can be both a
22 monopolar device and a bipolar device?

1 A Correct.

2 Q So as we talked about earlier, you have not
3 used such a device, correct?

4 A So as I mention, I have not used a
5 handpiece, but all of our -- majority of our
6 electrical consoles that provide the energy source
7 provide both unipolar -- or monopolar and bipolar, so
8 the only thing that doesn't combine the two is the
9 actual handpiece, so the part that we're applying to
10 the patient, but the consoles, but so the energy
11 sources provide both monopolar and bipolar.

12 So that's -- that's routine. That's
13 typical, and what's describing here are single
14 configurations, right? This is not the only way this
15 device can be activated. He's describing, and
16 actually, in this case, he's dividing -- just
17 describing activating multiple bipolar pairs because
18 he's activating four electrodes in a bipolar
19 configuration.

20 Q Okay, let's turn back to your reply
21 declaration, paragraph 23.

22 A Okay.

1 Q You state, "The understanding that bipolar
2 electrode pairs encompasses pairs that are active,
3 inactive or combinations of active and inactive pairs
4 is consistent with the '271 patent, which describes
5 bipolar electric pairs that are activated separately
6 and individually. Because the bipolar electrode
7 pairs are activated separately and individually,
8 there will be configurations where some pairs are
9 active and others are not." So John, do you agree
10 that each pair of electrodes can be separately
11 activated?

12 MS. COHEN: Objection.

13 A That reflects what's here in my
14 declaration.

15 Q Do you agree that the statement -- and let
16 me just go back. I didn't read this. You cite to
17 the '271 patent in paragraph 23, and your citation
18 reads, "For example, the needles or needle pairs of
19 figure 8F may be individually controlled to produce
20 an optimal treatment effect." Do you agree that this
21 statement means that the different needle pairs can
22 be chosen to be activated?

1 A That is my interpretation of the
2 description of how the device in '271 can be
3 configured.

4 Q So the device in '271, certain needles can
5 be selected to activate certain bipolar electrode
6 pairs?

7 A Right, and -- but specifically it says --
8 let me see, '271 is right here. Yeah, specifically
9 it says right here, actually, in the end of the
10 abstract, and the device is configured to deliver
11 radiofrequency energy from one row of electrodes to
12 the other row of electrodes, so it's configured
13 across rows.

14 Q And is that statement directed to the
15 embodiment in figure 8F?

16 A Well, I'd have to look to see if there's
17 any other description of 8F, and actually, I think I
18 may have -- here is 8F as described as on my reply
19 declaration, page 17 and page 18. Okay, right here,
20 under -- in paragraph 30, my previous declaration
21 includes my understanding that the terms of a claim
22 are to be interpreted in context of the entire

1 patent, including the patent specification and its
2 figures.

3 Okay, and we refer back to the original
4 declaration. Here, the term "row" appears only twice
5 in the '271 patent, in both instances describing rows
6 of electrodes where radiofrequency energy travels
7 from one row of electrodes to the other row of
8 electrodes, and -- and one is in the abstract, as I
9 just showed, the last sentence in the abstract.

10 This description of two rows where pairs
11 are formed between the rows is consistent with figure
12 F, which shows two rows of electrodes, and it says
13 blue because on the next page, on page 18 are what
14 are labeled row 1 and row 2, where bipolar pairs red
15 are formed between the rows, and that's from patent
16 '271. Now, there's another picture, figure 8G, which
17 is not -- we don't have right here, but that shows a
18 single row of bipolar electrodes with multiple
19 bipolar electrodes in a single row as another
20 embodiment in patent '271.

21 Q So let's first take the statement in the
22 abstract.

1 A Okay.

2 Q Is there any indication that that statement
3 is directed to the figure 8F embodiment?

4 MS. COHEN: Objection, form.

5 BY MR. WARD:

6 Q In the abstract itself.

7 A In the abstract.

8 MS. COHEN: Objection, form.

9 A It's not -- it's not referring to that
10 figure, so I can't tell you whether it is directly
11 referring to 8F, but it's referring to the technology
12 that's being patented here, and it's saying that
13 bipolar radiofrequency energy is going from one row
14 of electrodes to the other.

15 Q Let's take a look at the other citation you
16 give, which is column 8, line 21.

17 A Okay.

18 Q It states, "In some embodiments, the
19 protruding electrodes may include two rows of
20 electrodes, where the energy delivery member
21 comprises a bipolar radiofrequency delivery member,
22 and where the radiofrequency energy travels from one

1 row of electrodes to the other row of electrodes."

2 A Right.

3 Q You would --

4 A It's essentially saying the same thing as
5 the -- as the abstract.

6 Q And is there any indication in that
7 sentence that this is -- that this is directed to the
8 embodiment in figure 8F?

9 A It doesn't --

10 MS. COHEN: Objection, form.

11 A It doesn't directly say 8F, but let's see.
12 I want to check something here. So the first
13 description of 8F, 8G -- 8G just -- or describes
14 multiple embodiments. I'm just looking to see what
15 -- what it says about 8F back here, but those are the
16 only two places where it describes the rows, and both
17 -- in both instances, it describes bipolar energy
18 going from electrodes in one row to electrodes in
19 another row, and that's the embodiment that shows two
20 rows of bipolar electrodes. So again, we have to
21 take the entire document together, the entire patent
22 together, and it -- if you can indicate somewhere

1 where it may be referring to a different figure, I'd
2 be happy to listen, but I would interpret that as
3 being directly applicable to figure 8F.

4 Q But you would agree there's no express
5 reference in either of those statements to figure 8F.

6 MS. COHEN: Objection, form.

7 A And when we look at -- let's see, as shown
8 in figure 8F -- I'm just reading through this. On
9 paragraph 23, as shown in figure 8F, in some
10 embodiments, an array of electrodes comprising one,
11 two or many pairs of bipolar needles are located on a
12 treatment element configured to be placed in contact
13 with the cartilage. Yeah, it says pairs of bipolar
14 needles.

15 So now, I am happy -- all the embodiments
16 are 8A to 8J, and there's only a single embodiment
17 that shows two rows of bipolar needles, two rows of
18 bipolar electrodes, period. So if you incorporate
19 the entire document, and it's referring to energy
20 going from one electrode -- electrode in one row to
21 an electrode in another row, and there's only one
22 figure that has two rows of electrode, then I would

1 naturally make the connection that it's referring to
2 that particular. Now, figure G doesn't have two rows
3 of electrodes. It has a single row of electrodes.

4 Q Let's take a look at 23G. Sorry, same --
5 in the patent, the '271 patent, take a look at figure
6 23G for me. Do you see the device 550 depicted in
7 23G?

8 A I do.

9 Q I'm going to read you the description of
10 23G from the patent at column 31 line 40.

11 A Uh-huh.

12 Q It says that, "Figure 23G depicts a larger
13 view of the distal tip 556 of device 550. As shown
14 best in figure 23G, the treatment element 552
15 comprises a generally elongate shape. The front of
16 the treatment element 552 comprises a shallow curved
17 surface providing a convex shape to deform the nasal
18 tissue and create a concavity therein. In some
19 embodiments, the front of the treatment element
20 comprises a concave shape. The shape of the front
21 surface of the treatment element may be selected to
22 conform to the nasal tissue. The back surface of the

1 treatment element comprises a shallow curved surface
2 along most of its length. As best seen in figures
3 23B and 23C, back surface narrows distally along the
4 length of the element 552 from approximately the
5 distal end of the needle electrodes to the distal tip
6 of the treatment element 552." Skipping down to line
7 63 there, it says --

8 A What -- what line -- what paragraph?

9 Q Yeah, if you go to column 31 --

10 A Thirty-one, okay.

11 Q You can follow me at line --

12 A No, go ahead. I just want to know.

13 Q Yeah, line 64, it says, "The treatment
14 element 552 comprises a monopolar or bipolar needle
15 array comprising multiple needles 554. In some
16 embodiments, the needles are energized in between the
17 select needles to deliver bipolar energy. In other
18 embodiments, the energy is delivered between the
19 needles 554 and a remote grounding pad not shown. In
20 some embodiments, the electronic needle pairs are
21 arranged horizontally across the treatment element
22 552. In some embodiment, the electronic needle pairs

1 are arranged vertically across the element" --
2 "across the treatment element 552, or along the
3 direction of the shaft 558 and handle 560. Other
4 configurations are also possible. For example, the
5 needle pairs may be arranged diagonally across a
6 treatment element 552."

7 A Okay.

8 Q So do you agree that figure 23G of the '271
9 patent discloses multiple rows of multiple bipolar
10 electrodes, John?

11 MS. COHEN: Object to the form.

12 A So first I've got to preface it by saying
13 it's -- this diagram is very difficult because of the
14 -- how it's turned. It would be easier if it was --
15 we were face on --

16 Q Uh-huh.

17 A -- because we're looking at it kind of from
18 an oblique angle.

19 Q Right.

20 A It does appear that there are multiple rows
21 of needle electrodes. I can't tell because even if
22 you look at it from this right side, it doesn't even

1 look like a straight row. It's kind -- there's
2 almost a little curvature to the row, but it does
3 appear, assuming that what we're seeing kind of in
4 the -- on the far part of it is additional
5 electrodes, that this does show what you just
6 described, multiple rows.

7 Q So you would agree that 23G discloses
8 multiple rows of multiple bipolar electrodes.

9 A Correct.

10 MS. COHEN: Object to the form.

11 A Correct, or what can be configured as
12 multiple bipolar electrodes, because it does describe
13 also monopolar.

14 Q Right, but based upon the description I
15 read, would you understand that it discloses that
16 configurability, i.e., that different needles can be
17 configured to create multiple bipolar electrode
18 pairs?

19 A It does.

20 Q Let's take a look at the statement -- I
21 want to go back to your declaration.

22 A Uh-huh.

1 Q The same paragraph we were in before. It's
2 paragraph 30 of --

3 A Okay.

4 Q -- Exhibit 1083.

5 MS. COHEN: Sorry, Counsel before you ask a
6 question, we've been going for like an hour and 20
7 minutes. Do you want to take a little bit of a
8 break?

9 MR. WARD: Sure, we can take a break.

10 (Recessed at 11:52 a.m.)

11 (Reconvened at 12:15 p.m.)

12 BY MR. WARD:

13 Q Okay, John, let's turn to your reply
14 declaration, Exhibit 1083, paragraph 23.

15 A Okay.

16 Q You state, "The understanding that bipolar
17 electrode pairs encompasses pairs that are active,
18 inactive or combinations of active and inactive pairs
19 is consistent with the '271 patent, which describes
20 bipolar electrode pairs that are activated separately
21 and individually," and you provide two citations
22 there, and you say, "Because the bipolar electrode

1 pairs are activated separately and individually,
2 there will not be configurations where some pairs are
3 active and others are not." So do you agree that the
4 statement in the patent that you cited, "The needles
5 or needle pairs of figure 8F may be individually
6 controlled to produce an optimal treatment effect"
7 means that different needle pairs can be chosen to be
8 activated?

9 A So when you read that, I thought you said
10 there will not be configurations. I'm -- just to
11 clarify, it says there will be configurations where
12 some pairs are active and others are not, so could
13 you repeat your question? I just want to clarify
14 that because I -- I thought I heard not.

15 Q Uh-huh, right. You said there will be
16 configurations --

17 A Correct, correct.

18 Q -- where some pairs are active and others
19 are not.

20 A Correct.

21 Q So do you agree that that means that
22 different needle pairs can be selectively activated?

1 A Correct.

2 Q Okay. Let's take a look at Stern, Exhibit
3 1033.

4 A Uh-huh.

5 Q And if you take a look at column 24, I'm in
6 the --

7 A I was going to say, there is no column 24.

8 Q Yeah, yeah, take a look at Exhibit 1001,
9 the '271 patent.

10 A Oh, all right. Now 24?

11 Q Now column 24. It says, column 24 line 10,
12 "Separate control may also allow energy to be focused
13 and/or intensified on a desired region of the
14 treatment element in cases where the anatomy of the
15 nasal tissue structure does not allow the entire
16 electrode region of the treatment element to engage
17 the tissue. In such embodiments, the nasal tissue
18 that is in contact with the treatment element may
19 receive sufficient energy to treat the tissue." So
20 John, do you understand that this statement means
21 that the ability to selectively activate certain
22 electrodes can be important to the effectiveness of

1 the treatment?

2 MS. COHEN: Object to the form.

3 A Correct, yes, I do.

4 Q And how is that? Can you explain that to
5 me, how selectively activating certain electrodes is
6 important to having effective treatment?

7 MS. COHEN: Objection, form.

8 A Well, let's take the nose, for example.

9 Q Uh-huh.

10 A So if you have a device that's a certain
11 size, but you want to treat an area that's a little
12 smaller, you can still use the same device by
13 activating only a portion of it and not the entire
14 thing so only the portion that is contacting the --
15 the nasal tissue that you want to treat is active,
16 and you're not getting treatment in areas that are
17 not -- you're not getting bipolar energy,
18 radiofrequency energy --

19 Q Uh-huh.

20 A -- in areas that are not contacting the
21 tissue, so you're not treating areas you don't want
22 to treat.

1 Q And do you do that on the fly during the
2 procedure, or how do you --

3 MS. COHEN: Objection, form.

4 BY MR. WARD:

5 Q How do you determine which to activate?

6 A Well, so just -- this is obviously a
7 hypothetical.

8 Q Uh-huh.

9 A So the way electrical devices -- so for
10 instance, say this device, right? The -- Stern talks
11 about flipping switches, opening switches, opening
12 circuits and closing circuits and things like that.
13 That would not be a acceptable way to do things in a
14 medical device.

15 Q Uh-huh, yeah.

16 A Right, the way it would be is it would be
17 programmed. So say you have a device that has four
18 sets -- four -- four pairs of bipolar pairs, right?

19 Q Uh-huh.

20 A So four rows of bipolar pairs, and it's a
21 certain length, and it may be that the device is --
22 is configured so maybe you can activate all four --

1 all four at once.

2 Q Uh-huh.

3 A Maybe you can activate the front two and
4 not the back two, or the back two and not the front
5 two, but it would be -- it would be configured on a
6 console where you'd probably just pick it out of a
7 menu rather than having to do the -- what's described
8 in Stern and what is not described in '271 says you
9 can do this, but it doesn't tell you how to do it,
10 whereas Stern says you can do it and gives examples
11 of how to do it.

12 Q Uh-huh.

13 A So -- but from a clinical standpoint, it
14 would be, you know, pick program 1, which is
15 everything, pick program 2, which is just the front
16 two.

17 Q Yeah.

18 A Program 3, which -- and it would have --
19 usually it would have pictures too.

20 Q Yeah.

21 A Something that makes it very simple, very
22 easy, user friendly.

1 Q Uh-huh. So at the top of column 24 there
2 where it says, "The needles or needle pairs of figure
3 8F may be individually controlled to produce an
4 optimal treatment," do you agree that those
5 disclosures teach the needles can be individually
6 controlled?

7 MS. COHEN: Objection, form.

8 A Well, that's what it says, and that, you'd
9 have to refer back to, if it's a single needle, then
10 we're talking about monopolar. It's not going to be
11 bipolar because you can't have a single needle that
12 gives bipolar energy. So what they're saying -- yes,
13 they can be individually controlled as monopolar or
14 bipolar, and as one pair or multiple pairs.

15 Q It says the needles or needle pairs of
16 figure 8F may be individually controlled.

17 A I'm sorry, what number is that? Where --

18 Q Column 24, line 2.

19 A Line 2.

20 Q The needle --

21 A Needles or -- okay.

22 Q Needle pairs.

1 A So in that case, it'd likely be all
2 bipolar. I thought you said needle singular, not
3 needle plural, yeah.

4 Q But you --

5 A It could still be monopolar with multiple
6 needles, but definitely it can be bipolar also.

7 Q But you understand that the '271 patent is
8 disclosing that certain needle pairs can be
9 individually controlled.

10 A Sure.

11 MS. COHEN: Objection, form.

12 BY MR. WARD:

13 Q So the operator could selectively activate
14 certain needle pairs, true?

15 A So the patent --

16 MS. COHEN: Object to the form.

17 A The patent describes that, but it doesn't
18 give any details on how it's done, correct.

19 Q Well, let's take a look at your -- your
20 declaration, reply declaration, paragraph 30, and
21 it's actually page 18 where you give the annotated --

22 A Yes.

1 Q You're on it there.

2 A Right.

3 Q So you've provided an annotated version of
4 this figure we've been discussing, figure 8F, and can
5 you describe to me what are your annotations here,
6 John?

7 A Right, so the annotations are in blue. It
8 says row 1 and row 2, which is depicting the
9 longitudinal or lengthwise orientation of the needles
10 in two rows, and in red, it says pair 1 and pair 2,
11 which is depicting the, as is mentioned in the '271
12 patent, is the pairing of the electrodes across rows
13 to create a bipolar electrode pair.

14 Q And so your -- your red annotation circles
15 indicate that the bipolar electrode pair 1 as you've
16 labeled it is across row 1 and row 2?

17 A Correct.

18 Q And similarly, pair 2, you've annotated it
19 so it's across row 1 and row 2?

20 A Correct.

21 Q Okay, let's take a look at the patent
22 again, column 24 of the patent.

1 A Uh-huh, okay.

2 Q This is where it's discussing figure 8F,
3 and it actually starts on the bottom of column 23,
4 where it begins describing figure 8F. Can you
5 identify a description in this disclosure with
6 respect to figure 8F where it discloses that the
7 pairs are defined horizontally rather than vertically
8 in relation to the shaft?

9 MS. COHEN: Objection, form.

10 A And the paragraph starts at line 40 on 23.

11 Q Uh-huh.

12 A It doesn't -- it says some embodiments,
13 array of electrodes comprising one, two or many
14 pairs, the bipolar needles are located on a treatment
15 element configured to be placed in contact with the
16 cartilage. It doesn't say specifically there that
17 it's across rows, but as I said, it just says in the
18 abstract in the other -- in the abstract in the other
19 reference that's in the -- that we've already
20 covered.

21 Q Looking back there at column 23 and 24 --

22 A Uh-huh.

1 Q And then just focusing on that statement in
2 line 2 of 24 where it says, "The needles or needle
3 pairs of figure 8 may be individually controlled to
4 produce an optimal treatment effect" --

5 A Uh-huh.

6 Q You would agree that it's disclosing
7 selective configuration of the needle pairs shown in
8 figure 8F, correct?

9 MS. COHEN: Objection, form.

10 A It seems -- right, it seems to be
11 indicating that, although it's not -- it's not --
12 it's very nonspecific about which electrodes can be
13 paired.

14 Q But there's no disclosure in this portion
15 of the specification about the pairing occurring in
16 accordance with your annotations, correct?

17 A No.

18 MS. COHEN: Objection to the form.

19 A Not in this location.

20 Q Okay, going back to your paragraph 30 of
21 your declaration, 1083 --

22 A Uh-huh.

1 Q There's a statement at the -- sort of the
2 bottom of the paragraph 30 on page 17, and it's a
3 parenthetical that you cite there. It says, "As
4 opposed to figure 8F, where the pairs of electrodes
5 are arranged side by side, the embodiment of figure
6 8G arranges the pairs of electrodes along the length
7 of the treatment element." So let's take a look at
8 Exhibit 1001 and figure 8G. Okay, so refresh your
9 recollection as to the configuration of 8G. So maybe
10 you can hold that page and let's go back and look at
11 the column 23 again where it describes figure 8G.

12 A Okay.

13 Q And I'll read it for us. It says, "Figure
14 8G illustrates another embodiment of a treatment
15 element, comprises one, two or many pairs of bipolar
16 electrodes 260. As opposed to figure 8F, where the
17 pairs of the electrodes are arranged side by side,
18 the embodiment of figure 8G arranges the pairs of
19 electrodes along the length of the treatment element.
20 The electrodes of figure 8G are also nonpenetrating
21 in contrast to the needles of figure 8F." Do you
22 understand that --

1 A What line is that again? It's in 24?

2 Q Yeah. Sorry. No, it's in 23.

3 A Twenty-three.

4 Q Let's do it again. I'll --

5 A Okay. Just show me. Twenty-three -- what
6 -- what --

7 Q Fifty-four.

8 A Fifty-four, okay, got -- okay. There you
9 go. Okay, I got it.

10 Q So it says, yeah, "Figure 8G illustrates
11 another embodiment of a treatment element, comprises
12 one, two or many pairs of bipolar electrodes 260."
13 So just turning back to figure 8G then --

14 A Okay, so just go back to one of your
15 previous questions though --

16 Q Yeah.

17 A -- because you asked me where -- and I kept
18 looking under 8F, where does it say that the pairs
19 are across rows, where does it say that in the
20 document.

21 Q Uh-huh.

22 A And you just read where -- another place

1 where it says it in the document, because it says as
2 opposed to 8F, where the pairs of electrodes are
3 arranged side by side, okay? The embodiment --
4 figure 8G arranges the pairs along the length of the
5 treatment element. So that, even though it's not a
6 description -- this is the description of 8G, it's
7 confirming that 8F is showing the pairs across rows.

8 So '271 is confirming what's in the
9 abstract, which in our other reference right here is
10 confirming that 8F is depicting across rows, not the
11 other way. Doesn't mean that the other way is not
12 possible, but it is describing that 8F is across
13 rows, whereas in contrast to 8G, that is along the
14 length of the treatment element.

15 Q But you would agree that's one way to
16 configure 8F, correct?

17 A Correct.

18 Q And so 8G's configuration it tells us is a
19 treatment element comprises one, two or many pairs of
20 bipolar electrodes 260. So would you understand 8G
21 to provide a single row having multiple bipolar
22 electrode pairs?

1 A I would agree with that.

2 Q And is there any indication in 8G as to
3 what -- what pairs are provided?

4 MS. COHEN: Objection, form.

5 A I don't see -- not in that particular area.
6 I'd have to look through all the references to 8G to
7 see, but based on previous statements that electrodes
8 are individually and multiply activated, that it
9 should be able to activate multiple pairs.

10 Q So just, I mean, looking at 8G itself --

11 A Uh-huh.

12 Q -- it provides positive and negative
13 indications next to the electrodes, correct?

14 A Right, only on one side, so each one of
15 those is only a single electrode, so this is a single
16 row of electrodes.

17 Q So would your understanding that -- be that
18 one way to configure 8G would be that the first --
19 the top two electrodes, which are actually labeled
20 260, form a single bipolar electrode pair?

21 A Correct.

22 Q And then the next two electrodes would form

1 a second bipolar electrode pair?

2 A Correct.

3 Q And then a third bipolar electrode pair?

4 A Correct.

5 Q So in this particular configuration, one
6 way it could be configured is that 8G provides a
7 single row with three bipolar electrode pairs?

8 A That can be --

9 MS. COHEN: Objection, form.

10 A That can be interpreted that way.

11 Q Looking back at your declaration --

12 A Uh-huh.

13 Q -- 32, paragraph 32 of your declaration --

14 A Okay.

15 Q You -- middle of the paragraph 32, it
16 begins, "However, the phrase that Dr. Martin was
17 asked about, 'The single row of bipolar electrode
18 pairs,' is not claimed and presents different issues
19 than the phrase 'Two rows of bipolar electrode pairs'
20 in terms of what the plural term 'pairs' can modify.
21 Namely, when there's only a single row, any pairs
22 necessarily fall within that row, so to have multiple

1 pairs requires multiple pairs in a row." So do you
2 agree that the '271 patent discloses having multiple
3 pairs in a single row?

4 A I agree that that particular embodiment,
5 8G, shows multiple pairs in a single row. 8F does
6 not show multiple pairs in a single row, so there are
7 two different embodiments, so both are possible.

8 Q And going back to our earlier discussion,
9 I'd like you to take a look at figure 23G in the '271
10 patent --

11 A 23G, okay.

12 Q And you would agree that that figure
13 discloses multiple pairs of bipolar electrode pairs
14 in a -- in multiple rows?

15 MS. COHEN: Object to the form.

16 A And again, I -- I'm just going to say
17 because of the orientation, it's just hard to see
18 where all of those -- it appears that there are
19 multiple electrodes in multiple rows, but it's just
20 -- it's just an oblique view that makes it a little
21 difficult to completely interpret, but I would say it
22 looks like -- and it's hard to say, whether there may

1 be three rows of multiple electrodes.

2 MR. WARD: Counsel, I'd like to show John a
3 blown-up view of this figure if I can.

4 MS. COHEN: On your iPad.

5 MR. WARD: On my iPad.

6 MS. COHEN: Okay.

7 BY MR. WARD:

8 Q So just to give you, John, the capability,
9 as you said, the orientation is not --

10 A Yeah, it's just -- it's --

11 Q So the capability to look at the figure --

12 MS. COHEN: So you're just like zooming in
13 on a PDF on your iPad?

14 BY MR. WARD:

15 Q Yeah, I'm going to zoom in on the PDF of
16 the -- so John, this is -- as you can see --

17 A Yes.

18 Q This is figure 23G, and so --

19 A Yeah.

20 Q -- by zooming in, does that give you any --

21 A Yeah, I mean --

22 MS. COHEN: Can we also just represent for

1 the record that the figure you're showing him has
2 writing on it that does not appear in the original
3 version?

4 MR. WARD: Sorry, yeah, the figure contains
5 handwriting that doesn't appear in the original
6 figure.

7 MS. COHEN: Is the handwriting from
8 counsel?

9 MR. WARD: Yes.

10 BY MR. WARD:

11 Q So John --

12 A So yes, so it appears -- it's a little --
13 it's obviously a bigger version of the same -- it's
14 still the exact same view. It appears that there are
15 -- it depends on what way you look at it. If you
16 look at it along the length, it looks like there's
17 probably three rows of electrodes. I can't -- I
18 don't have the equal number of electrodes in each row
19 because it looked like this row may have four. That
20 middle row may have five, and -- and the distal row
21 has four or five, so there's multiple -- it appears
22 multiple rows of electrodes.

1 MS. COHEN: Also, Counsel, I think we're
2 going to need to have a clip of that figure with the
3 annotation sent so we enter it as an exhibit.

4 BY MR. WARD:

5 Q Certainly. So John, you would agree that
6 23G discloses multiple rows of multiple bipolar
7 electrode pairs?

8 A Yes, it appears to, if they are -- if they
9 are configured as bipolar pairs. There's multiple
10 rows of electrodes that can be configured in multiple
11 bipolar electrode pairs.

12 Q Let's take a look at paragraph 36 of your
13 declaration.

14 A Okay.

15 Q You state, "As I explained in my first
16 declaration, Stern discloses various arrangements of
17 electrodes on the surface of a bladder along with
18 techniques for selectively energizing certain
19 electrode pairs" -- "electrode pairs in the array.
20 Such" -- "One such arrangement is shown in Stern's
21 figure 4A, which shows an ordered arrangement of
22 electrodes can be configured as a first row with four

1 electrodes, row 1 purple, and a second row with three
2 electrodes, row 2 orange." Your first citation in
3 that paragraph, John, you cite -- your first citation
4 to Stern, Exhibit 1033, is to column 2 line 36. I'd
5 like you to take a look at that particular statement.

6 A Okay.

7 Q It says, "It is a further object of the
8 present invention to provide a system of selective
9 delivery of either monopolar RF energy to a single
10 electrode or bipolar RF energy to chosen pairs of an
11 array of separate electrodes, which are used to bring
12 the endometrial temperature to a desired level." So
13 John, do you agree that this disclosure, this
14 particular disclosure in Stern's not specifically
15 directed to figure 4A?

16 MS. COHEN: Object to the form.

17 A This is directed towards the -- to the
18 embodiments in general. It doesn't directly -- right
19 here it doesn't directly refer to 4A.

20 Q And just taking a look back at your
21 declaration in your annotations --

22 A Uh-huh.

1 Q -- to figure 4A --

2 A Yes.

3 Q Can you describe to me what -- what it is
4 that you've annotated in the colors there?

5 A Sure. It says row 1 in purple with an
6 arrow pointing towards the distal tip of the
7 treatment element, which has four electrodes across
8 the surface of the treatment element, and then below
9 it, it says row 2 in orange, with an arrow pointing
10 to the second row, which has three electrodes
11 horizontally across the row.

12 Q And you don't provide a citation there I
13 don't believe to -- I'm looking back at your
14 declaration, and under the figure, you cite to figure
15 4A of Stern. Can you identify where Stern discloses
16 this information about figure 4A?

17 A Let me see if it's in the declaration. It
18 definitely -- you know, Stern discloses operating the
19 electrodes in 4A utilizing a bipolar construction.
20 This is 37 I'm looking at. Example 1033, Stern,
21 explaining that Figure 5A can be operated using a
22 bipolar construction. Stern discloses the details

1 for how to implement bipolar operation by referring
2 to figure 15, which illustrates how to configure a
3 plurality of electrodes for either monopolar or
4 bipolar operation.

5 Although figure 15 illustrates configurable
6 bipolar operation using a two-by-two array of
7 electrodes, a person of ordinary skill in the art
8 would have readily applied these teaching to the
9 order arrangement in figure 4A. The only difference
10 is the number of electrodes in each row. I note that
11 '271 patent does not describe how to implement
12 bipolar operation at all, which further suggests that
13 it would have been trivial to adapt figure 15 to
14 match the number of electrodes shown in figure 4A.

15 Q How would you have gone about modifying
16 Stern's figure 15 embodiment with figure 4A, John?

17 MS. COHEN: Objection, form.

18 A Figure 15? Let me pull that up just so I
19 know exactly --

20 Q Uh-huh.

21 A -- what we are discussing. So figure 15 is
22 the circuitry for -- for 19, okay? And obviously as

1 we've already discussed, there is switches that can
2 be open and closed --

3 Q Uh-huh.

4 A -- to activate or deactivate certain
5 electrodes and create electrode pairs. The only
6 difference between this, which is 4A -- I'm sorry,
7 which is 19, and 4A, which we have depicted in my --
8 both of which are depicted in my declaration, is the
9 number of electrodes. So it's obviously not the same
10 circuitry. It would require more circuits because
11 there's a difference of five electrodes in figure 19,
12 whereas there are eight electrodes in figure 4A, so
13 it would require more circuits obviously to
14 accommodate more electrodes. So it's a matter of
15 extrapolating the number of electrodes -- the
16 circuitry to the number of electrodes.

17 Q So figure 15 has this two-by-two array of
18 electrodes, correct?

19 A Well, it's depicted as a two-by-two here,
20 but figure 15 -- figure 19 actually has five
21 electrodes. This is -- and again, this array is only
22 as a descriptor. This -- it isn't necessarily the

1 array for the entire device. This is the array just
2 to describe how to activate and deactivate those top
3 four electrodes in figure 19.

4 Q And -- and what would have been the
5 motivation for a person of skill in the art to modify
6 figure 15 with figure 4A?

7 MS. COHEN: Object to the form.

8 A Well, it would have been -- you know,
9 someone -- a person of ordinary skill would have
10 understood that since figure 15 is specifically the
11 circuitry to activate or deactivate electrodes on
12 figure 19, the two-by-two with the additional
13 electrode, that that same circuitry would not apply
14 to the four-by-three-by-one arrangement in figure 4A.
15 That would require circuitry to particularly -- to
16 directly activate or deactivate each of those eight
17 electrodes.

18 So that's -- would be fairly well
19 understood that there have to be modification,
20 adaptation of the circuitry for more electrodes.

21 Q John, isn't your overall proposal in this
22 case that it would have been obvious to modify the

1 Edwards '535 reference with Stern's disclosures?

2 A Yes, it is.

3 Q And so is it your contention that a person
4 of skill in the art would first have been motivated
5 to modify Stern's figure 15 with figure 4A, and then
6 later use that to modify Edwards '535?

7 A Not at all.

8 MS. COHEN: Objection to form.

9 A Not at all. This -- the issue with the
10 different examples of the embodiment in --
11 embodiments in Stern are related to -- are brought up
12 obviously in my original declaration, this
13 declaration's figure 19, and that is to fulfill the
14 claim of multiple rows of bipolar electrode pairs,
15 and that's -- claim is satisfied by figure 19.

16 Subsequently, there was a -- there was --
17 by Dr. Bikson claimed that -- in his deposition, in
18 his declaration that the '271 patent requires
19 multiple pairs of electrodes in a single row, okay?
20 That is another embodiment of Stern, and that's
21 figure 4A. Figure 4A discloses multiple pairs of
22 bipolar electrodes in a single row, and that can be

1 oriented either vertically or horizontally, and it
2 fulfills that claim.

3 So that's why there are two separate
4 embodiments that we bring up, and they're both in
5 this reply. Can you repeat your question because I
6 think I forgot something else I wanted to say.

7 Q Well, let me ask a different question,
8 John. Is it common to use a device for endometriosis
9 to improve devices for otolaryngology?

10 MS. COHEN: Object to the form.

11 A It is absolutely commonplace to adapt
12 instrumentation technology, techniques from one
13 specialty to another. We're dealing with cavities,
14 with surfaces, and both of these cavities are
15 exposed, whether you, believe it or not, are exposed
16 to the environment, as opposed to the cardiac cavity.
17 Even though we adapt a lot of cardiac technology to
18 rhinology, to the nose, we adapt a lot of things from
19 like urology and gynecology and cardiology and
20 gastroenterology.

21 So it's very common, and matter of fact, in
22 Edwards '535, Edwards is looked specifically at

1 treatment for endometrial tissue when he refers to
2 Baker, and Baker talks about -- and he refers to
3 Baker for appropriate materials for the surface
4 bladder of the treatment element and Baker's
5 treatment of endometrial mucosa, and it's using
6 radiofrequency to treat endometrial mucosa, but this
7 is extremely common.

8 A lot of the technology that we have --
9 when I mentioned the microdebrider, the microdebrider
10 was developed for orthopedic surgery, and now it was
11 adopted for otolaryngology. It's not going to be the
12 same device anymore, but it's the exact same -- exact
13 same theories and the exact same base device, but
14 it's going to be modified for the area that we're
15 treating.

16 Q But John, you would agree you've never used
17 a device for endometriosis, correct?

18 MS. COHEN: Objection, form.

19 A Honestly, I can't tell you where all of the
20 -- I've been doing this for 30 years in practice and
21 36 years if you include my residency, 35 years, so I
22 can't tell you where all the different instruments

1 were adapted from. There very well may have been
2 because I've used instruments that have been used in
3 cardiology, I've used instruments that are -- that
4 are used in gastrointestinal surgery. I've used
5 instruments that are adapted from urology. So
6 honestly, I would be very surprised if I haven't used
7 a device that was adapted from gynecology that may
8 have been used in the endometrium.

9 Q But you've never performed an endometriosis
10 procedure, correct?

11 A Probably not since I was -- or I probably
12 did when I was a medical student, but no, not since,
13 of course not.

14 Q Do you read literature regarding
15 endometriosis?

16 A I do not.

17 Q Is it common for those in otolaryngology to
18 read endometriosis literature?

19 MS. COHEN: Objection, form.

20 A So what -- what you're -- I think the way
21 you have to look at it is a little differently, and
22 the way you have to look at it is so if I'm trying to

1 find -- if I've got a problem that I'm trying to find
2 a solution for, and I'm looking for a device that
3 might work for my -- for the problem I'm trying to
4 treat, I'm not going to be searching for the
5 diagnosis. I'm not going to be searching for
6 endometriosis, right?

7 I may be looking for mucosal ablation,
8 right? And if you Google or if you do some kind of
9 search on mucosal ablation or -- or, you know, even
10 muscle ablation, because the endometrium is muscle,
11 you're going to come up with a lot of different
12 specialties, okay? So the search is not for the
13 place or the body part. The search is for the
14 treatment type, and that treatment type is going to
15 span multiple different subspecialties.

16 So that's where it wouldn't be very
17 uncommon -- I mean, that's why devices, techniques
18 get adapted from one specialty to another, and it's
19 not because of the -- the endometrium or the
20 endometriosis or -- or menorrhagia or whatever the
21 diagnosis is going to be, it's because the type of
22 treatment, which can easily be adapted, and they

1 frequently are from one body part to another, one
2 cavity to another.

3 Q Do you agree that you did not address this
4 proposed modification of figure 15 with figure 4A in
5 your original declaration?

6 MS. COHEN: Objection to the form.

7 A So I'm not proposing modifying figure 4A
8 with figure 19. There are two different embodiments
9 --

10 Q Uh-huh.

11 A -- each of which fulfill the claim in
12 patent '271. I'm not -- I've never discussed
13 modifying figure 19 in light of figure 4A.

14 Q So paragraph 37, your statement is,
15 "Although figure 15 illustrates configurable bipolar
16 operation using a two-by-two array of electrodes, a
17 person of ordinary skill in the art would have
18 readily applied these teachings to the ordered
19 arrangement in figure 4A." So aren't you suggesting
20 there that the learnings be combined?

21 A No.

22 MS. COHEN: Objection, form.

1 A No, not at all. It's like saying, you
2 know, I've got two cars. I've got an 18-wheeler and
3 I've got a pickup truck, and I want to switch out the
4 tires. You can't just put four tires on an
5 18-wheeler. You've got to modify it, okay? We're --
6 I'm just saying here that there are two different
7 ways of interpreting '271, and that is multiple rows
8 of bipolar pairs and multiple bipolar pairs in a row,
9 okay?

10 So because Stern only speaks about the
11 circuitry in figure 15 that applies to -- to 19, to
12 the treatment device in figure 19, and he doesn't
13 specifically draw out the circuitry in figure 4A,
14 that it would be understood by a person of ordinary
15 skill that that circuitry would need to be changed,
16 increased to accommodate eight electrodes as opposed
17 to five electrodes, which is the difference between
18 4A and 19.

19 It's not a modification. There are two
20 different -- we're not combining. I'm not combining
21 19 and 4A. I'm, as a person of ordinary skill,
22 looking and say well, yeah, this isn't going to fit,

1 this circuitry for five electrodes is not going to
2 fit eight electrodes, so it makes sense to anyone
3 looking at it that we need -- we will need more
4 circuitry to accommodate three additional electrodes.
5 That fulfills the criteria of multiple bipolar pairs
6 in a single row.

7 Q Let's take a look at paragraph 39 of your
8 declaration.

9 A Okay.

10 Q You say, "In addition to figure 4A, Stern
11 discloses various other arrangements of electrodes
12 that satisfy Dr. Bikson's interpretation. For
13 example, in configurations where the fifth electrode
14 at the bottom of figure 19 is activated, there is a
15 third electrode for each of the rows, such that the
16 rows can be configured to contain two pairs within
17 each row." John, can you identify where for me in
18 the Stern patent it discloses that that polygon at
19 the bottom of figure 19 is an electrode?

20 A Sure. So again, this would be something
21 someone -- someone with ordinary skill would be --
22 could look at Stern, and actually, go back to figure

1 4A, because if you go back to 4A and you look at that
2 embodiment, and it shows the electrodes as marked as
3 number 44, and it marks the one on the bottom that's
4 very similar appearance, the fifth electrode on the
5 bottom of figure 19.

6 Figure 19 never marks the bottom one as an
7 electrode, but figure 4A does, and as a matter of
8 fact, if you were to look at the circuitry for -- and
9 I believe let's go back to figure 19. Let's see.
10 There's another figure. Here we go. Well, and you
11 look at figure 26, and 26 shows an unfolded, since
12 obviously the electrodes are active on both sides,
13 and it shows five on each side, and there may be
14 additional figures.

15 So if you look -- and actually, if you look
16 on figure 7, figure 7's actually a depiction of 4A,
17 but it shows the circuitry, and I believe all -- look
18 at all -- the number of round paddle-looking circuits
19 completely correspond to the electrodes. There's
20 eight of them, four across the top, three across the
21 middle, one on the bottom, which should indicate each
22 of them are associated with an electrode.

1 Q Is there any disclosure with respect to
2 figure 19 that that bottom polygon is an electrode?

3 A No, I do not believe there is a specific
4 disclosure, but a person of ordinary skill, knowing
5 that putting together the -- considering the entire
6 patent in Stern, that the eighth and bottom electrode
7 in 8A is marked -- 4A, I'm sorry, is marked as an
8 electrode, and that that would make me and a person
9 of ordinary skill consider that that fifth electrode
10 on the bottom of 19 would also represent an
11 electrode. Otherwise why would it be there?

12 I mean, it doesn't -- wouldn't make sense
13 for it to be a -- why not just leave it an empty
14 space and not have it be a fifth electrode? It
15 increases the possibilities, and this is a
16 configurable device and increases the possibilities
17 of pairs and bipolar electrode pairs and monopolar
18 application.

19 Q So looking back at your declaration,
20 paragraph 39 --

21 A Uh-huh.

22 Q Your annotations --

1 A Right.

2 Q -- there, you appear to indicate that row 1
3 is the purple -- annotated in purple, correct?

4 A Correct, it's annotated vertically and
5 purple.

6 Q And row 2 is annotated in orange?

7 A Correct.

8 Q So if each row shares the same bottom
9 electrode of figure 19, how is it that you allege
10 that there are two rows with multiple pairs of
11 bipolar electrodes?

12 MS. COHEN: Object to form.

13 A Sure, if we're considering that each
14 electrode can be individually activated or
15 deactivated, then the top one and the middle one
16 would be one pair, since you would have a negative
17 and a positive or a positive and a negative, and then
18 the one on the bottom will be the opposite. So say,
19 take the three on the left side, positive, negative,
20 positive, and you're going to get flow between the
21 positive and the negative, that would -- even though
22 it's only three, that could create two pairs that

1 share the center electrode.

2 Same thing on the opposite side, two pairs
3 that -- and since the top two will be negative,
4 negative, positive, positive, negative on the bottom,
5 there's not going to be flow across vertically.
6 It'll be -- I'm sorry, it won't be flow horizontally.
7 It'll be vertical pairs from three electrodes.

8 Q And is your allegation then that you can
9 have two active bipolar electrode pairs in each row
10 at the same time?

11 MS. COHEN: Objection, form.

12 A Theoretically, that's possible.

13 Q And how --

14 A Although this is only one embodiment, as I
15 said, because this is -- we're just -- we did -- I
16 did present figure 19 in my original declaration, and
17 showing that figure 19 itself, when all these
18 electrodes are active, meet the criteria, satisfy
19 claim that multiple bipolar electrode pairs in a
20 single row. In addition obviously figure 4A, which
21 we include in this declaration, also satisfies that
22 claim, but this is to show that figure 19 also does.

1 Q Taking a look at the next paragraph,
2 paragraph 40 of your declaration --

3 A Uh-huh.

4 Q -- you state, "Furthermore, to the extent
5 that Dr. Bikson opines that forming bipolar pairs
6 between two rows such that each row contains a single
7 electrode from each pair satisfies its
8 interpretation, Stern discloses multiple pairs within
9 each row under this interpretation as well. For
10 example, as shown below, each row can be configured
11 to include one electrode from a first pair and one
12 electrode from a second pair," and you provide an
13 annotated version of figure 19, correct?

14 A Correct.

15 Q So are you alleging that your annotations
16 to figure 19 on page 24 of your declaration
17 illustrate two rows with multiple bipolar electrode
18 pairs?

19 A This is showing two rows, multiple rows of
20 bipolar electrode pairs, so there's two rows, each
21 with a bipolar electrode pair, but they can be
22 oriented in different directions.

1 Q Explain that to me, John.

2 MS. COHEN: Objection, form.

3 A Right. Well, here it shows pair 1
4 vertically.

5 Q Uh-huh.

6 A Right, so two left are one pair. The two
7 on the right are another pair. So we've got multiple
8 rows, there's two rows, and there are multiple
9 electrode pairs. There's two electrode pairs. It
10 can be off -- it can be oriented the other direction
11 too, so you could have pairs across, and we've
12 discussed that before. We'd shown that.

13 Q So in this vertical orientation that you
14 provide, and the annotations for paragraph 40, there
15 isn't a bipolar electrode pair in row 1?

16 MS. COHEN: Objection, form.

17 A Right, what we're saying here, because
18 previously row 1, we demonstrated that you can pair
19 the two in row 1, and that is one bipolar electrode
20 pair, and you pair the two across in 2. We're
21 showing here that you can -- that Stern says that you
22 can orient them differently. You can pair different

1 electrodes to make a bipolar electrode pair. So in
2 this embodiment, the pair is vertical. The two left-
3 sided electrodes are one bipolar pair, and the two on
4 the right are one bipolar pair. So what was our
5 original rows are not making bipolar pair. The
6 bipolar pairs are now vertical.

7 Q So the pairs in your annotations for
8 paragraph 40 occur across row 1 and row 2, correct?

9 A In 40, no. This is the pairs are occurring
10 vertically, pairs are up and down.

11 Q Meaning that in order to have a pair, you
12 have to have an electrode from row 1 and an electrode
13 from row 2, correct?

14 A Correct, in this embodiment, right, and
15 that's not including the previous, in 39, when we
16 include that fifth electrode to make multiple pairs,
17 bipolar pairs in a single row.

18 MR. WARD: Can we go off the record?

19 (Recessed at 1:03 p.m.)

20 (Reconvened at 1:10 p.m.)

21 BY MR. WARD:

22 Q Let's turn to paragraph 45 of your

1 declaration, John.

2 A Okay.

3 Q You state, "First, Dr. Bikson appears to
4 disagree with Dr. Martin's explanation that by
5 referring to Baker, a reference that describes
6 non-nasal ablation device with embodiments similar to
7 those of Stern, Edwards '535 establishes that a
8 person of ordinary skill in the art would have been
9 motivated to look to non-nasal ablation devices like
10 those described in Stern to improve Edwards '535's
11 nasal ablation device," and so what is it that the
12 Baker reference discloses, John?

13 MS. COHEN: Objection, form.

14 A I'd have to look completely at it, but it's
15 an -- we're referring to the Baker reference that is
16 referred to in Stern -- I'm sorry, in Edwards,
17 correct?

18 Q Yes.

19 A Okay, and the Baker reference is also an
20 endometrial ablation device that is referenced in
21 Edwards. Edwards advises the reader to consult with
22 Baker --

1 Q Uh-huh.

2 A -- on appropriate surface -- or various
3 appropriate material for the surface of the ablation
4 device, and you know, obviously if Edwards is
5 advising that Baker be evaluated, that is also an
6 endometrial ablation device --

7 Q Uh-huh.

8 A -- which a person of ordinary skill would
9 recognize that and say well, there may be other
10 endometrial ablation devices that are appropriate
11 which could lead -- would lead them to Stern.

12 Q You go on in the bottom of the paragraph 45
13 there, the sentence starts, "Whether or not the
14 entire Baker reference was incorporated by reference
15 into Edwards '535, because Edwards, a reference
16 describing a nasal ablation device, points a person
17 of ordinary skill in the art to Baker, a reference
18 describing a non-nasal ablation device with
19 attributes similar to Stern, it would have motivated
20 a person of ordinary skill in the art to use the
21 teachings like those found in Baker and Edwards." So
22 you're saying that it would have been obvious to

1 apply the teachings of Baker to Edwards?

2 MS. COHEN: Objection, form.

3 A Well, Edwards actually says that you can
4 apply the teaching of Baker to his --

5 Q Uh-huh.

6 A -- invention in his patent because he
7 directs the reader to Baker to -- you know, because
8 he discusses various surface electrodes and surface
9 ions that can be used to distribute energy off the
10 surface of the inflatable device, and as I said, a
11 person of ordinary skill reading Baker with Baker
12 provides a -- describes a device very similar to
13 Stern.

14 It's almost the same shape. It has surface
15 electrodes that can be configured in a bipolar
16 fashion, but a person of ordinary skill seeing that
17 Edwards refers them to evaluate Baker's device, which
18 is an endometrial ablation device, would then further
19 evaluate other endometrial ablation devices, such as
20 the one from Stern.

21 Q So would you agree that the teachings of
22 Baker are necessary to make the amendment to Edwards?

1 A No, I did not use Baker in combination with
2 Edwards. I described combining Stern with Edwards.

3 Q So how did you use Baker?

4 MS. COHEN: Objection, form.

5 A I didn't use Baker. Like I said, Edwards
6 actually directs the reader to Baker to provide
7 additional -- he leaves a lot -- Edwards leaves a lot
8 for the reader to -- you know, leaves a lot that can
9 be modified --

10 Q Uh-huh.

11 A -- because he's very nonspecific about a
12 lot of things, including the surface electrodes. He
13 describes a single row of surface electrodes but does
14 not go into great detail about it, but he does
15 specifically direct the reader to Baker for various
16 possibilities.

17 Q So a person of skill would have looked to
18 Baker to fill the gaps in Edwards?

19 MS. COHEN: Objection.

20 A Well, a person of skill would have -- since
21 Baker is being directly referred to --

22 Q Uh-huh.

1 A Obviously the -- the reader, the person of
2 skill would have had Baker available, and that --
3 since Baker's an endometrial device, would have
4 naturally looked at other endometrial ablation
5 devices as options for modifying Edwards.

6 Q So what if anything is needed from Baker?

7 A Nothing is absolutely needed from Baker,
8 but Baker provides additional possibilities and
9 additional -- additional wisdom or teachings on
10 constructing the device.

11 Q Taking a look at paragraph 46 --

12 A Uh-huh.

13 Q -- of your declaration, you state, "Second,
14 Dr. Bikson appears to disagree with Dr. Martin's
15 explanation that Stern's electrode arrangement
16 provides simplified spatial resolution of the applied
17 energy such that a person of ordinary skill in the
18 art would have been motivated to combine its
19 teachings with those of Edwards '535. According to
20 Dr. Bikson, Stern's arrangement of two rows of
21 bipolar electrode pairs is just one possible ordered
22 arrangement of many possibilities. I disagree. My

1 first declaration explains why a person of ordinary
2 skill in the art would have chosen to apply Stern's
3 teaching of two rows of bipolar electrode pairs to
4 the teachings of Edwards '535, and my discussion with
5 Dr. Martin and my review of his declaration confirmed
6 those reasons. For example, Dr. Martin explained
7 that Stern's arrangement of two rows of bipolar
8 electrode pairs provides even heating and precise
9 energy control, and I explained how this benefit
10 would have contributed to a person of ordinary skill
11 in the art's motivation to combine the references."

12 John, do you agree that there are other
13 arrangements of the electrodes that are possible?

14 MS. COHEN: Objection, form.

15 A I'm sure there's an indefinite number of
16 arrangements of electrodes that are possible. The
17 question is what -- what are the electrode arrays
18 that are -- would be most efficacious.

19 Q And what are those?

20 A Well, it would depend on what body part is
21 being treated, and in this case, you know, we're
22 treating the nasal cavity. Nasal cavity is a

1 structure that contains multiple structures,
2 therefore, it has multiple folds --

3 Q Uh-huh.

4 A -- multiple turbinates, septum, lateral
5 nasal wall. So, you know, something -- you know,
6 orientation of the electrode that can be adapted to
7 best fit the needs of various anatomic structures in
8 the nose would be an appropriate arrangement that a
9 person of ordinary skill would look to to have.

10 Q In the next paragraph, you say -- it's
11 paragraph 47, "However, the existence of other
12 potential arrangements, e.g., single row of
13 electrodes, would not have discouraged a person of
14 ordinary skill in the art from choosing Stern's
15 embodiment that uses two rows of electrode pairs. In
16 general, a person of ordinary skill in the art would
17 have understood a medical device to have a single
18 optimal configuration that overrides the benefits of
19 other configurations." So do the devices you use,
20 John, always have a single optimal configuration?

21 MS. COHEN: Object to the form.

22 A So no, they are usually -- well, each

1 particular device for the most part has a
2 configuration, but frequently we have devices that
3 have -- come in sets, so they have multiple different
4 configurations within a set of instruments, for
5 instance, bipolar forceps. I've got a set of bipolar
6 forceps that have three different -- each one has a
7 different angle or angulation of the active portion
8 so it can best reach certain -- different areas that
9 I need to address.

10 Q You go on in paragraph 47, you say,
11 "Medical devices are often designed to be used on a
12 range of anatomical structures, and patient anatomy
13 and physiology differs from one patient to the next,
14 so what is optimal for one patient may be different
15 for another patient." So you're saying you have to
16 have a different configuration for each patient?

17 MS. COHEN: Objection, form.

18 A No, I'm not saying you have a different
19 configuration, but something that is adaptable and
20 can be applied to multiple different anatomies. So
21 everyone's anatomy, even though they have similar
22 structures, you know, a young woman, you know, could

1 be four foot 11 and 90 pounds, and you can have a man
2 who's six foot eight and 300 and something pounds,
3 and their anatomy's not going to be the same. So do
4 we have different instruments for every different
5 size person? No. What we do is hopefully we'll have
6 instruments that can be adapted or adjusted, just
7 like we've described before in both Stern and in the
8 '271 patent is that they can be configurable.

9 So certain electrode pairs can be activated
10 while others are deactivated, and actually, '271
11 described that, where only maybe a portion of it, and
12 we discussed this, only a portion of it, maybe the
13 distal portion will be activated because that's in
14 contact with tissue, whereas the proximal portion may
15 not be, and Stern describes that also by being able
16 to conform to irregular surfaces by activating
17 certain electrodes compared -- and not others, or
18 various pairs.

19 Q So in your practice, how does that change
20 -- how do you modify the nasal ablation equipment to
21 account for the characteristics of the patient?

22 A Yeah, well, we can do that multiple

1 different ways. You can do it by changing the number
2 of applications that can be done, so instead of
3 treating an area four times, you can treat it six
4 times if it's a bigger structure.

5 Q Uh-huh.

6 A If it's a structure -- let's give an
7 example. The turbinates, just for -- the easiest and
8 largest structures in the nose. If we want to treat
9 more of the mucosa, we can treat longer lengths of it
10 with the device on the surface, or we can treat it
11 more frequently. You know, so if you have a single
12 row of electrodes, you may have to treat something
13 more frequently as opposed to if you have multiple
14 rows of electrodes, you can treat the same amount
15 with fewer treatments.

16 Q Let's take a look at paragraph 49.

17 A Okay.

18 Q You state that, "Claim 11 recites in part
19 before removing the treatment element from the nasal
20 airway, repositioning the treatment element to
21 contact a different portion of nasal mucosa.
22 Dr. Bikson appears to disagree that a person of

1 ordinary skill in the art would have understood
2 disclosures that teach using treatment elements to
3 apply energy to different portions of the nasal
4 mucosa as taught by multiple references to mean that
5 the treatment element is repositioned without first
6 removing treatment element from the nasal airway. I
7 previously explained that a person of ordinary skill
8 in the art would have understood that the treatment
9 element is repositioned before removing it from the
10 nasal airway, as this is a well understood sequence
11 for a clinical procedure and is consistent with how
12 similar procedures in the nose have been carried out
13 since long before the '271 patent was filed." So
14 John, can you identify where in the cited prior art
15 it discloses repositioning before removing from the
16 nasal airway?

17 MS. COHEN: Objection, form.

18 A Well, in Edwards, and if we can go back to
19 my original declaration, or we can go to Edwards, but
20 in my original declaration -- let me see where this
21 is. This would be -- let's see. Do you have -- do
22 you have Edwards?

1 Q I do.

2 A Edwards shows in 3A through 3D -- actually,
3 3B and 3D, the inflatable -- the inflatable member
4 contacting different parts of the middle turbinate.
5 He also states within his prior art that the
6 inflatable member can be used to treat multiple areas
7 within the nasal cavity, including the inferior
8 concha, middle turbinate and/or superior concha, and
9 that, you know, you cannot treat multiple areas
10 within the nose, including those structures, with a
11 single application.

12 You have to move the device in order to
13 contact those different areas, and since this is an
14 inflatable device, when you place it in, before you
15 ever inflate the device, as shown on figure 3A, that
16 balloon may be tightly wrapped on that cannula, but
17 once you inflate it, it's not going to be -- and then
18 deflate it, it's not going to be tightly wrapped
19 anymore.

20 So removing that device completely from the
21 nose and reinserting it again could be very
22 uncomfortable for the patient, so these procedures --

1 and we do these types of procedures all the time, and
2 when we access one side of the nose for a procedure,
3 whether that be radiofrequency or other procedures,
4 such as the microdebrider I described to you before,
5 we do everything that we could possibly do within
6 that nasal cavity with a single insertion before we
7 remove it unless we're caused to remove it for some
8 other reason like bleeding or pain or something, but
9 that is repositioning the -- you know, that's where
10 Edwards specifically states and shows repositioning
11 the treatment element before removing it.

12 Q Where does it specifically state before
13 removing it?

14 A Well, it --

15 MS. COHEN: Objection, form.

16 A It doesn't specifically state that, but it
17 does say treating multiple areas, inferior, middle
18 and/or superior concha, right? And it's not or. If
19 it was or, then it may not be, but we know clinically
20 -- I mean, Dr. Bikson -- no offense, but Dr. Bikson
21 has never treated a patient in his life, so he
22 wouldn't know that you don't remove these devices in

1 between applications, and obviously most of these
2 devices require multiple applications.

3 So what's the number one -- clinically the
4 number one thing we're trying to do? Well, we're
5 trying to treat a problem, but we're trying to treat
6 a problem with minimal patient discomfort, and in
7 order to minimally make a patient uncomfortable, we
8 don't want to keep putting instruments in and out
9 through the nasal cavity, okay?

10 Some of these instruments, such as the
11 device from Kong, which is a needle, same -- similar
12 to somnoplasty needle, which is actually Stuart
13 Edwards, who is the -- this is Edwards, who actually
14 designed somnoplasty also, we treat four or six
15 areas. We don't want to be taking a needle that is
16 hot outside the nasal cavity after each application.
17 That means the needle goes in and out six times,
18 right? That's not what we do.

19 So it is minimal discomfort to the patient,
20 and that's done by minimum manipulation of the tissue
21 and of the instrumentation.

22 Q But you would agree that Edwards does not

1 specifically state don't remove it when
2 repositioning.

3 A Well, he --

4 MS. COHEN: Objection, form.

5 A Yeah, he doesn't specifically state that,
6 but he -- a person of ordinary skill and a person who
7 -- of ordinary skill, especially who does clinical
8 medicine in otolaryngology treats nasal procedures
9 would have understood based on his depiction of
10 treating different areas of the inferior turbinate
11 and his figures, and also mentioning treating the
12 inferior, middle and/or superior turbinate, that
13 there would be repositioning of the instrument to
14 contact different areas of the mucosa prior to
15 removal.

16 Q So in paragraph 51 of your declaration,
17 John, you I think described the process you were just
18 talking about --

19 A Uh-huh.

20 Q -- procedure carried out using somnoplasty,
21 and you talk about advancing the needle --

22 A Uh-huh.

1 Q -- repositioning before removing, and you
2 state, "All of these steps are performed before
3 removing the treatment element from the nose. This
4 procedure is also described in prior art articles,"
5 and you cite the Cavaliere article, and what -- what
6 is that article, John?

7 MS. COHEN: Objection, form.

8 A I don't remember that specific -- the
9 details specifically of that article, but there are
10 many articles that -- I mean, like I said, I've been
11 doing this procedure since the '90s, so there are
12 many -- let me see. I can't tell you exactly what is
13 in this article at this time, but it's just going to
14 be an example of radiofrequency treatment of the
15 inferior turbinate, as I described here.

16 You know, you see a quote from it
17 underneath, which is what I described also because
18 it's a ten millimeter active portion of the electrode
19 that can be advanced first ten millimeters, then
20 additional ten millimeters, and that's the
21 repositioning, and then taking it out and reinserting
22 it.

1 Q Okay, take a look at paragraph 57 of your
2 declaration. You state, "Claim 16 recites bending a
3 shaft of the nasal airway treatment device before
4 contacting the treatment element with nasal mucosa.
5 In my first declaration, I explained that this
6 limitation would have been obvious in view of Edwards
7 '535's teaching of a shaft of a nasal airway
8 treatment device where the shaft is bent, as common
9 sense dictates that the shaft would have been bent
10 before contacting the treatment delivery element with
11 the mucosa." So John, are you saying there that it's
12 necessary that when you are treating, that you have a
13 bend in the shaft?

14 A In most cases, absolutely, absolutely. So
15 if you -- if you think about -- and I know you don't
16 do this, but I'm going to -- I'm going to --
17 actually, this -- this is a picture of it. It just
18 happened to be that way, but -- and you see there's a
19 bend in the shaft here.

20 Q Right.

21 A Right? So what you have to understand is
22 that there's a person here --

1 Q Yeah.

2 A -- obviously holding this instrumentation,
3 so if there's no bend in that shaft, then that
4 shaft's coming straight out this way.

5 Q Uh-huh.

6 A And you're trying to see beyond that shaft,
7 whether you're doing it with your naked eye or a
8 headlight or whether you're doing it with a scope.

9 Q Uh-huh.

10 A If you're doing it with a scope, then
11 you've got two instruments going in exactly the same
12 direction, so then you've got two instruments going
13 the same place, and if that shaft was straight, the
14 maneuverability is much worse, okay? If you have a
15 bend in the shaft, then that shaft where you're
16 holding that down here is out of the point of view of
17 the user, of the clinician.

18 So we do not -- I can't think of a single
19 instrument that I have aside from maybe something in
20 the operating room, but I can't think of a single
21 instrument that I use in the office that is perfectly
22 straight that I -- doesn't have a bend in the shaft

1 or require a bend in the shaft.

2 Q Take a look at your paragraph 63. You give
3 us a picture -- actually, sorry, 62. It's just above
4 62, you --

5 A Uh-huh.

6 Q -- provide this picture, and from what I
7 understand, you say that this is typical examples of
8 nasal treatment device as shown below, all of which
9 have prebent shafts to allow the device to be used
10 within the recesses of the nose and sinuses.

11 A Uh-huh.

12 Q It appears to me that the first one in the
13 image there, the one that's closest to the
14 photographer is straight, is it not?

15 A No, look at the -- look at the handpiece.
16 Look at the -- the -- which is on the right side.

17 Q Uh-huh.

18 A You see the little black tabs?

19 Q Yeah.

20 A So that's kind of where your finger goes.
21 So these are actually suction cannulas, okay? So
22 those are where your finger go -- your thumb would go

1 to hold it, and if I'm right-handed, I'm holding it
2 with my right hand, but if you look -- and again,
3 this is the same problem we have with that figure
4 that was -- we're seeing it obliquely --

5 Q Uh-huh.

6 A All of these are bent. If you look at the
7 metal as it first comes out, you see an angle, but
8 what you're also seeing is these are actually bent
9 down. So the handpiece is here, and it's coming out
10 this way, so that -- just like this bend in figure 3A
11 --

12 Q Uh-huh.

13 A -- of Edwards, it's going this way. You
14 can't see it well. You can see it on the one
15 furthest to the left --

16 Q Right.

17 A -- where it's angled, but these are all
18 angled.

19 Q So you're saying there's a -- there's a
20 bend in the shaft both proximal and distal.

21 A Right, but here is a bend proximally. Some
22 of them have a distal -- the one -- the one closest

1 to us on the right doesn't have a distal bend.

2 Q It has a proximal.

3 A It's straight, but the proximal shaft is
4 curved, is bent, as are all of them. These are just
5 examples of -- you see some of them are bent. The
6 distal shaft is bent to the right to access things on
7 the right side. The next one, next to last, bent to
8 the left, as is the last one. So they all have
9 proximal bends.

10 Q Uh-huh.

11 A The one on the right doesn't have a distal
12 bend, but the others have distal bends of different
13 angles, different directions.

14 Q Let's take a look at the '271 patent then,
15 just by comparison.

16 A Uh-huh.

17 Q And I'm -- we can take a look at a number
18 of the figures, but maybe we'll start with figure 9B.

19 A Okay, okay.

20 Q It appears to me that that shaft does not
21 have a bend. Would you agree?

22 A This shaft doesn't have -- I can't tell

1 from here. It looks like that the distal part has a
2 little bend right near the treatment area.

3 Q So is it your contention that in order to
4 work, the shaft has to have a bend?

5 A No, what I said is it's much easier if the
6 shaft has a bend, and most of our instrumentation has
7 a bend because it takes the -- the user's hand out of
8 the line of sight. Now, if -- this device depends on
9 the length of this device. If your hand is way
10 forward and you're using a scope, it would be a
11 little easier to get around it, but even that, most
12 of our instruments are going to have a bend because
13 they're going to keep them in different -- different
14 angles for each hand. Now, remember, if you're using
15 two hands, you got two -- you're trying to get them
16 in one nostril and you've got two devices that are
17 going straight, your hands are right next to each
18 other.

19 Q Uh-huh.

20 A Right? And you're going to be bumping your
21 hands into each other. So you want one below the
22 other or above the other, and you couldn't do that if

1 the instruments are perfectly straight, both of them,
2 okay? It's going to be more difficult. This looks
3 like it has a little bit of a distal bend, but again,
4 most of it looks to be fairly straight.

5 Q And looking at -- let's say, turn to figure
6 18. Would you agree that that one appears to be --

7 A Yeah, that's straight.

8 Q -- reasonably straight?

9 A Sure. I didn't say every instrument we
10 had, but a vast majority of our instruments are going
11 to have a bend in the shaft. There are -- obviously
12 there's going to be some straight instruments, but
13 there are going to be a lot of them, especially
14 instruments that we're going to be trying to treat
15 multiple areas within the nasal cavity are going to
16 have bends so that we can, again, keep our hand
17 that's holding the instrument out of the line of
18 sight. Now, some instruments, again, some are going
19 to be straight, but a lot of them are going to be --
20 have a bend also, and then there's some that --
21 obviously that you -- you know, you're going to bend
22 to the appropriate degree beforehand, and that can be

1 changed.

2 MR. WARD: Okay, that's all the questions I
3 have.

4 EXAMINATION BY COUNSEL FOR NEURENT MEDICAL, INC.

5 AND NEURENT MEDICAL LTD.

6 BY MS. COHEN:

7 Q I have a few questions. So first, Dr.
8 DelGaudio, if you take your reply declaration --

9 A I'm sorry, what?

10 Q Your reply declaration?

11 A Okay.

12 Q Okay, and if we go to pages 3 and 4 and
13 look at paragraph 9, do you recall counsel asking you
14 about your work on helping develop the image-guided
15 --

16 A Yes.

17 Q -- navigation system? And my question is
18 is it your opinion that this experience qualifies you
19 as a person of ordinary skill in the art under
20 Dr. Bikson's definition?

21 A Yes, I do.

22 Q Can you explain why?

1 A Well, because his -- let me access his
2 definition again. At least three years' experience
3 in the development of medical devices, right? Design
4 and development, and again, this -- we're talking
5 again about the image guidance, correct?

6 Q Correct.

7 A Correct, and as I mentioned previously that
8 the work that I did with the engineers, with the
9 reps, with the people at Medtronic were to
10 troubleshoot the problems with the system, with its
11 accuracy, with the problems that -- eventually some
12 of which turned out to be related to the registration
13 techniques and the imaging techniques, and that the
14 work that I did with them and the knowledge that they
15 gained from working with me resulted in changes and
16 advancements in the system, in the software and in
17 the registration techniques that were incorporated
18 into the next version of the update for that system.

19 Q I'm going to turn to a different line of
20 topics that counsel was asking you about. If you go
21 to page 11 of your reply declaration --

22 A Uh-huh, yes.

1 Q And you see figure 17 from Stern?

2 A Yes.

3 Q And you recall counsel asking you if you
4 had included figure 17 in your initial declaration?

5 A Yes.

6 Q Okay, can you take your initial declaration
7 in this case, Exhibit 1002, and go to page 61?

8 A Yes.

9 Q Okay, and then I'm going to ask you to look
10 in the middle of this paragraph, do you see the line
11 starting, "Specifically, figure 19," and then it goes
12 on and it has two citations?

13 A Yes.

14 Q Okay, can you pull up Stern?

15 A Yes.

16 Q 1033? You see where you cite column 13
17 lines 1 through 44 in Stern?

18 A Uh-huh.

19 Q Can you please turn to that and explain
20 what that section is?

21 A Thirteen, 1 to 44. I'm not sure I got
22 Stern. Okay, that's actually at -- it says 1 to 11,

1 but I think it's 3 to 44, yeah, yeah, because 1's the
2 last segment of the previous paragraph.

3 Q Uh-huh.

4 A Okay, starting on -- on line 3.

5 Q Yeah, so what is that paragraph describing?

6 A So let me -- you want me to read the
7 paragraph or --

8 Q You can read it to yourself.

9 A Okay. Okay, so this is describing -- and
10 I'm halfway through it, but this is describing --
11 exactly what we discussed, the monopolar and the
12 bipolar figures, so even though the figure's not
13 included here, we referenced the monopolar and the
14 bipolar electrodes from Stern.

15 Q Okay, so to be clear, the description of
16 figure 17 is cited in your --

17 A Correct.

18 Q -- declaration?

19 MR. WARD: Objection to form.

20 MS. COHEN: I have no further questions.

21 MR. WARD: We're off the record.

22 (Off the record at 1:42 p.m.)

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)

1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

2 I, Karen Young, Court Reporter and Notary
3 Public within and for the District of Columbia, do
4 hereby certify:

5 That John Michael DelGaudio, M.D., the
6 witness whose deposition is hereinbefore set forth,
7 was duly sworn by me before the commencement of such
8 deposition, and that such deposition was taken before
9 me and is a true record of the testimony given by
10 such witness.

11 I further certify that the adverse party,
12 Neurent Medical, Inc. & Neurent Medical Ltd., was
13 represented by counsel at the deposition.

14 I further certify that the deposition of
15 John Michael DelGaudio, M.D. occurred at the offices
16 of Wilmer Cutler Pickering Hale and DORR LLP, 2100
17 Pennsylvania Avenue, Northwest, Washington, D.C., on
18 Friday, February 7, 2025 commencing at 9:34 a.m. to
19 1:42 p.m..

20 I further certify that I am not related to
21 any of the parties to this action, and that I am in
22 no way interested, financially or otherwise, in the

1 outcome of this matter.

2 IN WITNESS WHEREOF, I have hereunto set my
3 hand this 18th day of February, 2025.

4
5 *Karen Young*



6
7 My commission expires:

8 September 14, 2029
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Transcript of John M. DelGaudio, M.D.
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ERRATA SHEET

Neurent Medical Inc., et al. -v- Aerin Medical Inc. / The Foundry, LLC (PTAB)

Witness Name: John M. DelGaudio, M.D.

Deposition Date: February 7, 2025

I, Dr. John DelGaudio, wish to make the following changes to the record:

Page	Line(s)	Now Reads	Should Read	Reason
102	13-14	if the two on the left were both positive and the two on the left are both negative	if the two on the left were both positive and the two on the right are both negative	Correct interpretation
167	16-18	a person of ordinary skill in the art would have understood a medical device to have a single optimal configuration	a person of ordinary skill in the art would “not” have understood a medical device to have a single optimal configuration	Read incorrectly by counsel from my reply declaration
169	17	certain electrodes compared	Certain electrode pairs	Erroneously transcribed
172	4	contacting different parts of the middle turbinate.	contacting different parts of the “inferior” turbinate.	Incorrect term spoken

ERRATA SHEET

Neurent Medical Inc., et al. -v- Aerin Medical Inc. / The Foundry, LLC (PTAB)

Witness Name: John M. DelGaudio, M.D.

Deposition Date: February 7, 2025

Date: 2/25/26

Signed: John M. DelGaudio

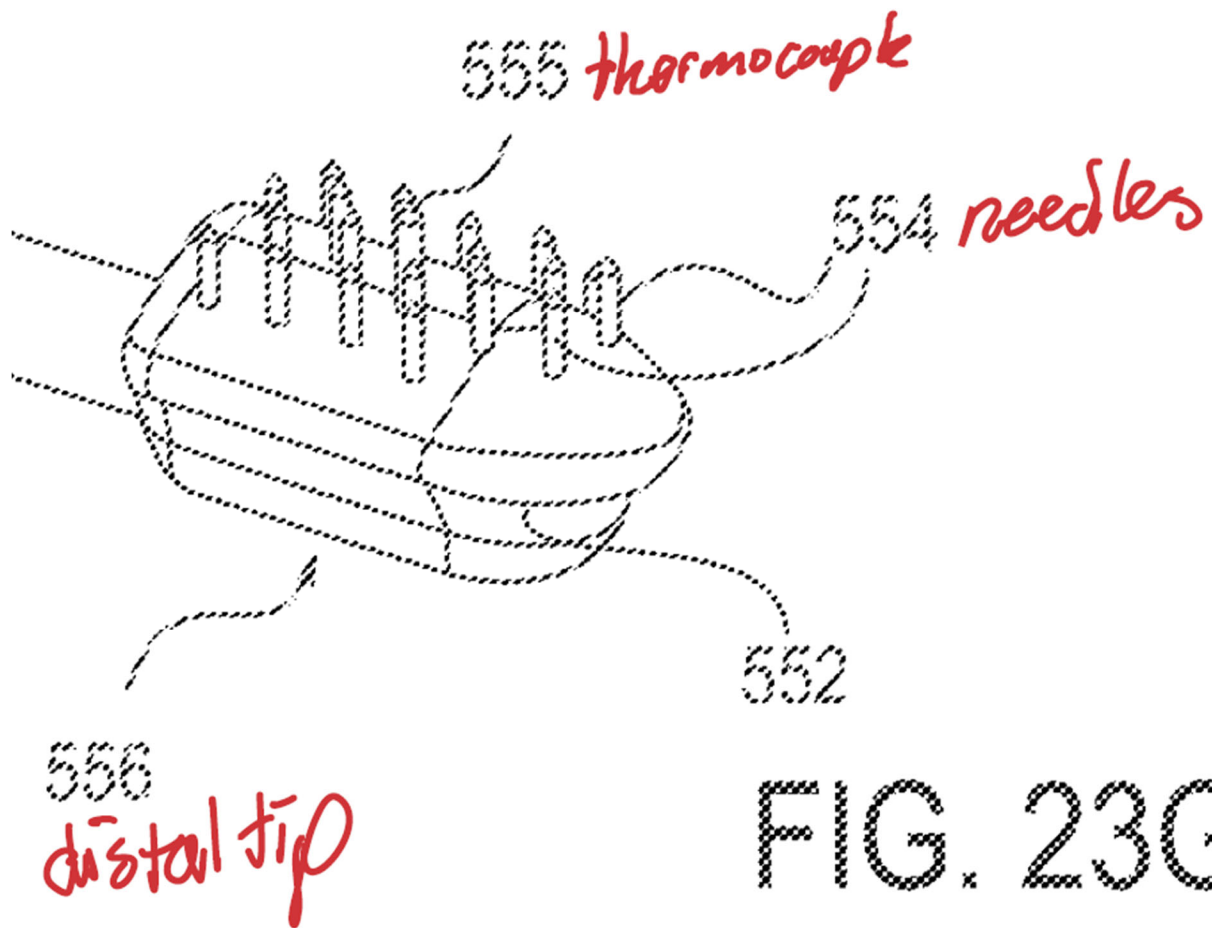


FIG. 23G