1 UNITED STATES PATENT AND TRADEMARK OFFICE

2 BEFORE THE PATENT TRIAL AND APPEAL BOARD

3 ----------X

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

5 Petitioners,

6

7 -against-

8

THE FOUNDRY, INC.,

9 Patent Owner.

10 ----------X

11 Case No. IPR2024-00279
U.S. Patent No. 10,610,675

12 Case No. IPR2024-00280
U.S. Patent No. 10,894,011

13 Case No. IPR2024-00669
U.S. Patent No. 11,679,077

14 ----------X

15

16 DEPOSITION OF

17 DR. HOWARD LEVINE

18 NEW YORK, NEW YORK

19 JANUARY 9, 2025

20

21 REPORTED BY: KIARA MILLER

22 FILE NO.: 566488

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16 Deposition of DR. HOWARD LEVINE, taken on behalf

17 of Petitioners, at One Vanderbilt Avenue, New York,

18 New York, commencing at 9:00 AM, January 9,

19 2025, before Kiara Miller.

20

21

22

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

2

3 ON BEHALF OF PETITIONERS:
WILMER CUTLER PICKERING HALE & DORR, LLP

4 60 State Street

5 Boston, MA 02109

6 EMAIL: ALEX.NEMTZOW@WILMERHALE.COM

7 JOSH.STERN@WILMERHALE.COM

8

9 BY: ALEXANDER J. NEMTZOW, ESQ.

10 JOSH STERN, ESQ.

11

12 ON BEHALF OF PATENT OWNER:
GREENBERG TRAURIG

13 1144 15th Street, Suite 3300

14 Denver, CO 80202

15 EMAIL: BRIGGSH@GTLAW.COM

16 ARAJE@GTLAW.COM

17

18 BY: HEATH BRIGGS, ESQ.

19 ELANA B. ARAJ, ESQ.

20

21 ALSO PRESENT:

22 TECHNICIAN, HAROLD RODRIGUEZ

1 H O W A R D L E V I N E, after having first been
2 duly sworn by a Notary Public of the State of New
3 York, was examined and testified as follows:
4
5 EXAMINATION BY
6 MR. NEMTZOW:
7 Q Good morning.
8 A Good morning.
9 Q I know we just introduced ourselves
10 already, but it's nice to meet you again.
11 A Thank you.
12 Q Could you please state you full name for
13 the record?
14 A Howard Dr. Levine.
15 Q Where do you live?
16 A My residence is Florida, Sarasota,
17 Florida.
18 Q How long have you been there for?
19 A Since 2007.
20 Q And you understand that the oath that
21 you just took is the same oath that you'd be
22 required to take if you were testifying in

1 the United States District Court?
2 A I do.
3 Q Is there any reason you can't provide
4 complete and accurate testimony today?
5 A None that I know of.
6 Q I'm just going to review a few ground
7 rules for today. I think you've been deposed
8 before, correct?
9 A I have.
10 Q A lot of this will be a review, but I
11 just want to make sure we're clear on them.
12 Please give audible answers, not just head
13 nods, so that the court reporter can write
14 down everything for a clear record.
15 Please let me finish my questions before
16 you answer; so again, that the court reporter
17 can make sure that they have the full
18 question and answer. Does that make sense?
19 A It does.
20 Q If you need a break, please feel free to
21 let me know and I will do my best to make
22 sure we take one as soon as possible. As you

1 probably know we can't take break when
2 there's a question pending.
3 A I understand.
4 Q Great. And after we take breaks I may
5 ask if you had a conversation with your
6 counsel about the substance of your
7 testimony. Do you understand?
8 A I do.
9 Q Now you submitted three declarations in
10 the matters that are at issue today; is that
11 right?
12 A I have.
13 Q Do you have them with you?
14 A I have them in front of me.
15 Q All right. So can you take the first
16 one from your pile there, and would you let
17 me what IPR number that is?
18 A It's the one ending in 675.
19 Q Okay. And, just for the record, this is
20 IPR, your declaration which is Exhibit 2003
21 in IPR2024-00279 relating to US Patent
22 No. 10610675; is that right?

1 A That's what's on the cover.
2 Q Put that one aside.
3 And can you grab the next one?
4 And which one is this?
5 A This ends in 011.
6 Q 011. Would you mind reading the Case
7 No. and then the patent number?
8 A Case number IPR 2024-00280.
9 Q I'll just pause for a moment, for the
10 previous declaration we looked at, will you
11 understand if I refer to that as your
12 declaration in the 077 IPR?
13 A Say.
14 Q The first one that you picked up, will
15 you understand me if I refer to declaration,
16 sorry the 675 declaration?
17 A Yes.
18 Q My apologies.?
19 A I will understand that, yes.
20 Q Then for the one that's sitting in front
21 seat of you for the patent number ending in
22 011 you'll understand me --

1 A I will understand that.
2 Q -- as the 011 declaration?
3 A I will.
4 Q Like wise the 675 Patent and 011 Patent?
5 A Yes.
6 Q And then, finally, is the last
7 declaration that you have in front of you,
8 the one in Case No. IPR 2024-00669
9 relating --
10 A Yes.
11 Q -- to US Patent No. 11679077?
12 A Correct.
13 Q And you'll understand me if I refer to
14 the 077 patent?
15 A I will.
16 Q And to your declaration relating to that
17 the patent is the 077 declaration?
18 A I will understand that.
19 Q Okay, great. I may sometimes refer
20 to -- actually, strike that.
21 You understand that today's deposition
22 is taking place in all three of the IPRs that

1 we just discussed, correct?
2 A I do.
3 Q And you're offering testimony for all
4 three proceedings?
5 A I am.
6 Q And I may sometimes refer to three
7 foundry patents that we just discussed
8 together as the foundry patents. Do you
9 understand that?
10 A I do.
11 Q And I may refer to your declarations as
12 the three declarations we just talked about
13 collectively?
14 A I understand that.
15 Q If you believe that there's something
16 unique to one of patents or one of the
17 declarations, you'll please tell me, right?
18 A I will.
19 Q And then otherwise I'll just understand
20 that your answers relate to all three patents
21 and all three declarations?
22 A Agree.

1 Q Thank you.
2 All right. I think we've already
3 established this, but have you been deposed
4 before?
5 A I have.
6 Q How many times?
7 A I don't have an exact number, but
8 probably about 25 to 30 times.
9 Q 25 to 30 times.
10 And how many of those depositions were
11 in cases that were related to intellectual
12 property?
13 A Two.
14 Q Two. And and were those in the same
15 case or different cases?
16 A In the same case.
17 Q And what was that case?
18 A I have in my declaration I have the --
19 those -- that listed it was a case that
20 involved intellectual property between a --
21 an individual, and a company, Acclarent
22 Johnson and Johnson.

1 Q Was that Acclarent verses Ford Albritton
2 case?
3 A Correct. That is right.
4 Q So you were deposed two times in that
5 case?
6 A Yes.
7 Q And then I believe you also listed in
8 your declaration the United States versus
9 Facteau case?
10 A Yes.
11 Q And what was that case about?
12 A That was a case of an alleged off-label
13 use of a medical device.
14 Q Okay. What's an off-label use?
15 A It is a use of a device that has not
16 been approved by the FDA.
17 Q And what was the device at issue in that
18 case?
19 A It was a drug-eluting stent that was
20 being placed into the nasal sinus cavity.
21 Q What was that stent intended to be used
22 for?

1 A It was intended to bathe, wash, irrigate
2 the nasal sinus passage way.
3 Q What was the off-label use for that
4 stent?
5 A It was the addition of the nasal
6 steroids, corticosteroids, the
7 corticosteroids having already been an
8 approved drug, but not indicated for its use
9 in that stent.
10 Q I see. Are you aware of other instances
11 where medical devices have been used
12 off-label in the nasal cavity?
13 A Have been used...
14 Q Off-label in the nasal cavity?
15 A I am not.
16 Q You're not, okay.
17 So you can't identify any instance where
18 a nasal medical device has been used
19 off-label aside from the one that you just
20 told me about?
21 A Let me qualify that. I know that
22 physicians and probably even I have used

1 different medical materials or devices.
2 We -- I as a physician have made that
3 decision to use it recognizing that there was
4 not approval, but believing that it would
5 provide some kind of therapeutic benefit to
6 my patient. So this was a physician chosen
7 decision versus my doing it under the
8 direction of a company saying use this device
9 in this manner.
10 Q Understood. So in the instances where
11 you've performed off-label use of medical
12 devices, you decided to perform that
13 off-label use based on your experience as a
14 clinician?
15 MR. BRIGGS: Objection. Form.
16 A Yes.
17 Q Okay. Now, taking a step back, you
18 identified 25 to 30 cases where you've been
19 deposed before; is that right?
20 A Yes.
21 Q Did any of those cases relate to devices
22 that deliver radio frequency energy to the

1 nose?
2 A I don't recall that any of them did.
3 Q Did any of them involve the design or
4 development of devices that deliver energy to
5 the nose?
6 A I do not recall that any of them did.
7 Q We can set the previous depositions
8 aside.
9 When did you first learn about the
10 dispute between Foundry and Neurent regarding
11 the patents at issue in this case?
12 A I don't have an exact date. I believe
13 it was about a year ago.
14 Q Okay. And do you recall from whom you
15 learned about the dispute?
16 A I don't. I received a phone call from
17 an individual who told me that they might
18 wish to engage me to provide an opinion
19 concerning these patents and they -- and we
20 had a conversation about my background,
21 qualifications, and they would get back to
22 me. And I didn't hear anything for quite an

1 extended period of time.
2 Q I see. Was that phone call from a
3 service that identifies experts for
4 litigations?
5 A I don't believe it was, but I don't
6 recall specifically.
7 Q Was it from a lawyer?
8 A I don't recall that either. I don't
9 recall if it was from an attorney or it was
10 an official from the company or it was an
11 attorney from that company.
12 Q So you said you first learned about the
13 dispute about a year ago, and then there was
14 some time between then and when you were
15 contacted again?
16 A Yes.
17 Q Do you recall the second time that you
18 were contacted?
19 A I don't recall the details other than
20 receiving a phone call asking if we could
21 meet and have a discussion.
22 Q Okay. And do you recall who called you

1 for that second outreach?
2 A I don't.
3 Q Was it a lawyer?
4 A I don't recall.
5 Q Was it someone at The Foundry?
6 A I don't recall.
7 Q Was it someone at Aerin Medical?
8 A I don't recall.
9 Q Okay. All right. And was there a
10 subsequent call after that second outreach to
11 you?
12 A Yes.
13 Q And do you recall who that was with?
14 A I don't recall the details. I would
15 suspect and believe that it was from an
16 attorney and to have further conversation
17 about engagement in these activities.
18 Q And was that an attorney at the Finnegan
19 law firm?
20 A I believe so.
21 Q Okay.
22 A I didn't recall that name until you

1 mentioned that name, but I believe that is
2 the case.
3 Q Great. And who retained you
4 specifically, was it an attorney from the
5 Finnegan law firm?
6 A I don't believe that there -- I was
7 retained by them, but I don't recall that
8 either. I have that in separate notes that I
9 have not reviewed for today.
10 Q Okay, understood. Let's see.
11 And do you recall if you were retained
12 specifically to work on inter partes review
13 proceedings?
14 A Yes.
15 Q Okay. And prior to this matter, have
16 you ever done any work with the Finnegan law
17 firm?
18 A I have not.
19 Q Prior to your work on this matter, have
20 you done any work for the Greenberg Traurig
21 law firm?
22 A No. I have not.

1 Q Are you familiar with a company called
2 Aerin Medical, Incorporated?
3 A I am.
4 Q How are you familiar with them?
5 A I'm familiar at several different
6 levels. At one level being a practitioner in
7 special interest in nose and sinus problems.
8 I'm familiar with the devices that they have
9 created and how it relates to me and the
10 management of my patients. I'm familiar with
11 the company in that many of the principals of
12 that company are people I worked with at
13 other companies, so I know those individuals.
14 I -- thirdly, I am familiar with a company
15 because I have provided as an independent
16 consultant for the company, advice concerning
17 safety of the devices that are used when
18 they're adverse events. I also have provided
19 that as it relates to the clinical use and
20 the use of those devices and any adverse
21 events in any of clinical trials that are
22 being undertaken.

1 Q All right. You mention that you worked
2 as an independent consultant for Aerin
3 Medical?
4 A Yes.
5 Q When were you first retained to serve as
6 an independent consultant for Aerin?
7 A Again, I don't have an exact date. I
8 would estimate, I could provide an exact date
9 if you wish separately, but about two years
10 ago.
11 Q About two years ago. And have you
12 worked with them continuously over the last
13 two years?
14 A Yes.
15 Q When was the last time you provided
16 consulting services for Aerin Medical?
17 A Within the last week.
18 Q Within the last week.
19 What did that involve?
20 A It involved reviewing adverse events
21 that occurred in the last quarter of 2024,
22 and seeing if any of those needed any

1 detailed discussion or by our safety
2 committee and I, as a physician, providing
3 any input to them about that.
4 Q Understood. And about how much has
5 Aerin Medical paid you for consulting
6 services to date?
7 A I don't have this number, I don't know.
8 Q Is it more than 40,000?
9 A Over the two years or more, I believe
10 so.
11 Q Is it more than 45,000?
12 A I don't know.
13 Q Do you report those payments to a
14 government database?
15 A I report them to Internal Revenue
16 Service as part of income earned.
17 MR. NEMTZOW: Can we have Tab 11.
18 Q While we're waiting for that, my
19 apologies.
20 Are you aware that The Foundry alleges
21 that Aerin Medical is the exclusive licensee
22 of The Foundry patents that are at issue in

1 these IPRs?
2 A I am.
3 Q Are you aware that Neurent has also
4 filed IPRs challenging patents owned by Aerin
5 Medical?
6 A I am.
7 Q Have you reviewed any of those patents?
8 MR. BRIGGS: Objection. O form.
9 A Which patents are you asking have I
10 reviewed?
11 Q Sure. I'll clarify. So we just
12 established that you're aware that Neurent
13 has filed IPRs challenging patents owned by
14 Aerin Medical, correct?
15 A Yes.
16 Q Of those patents owned by Aerin Medical
17 that Neurent has filed IPRs, have you
18 reviewed any of those patents?
19 A I don't know the answer to that. I have
20 only reviewed the issues as it relates to
21 Foundry. I'm aware that there are these
22 other patents that are being questioned. I

1 don't know what those patents are however.
2 It's possible that there are similar or
3 overlapping patents, I don't know that.
4 Q And do you recall ever having reviewed a
5 patent for Aerin Medical?
6 A The patents that I've reviewed are the
7 ones that relate to these -- The Foundry
8 issues that we've identified. I don't know
9 if any of these are similar in any way to the
10 Aerin patents. So I don't know if I reviewed
11 them or not.
12 Q Great. All right. I'd just like to
13 return to the payments point, just very
14 quickly.
15 A Sure.
16 Q I'd like to mark as Exhibit 1 to the
17 deposition of Dr. Levine, a printout from the
18 website Openpaymentsdata.cms.gov.
19 (Whereupon, Printout from
20 Openpaymentsdata.cms.gov was
21 marked as Exhibit 1 for
22 identification as of this date.)

1 MR. BRIGGS: We're going to object to
2 this as being relevant, at this time,
3 on the record.
4 MR. NEMTZOW: Understood.
5 Q And do you see here on the page -- or do
6 you recognize this document?
7 A I have not seen this document.
8 Q Are you familiar with the
9 openpaymentsdata.cms --
10 A I am.
11 Q -- .gov database?
12 A Yes.
13 Q And do you see here at the bottom of
14 Page 1, a selection for filters?
15 A Yes.
16 Q And those filters are for the "year
17 all", "record type", "general payments",
18 "nature of the payments", "all natures",
19 "company making payments", Aerin Medical
20 Inc."
21 A I see that.
22 Q Okay. And then do you see on the next

1 page, Page 2 of Exhibit 1, totals by record
2 type in all years?
3 A I see that.
4 Q And you see general payments record
5 listing $46,466.21?
6 A I see that.
7 Q Is that the amount of money that Aerin
8 Medical has paid you, to date, for your
9 consulting services?
10 A I don't know how accurate this is. And
11 one reason I don't know how accurate it is,
12 is that, first, the address that's listed
13 here, is not my medical practice address.
14 That's an address I've not practiced at for
15 probably 10 or 12 years. So I don't know,
16 and have not updated, if it was my
17 responsibility to. I have not.
18 So I don't know if this is complete or
19 not. I don't know the accuracy of this or
20 not.
21 Q Okay. Do you have any reason to believe
22 that you've been paid less than the

1 $46,466.21?
2 A I don't believe I've been paid less.
3 There's no reason to think I've been paid
4 less.
5 Q Thanks. You can put that aside.
6 Have you ever spoken to anyone at Aerin
7 Medical about this case?
8 A I have not.
9 Q Okay. And have you ever spoken to
10 anyone at The Foundry about this case?
11 A I have not.
12 Q Okay. Now, going back a little bit.
13 Earlier today, you mentioned that you
14 knew some individuals from other companies
15 who now work at Aerin Medical; is that right?
16 A Correct.
17 Q Could you tell me who those individuals
18 are?
19 A One would be Matt Brokaw, who is the, I
20 think, titled CEO of Aerin Medical.
21 Q That's one.
22 Is there any others?

1 A Yes. An individual, Anais, A-N-A-I-S,
2 Laborde, L-A-B-O-R-D-E, who was an
3 administrator at Aerin Medical, I think since
4 has left that the company. Matt Salkeld,
5 S-A-L-K-E-L-D.
6 Q Are there any others?
7 A It's certainly possible that there are
8 some others in other roles at Aerin, I don't
9 remember any others at this point in time.
10 Q Okay. And taking those in turn.
11 You mentioned the CEO, Mr. Brokaw?
12 A Yes.
13 Q And you've worked with Mr. Brokaw
14 before?
15 A Yes.
16 Q Is that at Acclarent?
17 A At Acclarent.
18 Q Have you worked with him at any other
19 companies before?
20 A I have not.
21 Q Okay. And what was the nature of your
22 working relationship at Acclarent with

1 Mr. Brokaw?
2 A He was in marketing, and then head of
3 marketing. I, as the only physician advisor
4 at Acclarent, was engaged with the marketing
5 team for several activities.
6 Q I see.
7 And do you still keep in touch with
8 Mr. Brokaw?
9 A I do.
10 Q And have you talked with Mr. Brokaw
11 about the dispute between Aerin Medical and
12 The Foundry?
13 A I have not.
14 Q Have you spoken with Mr. Brokaw
15 between -- sorry. My last question said
16 Aerin Medical and The Foundry, I think you
17 understood me to mean Neurent and The
18 foundry, the dispute between --
19 Let me strike that.
20 Have you spoken with Mr. Brokaw about
21 the dispute between Neurent Medical and The
22 Foundry?

1 A I have not.
2 Q Have you spoken to Mr. Brokaw about the
3 dispute between Neurent and Aerin Medical?
4 A I have not.
5 Q Okay. You also mentioned Ms. Laborde;
6 is that correct?
7 A Yes.
8 Q And what was your working relationship
9 with Ms. Laborde?
10 A My working relationship at which
11 location? At which company?
12 Q You worked with Ms. Laborde at
13 Acclarent?
14 A That is correct.
15 Q Did you work with Ms. Laborde at any
16 other company?
17 A At Aerin Medical.
18 Q What was the nature of your relationship
19 with Ms. Laborde while working with
20 Acclarent?
21 A She was administrative assistant for me,
22 overseeing research projects that I was

1 charged with. And specifically, looking at
2 research grants that my area provided to
3 independent physicians to advance areas of
4 nasal sinus research. She oversaw that for
5 me.
6 Q Okay. And by "oversaw that," what do
7 you mean?
8 A She did the administrative work.
9 Specifically, would help get applications out
10 to physicians. Would summarize those
11 applications. Would help to coordinate
12 meetings that were held at Acclarent, so that
13 we could determine which projects we would
14 fund. And then ongoing, monitoring of those
15 projects, where she would gather information
16 about the status of the projects, bring that
17 to me, and then be able to take it to our
18 in-house committee about where our research
19 moneys are being used.
20 Q Understood.
21 And did the research projects you're
22 referring to have to do with medical devices?

1 A Yes.
2 Q Okay. And were they devices
3 manufactured by Acclarent?
4 A Yes.
5 Q Okay. All right. And you said you work
6 with Ms. Laborde now at Aerin Medical; is
7 that correct?
8 A Until she left that position.
9 Q Understood.
10 A And moved out.
11 Q And what was the nature of your working
12 relationship with Ms. Laborde at Aerin
13 Medical?
14 A She was one of the individuals, part of
15 the quality team and clinical team at Aerin
16 Medical. So there were times that documents
17 that I needed to review, as far as quality,
18 adverse events would come from her to me.
19 She sat in the discussions that I was part of
20 when we talked about adverse events, and
21 there was -- would be dialogue, as there was
22 with all the members of the quality team.

1 Q Understood.
2 And do you still keep in touch with
3 Ms. Laborde?
4 A The only conversation I have had with
5 her since she left the company was her
6 telling me that she left and her just simply
7 asking that if I learned or knew of a
8 position that might fit her background and
9 skill set I would keep my eyes and ears open
10 on her behalf. I've had no other
11 conversation.
12 Q Understood. All right. And then,
13 finally, you mentioned Mr. Salkeld?
14 A Yes.
15 Q What was the nature -- strike that.
16 You worked with Mr. Salkeld at
17 Acclarent?
18 A Yes.
19 Q And have you worked with Mr. Salkeld at
20 any other company?
21 A None other than Aerin Medical.
22 Q What was the nature of your relationship

1 with Mr. Salkeld at Acclarent?
2 A He was in sales, one of our senior sales
3 individuals. I would work with him when it
4 was necessary for me as a physician who is
5 doing teaching and education on how to use
6 the medical devices. He would need me to go
7 off anywhere in the United States or actually
8 in the world to teach individuals that he was
9 in charge as far as sales, I would teach them
10 how to use and use our devices.
11 Q And does Mr. Salkeld have a similar role
12 at Aerin Medical now?
13 A I don't know the details of his role at
14 Aerin. My conversations with him have had to
15 do with reimbursement and strategies to get
16 appropriate reimbursement for the tools and
17 the procedure that's being used. But I don't
18 know his job description beyond that
19 conversation that I've had with him giving
20 him advice.
21 Q What do you mean by "reimbursement," is
22 that reimbursement from a third party?

1 A Correct.
2 Q Which third parties?
3 A It could be any third party. Any
4 commercial payer or Medicare or Medicaid.
5 Any payer, any insurance carrier of any kind.
6 Q Understood.
7 Do you know a Dr. Andre Chang?
8 A I do.
9 Q How do you know him?
10 A Andre Chang is a -- was a physician at
11 Acclarent. He was a medical officer and
12 involved with economics and reimbursement. I
13 worked closely with him at Acclarent in
14 adverse events. He would come to me because
15 he was an otolaryngologist. He was not a
16 practicing otolaryngologist, and he knew I
17 was a clinician and we would be engaged at
18 Acclarent in that way.
19 Q What was the nature of your working
20 experience with Dr. Chang at Acclarent?
21 A It was just what I had just said to you.
22 Maybe I said that in a confusing way, let me

1 clarify that. He was the medical officer
2 at -- early on my days at Acclarent, I was a
3 consultant, when there was any potential
4 suspected adverse event with any of the
5 Acclarent tools, even though he was a
6 licensed board-certified otolaryngologist he
7 would come to me for my advice as a clinician
8 to see the context of that event and whether
9 it needed to be reported to the FDA or not
10 through their database system. So I as a
11 consultant, he used to provide him that
12 information.
13 Q I see. Are you still in touch with
14 Dr. Chang?
15 A I am. And I neglected to mention to you
16 he's one of the people I worked with
17 previously at Acclarent that I now am in
18 communication with at Aerin, he was another
19 individual.
20 Q What do you understand his role to be at
21 Aerin Medical now?
22 A I understand his role is one of strategy

1 and in looking at potential ways that the
2 technology being created or potentially might
3 be created at Aerin could be used for the
4 benefit of patients.
5 Q Understood. What is the nature of your
6 working relationship with Dr. Chang at Aerin
7 Medical?
8 A It is that he will call upon me
9 periodically for conversation for both my
10 opinion on ideas that he may have for
11 strategy as it relates to creation of tools,
12 that or how present devices are used. Also,
13 any new ideas and potential for using radio
14 frequency energy or similar energy or similar
15 tools and other ways that had not been
16 considered.
17 Q Understood. So he comes to you with
18 questions of strategy for the devices that
19 Aerin Medical manufactures or is developing?
20 MR. BRIGGS: Objection. Form.
21 A Yes.
22 Q Are you familiar with Neuromark device?

1 A I know the name, I don't have
2 familiarity with it.
3 Q Have you discussed the Neuromark device
4 with anybody at Aerin Medical?
5 A I don't recall having that discussion.
6 I don't have any specific recollection at the
7 time when that could have been done.
8 Q Understood. And have you discussed the
9 details of this case with Dr. Chang?
10 A I have not.
11 Q All right.
12 Now, do you know Kaylynn Callister?
13 A I do.
14 Q How do you know her?
15 A She was our human resource individual at
16 Acclarent.
17 Q Okay. And just for the record, what was
18 the nature of your work experience with
19 Ms. Callister?
20 A I really didn't have to deal with the HR
21 individuals, it was one more of someone
22 working there with whom there was more of a

1 in-house social relationship and nothing
2 beyond that. I can't recall specific
3 professional issues that she and I were
4 engaged.
5 Q Are you still in touch with
6 Ms. Callister?
7 A I am.
8 Q And you're aware that Ms. Callister now
9 works for Aerin Medical?
10 A I actually just learned of that.
11 Q How did you learn of that?
12 A Someone mentioned her name and I said,
13 oh, how wonderful that she's there because
14 she was a respected individual at Acclarent.
15 Q Okay. And have you spoken with
16 Ms. Callister about this matter?
17 A I have not.
18 Q Understood.
19 All right. And do you know a William
20 Facteau I actually think we went over his
21 name, haven't we?
22 A I do know him.

1 Q No, we haven't. You do know William
2 Facteau?
3 A Yes.
4 Q And how do you know Mr. Facteau?
5 A He was the CEO of Acclarent. He is the
6 one who came to me early on in the Acclarent
7 days asking if I wished to be engaged in many
8 different ways at Acclarent, both as a
9 clinician, as an investigator, as someone
10 helping to create medical devices for
11 Acclarent.
12 I reported to him at Acclarent, after
13 Acclarent was acquired by Johnson and Johnson
14 he was still for a period of time the CEO,
15 and I reported to him in that role. As I
16 already mentioned to you, he was the
17 individual upon or for whom I have to provide
18 testimony as it related to the off-label case
19 brought by the Justice Department.
20 Q Understood. And are you still in
21 contact with Mr. Facteau?
22 A I am.

1 Q What is the nature of your relationship
2 with Mr. Facteau now?
3 A He is now the CEO of a company in Menlo
4 Park, California called Earlens. While my
5 medical practice does not involve otology,
6 problems of the ear, I have a severe
7 significant hearing loss and I wear and use
8 the Earlens technology. I have one in each
9 ear right now as we speak. I have provided
10 to Earlens and to Mr. Facteau, but really to
11 Earlens itself, consultation as it relates to
12 experience, not as a clinician, but as a
13 hearing loss sufferer and I stay engaged with
14 him in that role.
15 Q Understood. Did you use the Earlens
16 device before Mr. Facteau began working for
17 that company?
18 A I did not.
19 Q Did you start using it at the
20 recommendation of Mr. Facteau?
21 A It was at the recommendation of two
22 people. It was at his recommendation because

1 he knew I struggled with hearing loss. It
2 was recommendation of the founder of Earlens,
3 Rodney Perkins, for whom I had been a
4 consultant for many years in an area outside
5 of otology, outside of Earlens.
6 Q Understood. Well, it sounds like the
7 devices work pretty well; is that right?
8 A They are better than anything I've had.
9 The answer is yes.
10 Q I have a family history of hearing loss,
11 so we'll keep them in mind.
12 Just quickly, have you spoken with
13 Mr. Facteau about this matter?
14 A I have not.
15 Q Do you know a Greg Garfield?
16 A I do.
17 Q How do you know Greg Garfield?
18 A Greg Garfield was the in-house attorney
19 at Acclarent. And I was engaged with him on
20 many matters because as the in-house attorney
21 there were things that he would come to me
22 and question as it related to some of the

1 physician engagement with the company itself.
2 Greg Garfield had, I believe had a
3 responsibility, it appeared to me that he had
4 a responsibility, I never read his job
5 description, but that was to oversee the
6 business relationship between physician
7 consultants and the company itself.
8 Q Understood. All right.
9 Are you aware that Mr. Garfield is now a
10 board member of Aerin Medical?
11 A I am aware of that. I learned of that,
12 yes.
13 Q When did you learn of that?
14 A I don't have a specific date. I don't
15 know, I think in conversations I've just
16 heard or learned that he was a board member.
17 Q Understood. Are you still in contact
18 with Mr. Garfield?
19 A On occasion, but pretty unusual rare
20 occasion.
21 Q What is the nature of your contact with
22 him?

1 A I know that he moved on after he left
2 Acclarent and is involved in a, I guess -- I
3 use the word organization, I'm not a business
4 person, I'm probably using the term that is
5 not the best term in describing it, but where
6 he oversees funds to be invested in various
7 companies.
8 So there have been a few times,
9 emphasizing few, where I have learned of
10 perhaps a startup medical company that might
11 be looking for funding, and I have
12 communicated to him the nature of that
13 company to see if he or his team might have
14 interest in learning more about it.
15 Q Understood. And was Aerin Medical one
16 of those companies?
17 A I recall quite a long time ago, I don't
18 remember the exact time, where he and I had a
19 conversation. He reached out to me to ask me
20 what I knew of the company, what I knew of
21 the technology, where the technology might
22 fit as a clinician, and what competition

1 might be out there.
2 He had a lot more questions for me, and
3 I tried to provide those answers as best I
4 could, based on the information and knowledge
5 I had of both Aerin and the rhinology space.
6 Q Understood. And have you spoken with
7 Mr. Garfield about this matter?
8 A I have not.
9 Q Just returning back to Mr. Facteau for a
10 moment.
11 Are you aware that Mr. Facteau is now a
12 board member at Aerin?
13 A As you mention it, I do recall hearing
14 that. I had not even thought much about that
15 until you mentioned it just now.
16 Q Do you recall how you learned that he
17 was a board member at Aerin Medical?
18 A I don't.
19 Q And have you spoken to him about his
20 service as a board member at Aerin Medical?
21 A I have not.
22 Q Do you know a Karen Long?

1 A I do.
2 Q Okay. How do you know her?
3 A Karen Long was also an employee at
4 Acclarent. And her role was the vice
5 president of marketing. I believe it was
6 vice president of marketing. And I believe
7 that Matt Brokaw reported to her at that
8 time.
9 And then I know she subsequently left.
10 I know that she and Mr. Greg Garfield are
11 engaged in the same company. What their
12 relationship is, who reports to who or what
13 their responsibilities are, I do not know.
14 Q Understood.
15 Are you still in touch with Ms. Long?
16 A I have not spoken to her in many years.
17 Q And are you aware that Ms. Long is a
18 board member at Aerin Medical?
19 A I'm not aware of that.
20 Q Have you spoken with Ms. Long about this
21 matter?
22 A I have not.

1 Q And then, I think in your declarations
2 you discussed a patent that names Joshua
3 Makower as an inventor.
4 Are you familiar with Mr. Makower?
5 A Yeah. Makower. I'm very familiar with
6 him.
7 Q Thank you for the correction.
8 How are you familiar with Dr. Makower?
9 A Dr. Makower was the founder of the
10 balloon sinus technology, which was the
11 technology at Acclarent.
12 Q And did you work with Dr. Makower while
13 you were performing services for Acclarent?
14 A Yes.
15 Q What was the nature of that
16 relationship?
17 A That was in the creation and development
18 of new devices. The improvement of the
19 present devices that we had had.
20 Q Understood.
21 A And looking at things such as safety and
22 efficacy. I sat on the board at Acclarent.

1 He sat on the board. So there was, as would
2 be in any kind of a board meeting, engagement
3 and dialogue between us.
4 Q Understood. And are you still in touch
5 with Dr. Makower?
6 A Yes.
7 Q What is the relationship of your
8 relationship now?
9 A One is a personal relationship, where I
10 would just communicate with him from time to
11 time. Only because we were also friends
12 besides colleagues. We don't do that often.
13 Separate from that, he is involved in
14 other companies by virtue of his work at
15 Stanford Bio Design, by virtue of his
16 involvement at NEA, which is a venture group.
17 And there have been times where also
18 individuals have come to me with ideas and
19 are looking for either mentorship in the
20 development or looking for funding. And I
21 will on occasion reach out to him to make an
22 introduction.

1 Q And Dr. Makower is an engineer; is that
2 right?
3 A Yes.
4 Q Do you respect his work as an engineer?
5 A I respect his work as an engineer as
6 high or beyond anyone that I know.
7 Q Understood. Just circling back. You
8 mentioned that you worked with Dr. Makower at
9 Acclarent; is that correct?
10 A Yes.
11 Q Acclarent is the company that you've
12 identified in this proceeding as providing at
13 least some of the relevant experience from
14 which you've drawn on; is that correct?
15 A Yes.
16 Q Would now be a good time for a break?
17 A I'm fine. I don't need one now, unless
18 if someone else does, that's fine, but I am
19 okay.
20 MR. NEMTZOW: I think maybe
21 five minutes. The coffee has come
22 through. Thank you.

1 (Whereupon, a recess was taken
2 from 9:44 AM until 9:54 PM.)
3 Q So before the break we were talking at
4 least a little bit about nasal procedures; is
5 that right?
6 A Yes.
7 Q And you've performed nasal procedures
8 before?
9 A I have.
10 Q And have you performed RF ablation
11 before?
12 A I have.
13 Q In the nose?
14 A I have.
15 Q I'd just like to get a little bit of an
16 understanding of your practice and how you've
17 used that before.
18 Does that sound good?
19 A Okay.
20 Q For what purposes have you used RF
21 ablation before?
22 A I've used RF ablation in a couple of

1 places. One has been in the nose to reduce
2 mechanical obstruction. And that was
3 typically of the nasal turbinates, where they
4 were blocking and obstructing breathing.
5 That was a common place where I had used RF.
6 I had used RF in the mouth and throat,
7 trying to reduce the size of tonsils, trying
8 to avoid a tonsillectomy, which is not a fun
9 procedure for the patient, terrible recovery.
10 Trying to see if that would be effective in
11 any way to shrink the -- shrink the tissue.
12 And, then, more recently I've used the Aerin
13 Medical devices and RF technology.
14 Q And that is -- what did you use the
15 Aerin Medical devices for?
16 A In several areas. One has been the
17 management of the nasal valve, which is the
18 area at the very tip of the nose. I'm happy
19 to discuss the details of what that is and
20 what that area is and how it's used.
21 To try to be concise, it is an attempt
22 to remodel the cartilage around the tip of

1 the nose for improvement of airway. I've
2 used the Aerin Medical device radio frequency
3 on the nasal septum, where there have been
4 areas of widening of the septum obstructing
5 the nose. So those would be for mechanical
6 obstructions within the nose, both the nasal
7 valve, and also for a nasal septal deformity.
8 And, then, thirdly, I've used the Aerin
9 Medical for ablation of tissue in the
10 posterior back end of the nasal cavity,
11 managing things such as allergic rhinitis,
12 mucus secretion, congestion.
13 Q Understood. And so when you use RF
14 ablation, like, what is the tissue's response
15 to the RF ablation?
16 MR. BRIGGS: Object, form.
17 A The tissue response can be -- is one of
18 ablation or of an alteration of cells.
19 Q Is there a difference between ablation
20 and alteration?
21 A There can be. In that, you know, in
22 ablating a cell, I see it as altering it

1 actually so that it does not function or will
2 not function in the same capacity or at all
3 as it did before. And I guess that would be
4 one of the main reasons or places where I
5 would use it.
6 Q When you say that you've used RF
7 ablation for shrinking tissue, is that
8 because it destroys cells?
9 MR. BRIGGS: Objection to form.
10 A That's used really in the creation of
11 creating scar tissue that is a tougher
12 tissue, so it could be to generate scar
13 tissue. As it relates specifically to the
14 turbinates, where I used this more than any
15 other place than I mentioned, that's because
16 of obstruction.
17 The turbinates, as you may or may not
18 know, change in size throughout the day.
19 It's an erectile type of tissue, getting
20 bigger and smaller, blocking the nose. And
21 the technologies that I've used to manage
22 that have been many in an attempt to create

1 scar, in my vision, that scar being tougher,
2 preventing that structure, the turbinate from
3 expanding.
4 Q I see. So does it actually make the
5 tissue smaller or does it just change the
6 type of tissue?
7 A Using it within the turbinate itself, it
8 appears to make it smaller.
9 Q Okay. And it does that by destroying at
10 least some of the tissue?
11 A Yes.
12 Q Okay. And is that tissue on the surface
13 or underneath the surface?
14 A It could be either or both. And
15 specifically, if it were on the surface, it
16 could create scar tissue on the surface that
17 might achieve the inability for that
18 structure to enlarge. It might be within the
19 turbinate itself. Again, trying to destroy
20 some of the tissue and create scar tissue by
21 ablating, removing that tissue.
22 Q And have you performed RF ablation in

1 the nose with the intention of creating scar
2 tissue on the mucosa?
3 MR. BRIGGS: Objection to form.
4 A Yes.
5 Q What for?
6 A That was for the nasal turbinates
7 working for nasal obstruction.
8 Q Have you performed RF ablation in the
9 nose for the purpose of creating scar tissue
10 under the mucosa?
11 A Yes. It is under the mucosa because
12 that's where this cartilaginous structure,
13 whether it be the nasal septum or the nasal
14 valve exist, and that's the tissue that is
15 being remodeled and that is under the mucus
16 membrane.
17 Q So when you perform RF ablation for a
18 mechanical obstruction on the turbinates, for
19 example, there will be scar tissue formed
20 underneath the mucosa?
21 A That is my hope and desire.
22 Q Understood. All right. I'd like to

1 talk a little bit more about your background
2 in RF ablations.
3 When was the first time you performed RF
4 ablation of the nose?
5 A I don't have the exact date. I believe
6 it was in the 1990s, but I could be wrong on
7 that date. It was using a device called
8 Somnoplasty manufactured by Somnus. I think
9 they were based in Sunnyville, California, as
10 I recall.
11 Q Understood. And you talked about the
12 Somnoplasty device in your declarations; is
13 that right?
14 A I did.
15 Q And you think that experience is
16 relevant to the opinions that you've offered
17 in this case?
18 A I think it is.
19 Q And what -- I understand that this was
20 back in the 1990s, but trying to recall back
21 into the 1990s, when you first started using
22 RF ablation on the nose, what was the purpose

1 for applying that ablation?
2 A It was to create scar tissue in the
3 nasal turbinates, cause them to shrink, and
4 to open the nose for breathing.
5 Q Understood. All right. And that was
6 back in the 1990s?
7 A Yes.
8 Q With the Somnoplasty device?
9 A Yes.
10 Q And when did you start using RF ablation
11 for other purposes in the nose? We talked
12 about a few.
13 A Within the last couple of years. Last
14 two years, I would say.
15 Q Okay. So is it fair to say the vast
16 majority of your experience with RF ablation
17 in the nose has been to ablate tissue in the
18 turbinates?
19 A I can't say the vast majority, because I
20 really haven't kept track of the numbers and
21 what percentage I've used it in one place and
22 what percentage I've used it in another. So

1 I don't know if I'd say majority.
2 Q Do you recall using RF ablation in the
3 nose for any purpose other than treating the
4 turbinates prior to 2006?
5 A No.
6 Q All right. So taking a step back.
7 We've been talking about RF ablation,
8 correct?
9 A Yes.
10 Q And are any of the devices that you've
11 used for the RF ablation, do they employ
12 bipolar electrodes?
13 A I don't recall if the Somnus was bipolar
14 or not. I'd have to go back and look at
15 that.
16 Q Have you used any other bipolar devices?
17 A I have used cautery.
18 Q Okay. And what cautery devices?
19 A I can't give you the manufacturer, but
20 Bovie is the typical cautery that we use.
21 And I've used that also to shrink the nasal
22 turbinates.

1 Q Can you tell me a little bit more about
2 what a bipolar cautery device looks like?
3 A It will be a device generating energy
4 that will have two points. That's where the
5 name bipolar comes from, where the energy
6 will be transmitted between those two points.
7 Q Understood. Sorry. I didn't mean to
8 interrupt.
9 A I was just going to say, and to my
10 understanding and recollection, I'm not an
11 electrical engineer, but I know a little bit
12 about this, is that there could be a
13 grounding pad that could be the second
14 electrode with energy being transmitted from
15 one place to another.
16 Q Would you call a device with a grounding
17 pad a monopolar device?
18 A I would.
19 Q Is that different, in your mind, than a
20 bipolar device?
21 A It is.
22 Q And you were just describing cautery

1 devices that are bipolar. When was the first
2 time you used one of those?
3 A I've used cautery throughout my entire
4 surgical career. Cautery has been around way
5 before I became a surgeon.
6 Q So bipolar cautery devices were known
7 before the Foundry patents in 2006?
8 A The cautery -- the Bovie cautery devices
9 that I've used throughout my career have been
10 monopolar with a grounding pad. That's been
11 the frequent one that I have used.
12 Q Thinking, though, about bipolar cautery
13 devices. You've mentioned that you've used
14 bipolar cautery devices?
15 A Yes. So that I have used and that has
16 been for bleeding, it has been usually
17 forceps, a forcep having of course two
18 prongs, bringing them together to manage
19 usually bleeding of some kind.
20 Q Have you used bipolar cautery devices
21 for other purposes other than bleeding?
22 A I have not.

1 Q No, okay. So you've never used a
2 bipolar cautery device in your career for
3 anything other than managing bleeding?
4 A I can't recall that I have.
5 Q Do you recall others using bipolar
6 cautery devices for other purposes?
7 A I can't speak to how other people are
8 using devices. I don't know.
9 Q Okay. All right. I'd like to return
10 back to the somnoplasty device we were
11 talking about earlier.
12 A Yes.
13 Q You didn't help design or develop that
14 device, did you?
15 A I was one of the early investigators --
16 I was one of the early users, I shouldn't say
17 investigators. I was one of the early users
18 of that device. And prior to there being
19 widespread use of Somnus there were a few
20 physicians selected to try it to do, what I
21 guess is called post-market research or
22 marketing and I was one of those individuals,

1 so I was an early user. I provided feedback
2 to the company about -- on several areas.
3 One was the physician-patient experience, was
4 it a reasonable experience for the patient.
5 And that related mostly to the design of the
6 instrument and whether the tools and
7 instruments that were designed were easy to
8 use, easy for a patient to tolerate, and then
9 second part of that was what was the short
10 and long-term results of that. And adverse
11 events, so it was the usability, safety,
12 efficacy.
13 Q Okay. And about what time was this
14 early use that you we're describing?
15 A That was probably in 1997. Again, I
16 don't have a specific date for that.
17 Q In 1997, okay.
18 A I guess I would add to it as you're
19 asking me this question so I can be complete,
20 I then was an individual that the company
21 asked to teach others, so I traveled around
22 the country teaching how to use this device,

1 it was included the technology and my
2 experience was used in countless lectures on
3 how to manage the nose and sinus, so that
4 while I might be talking about lots of tools
5 and procedures without question a portion of
6 my lecture would be how to use this, what the
7 basis was, how it worked, and then how to use
8 it and what the results were.
9 Q And how did you familiarize yourself
10 with the somnoplasty device?
11 A What do you mean by familiarize, I'm not
12 clear on what means.
13 Q Sure. Happy to clarify.
14 So you mentioned that, for example, you
15 taught others how it worked, how did you
16 learn how the somnoplasty device worked?
17 A This was introduced to me by both
18 engineers and salespeople both through just a
19 didactic lecture and then trialing this on
20 what we often use was a chicken breast,
21 that's the typical kind of thing that we use,
22 so I would at least have my hands on, get a

1 feeling of the equipment, how it would
2 operate, what I would need to do for myself
3 to hold, use the equipment.
4 Q Sorry, I didn't mean to the cut you off
5 there.
6 A No. That's fine, thank you.
7 Q Did you receive any instructions for use
8 for the somnoplasty device?
9 A Yes.
10 Q Did that help you learn how the device
11 worked?
12 A Yes.
13 Q So you were able to understand from your
14 use of the device and the instructions for
15 use how the device worked?
16 A Yes.
17 Q And from the instructions for use and
18 your use of the device you were able to
19 understand how to safely and effectively use
20 the somnoplasty device?
21 A Yes.
22 Q And again, from the instructions for use

1 and your use of the device you were able to
2 understand the effects of the use of the
3 somnoplasty device on the patient?
4 A Yes.
5 Q Okay. And so let's go back to your
6 early use in 1997.
7 I think we established that most of your
8 use of ablation in the nose around that time
9 was for reducing the size of turbinates; is
10 that right?
11 A Yes.
12 Q So that's how you used the somnoplasty
13 device at that time?
14 A Yes.
15 Q Was there anything else that you used it
16 for?
17 A I don't recall using it anywhere else.
18 Q Okay. Now, I know we talked a little
19 bit earlier that you didn't exactly recall
20 whether the somnoplasty device is a bipolar
21 device, could you provide me some more
22 details about how the device works aside from

1 whether it's bipolar or not?
2 A I think I understood your question. It
3 was a needle that was placed into the
4 turbinate. I would dial in the dosage of the
5 amount of energy and that would be combined
6 with what was a time period for applying the
7 energy.
8 Q And why is the time period for applying
9 the energy relevant?
10 A It was because the energy -- my
11 understanding was that the energy, the longer
12 this electrical energy would be applied, the
13 more alteration there would be in the tissue
14 underneath.
15 Q Does the application of that energy
16 generate heat?
17 A I don't recall how much heat, but I
18 believe that there was some heat that was
19 generated, but I don't recall specifically
20 how much or what those parameters were.
21 Q And what happens to the cells after
22 you've applied the radio frequency energy

1 with the somnoplasty device?
2 A The cells were irreversibly altered
3 where they would be change, there would be
4 scar that would form and didn't function, in
5 my understanding and in my observation in the
6 way they had functioned before.
7 Q Did the cells die?
8 A I can't speak to that for this reason:
9 to know if they died I would have to look at
10 histologic sections, which maybe at one point
11 I looked at in the early days when I was
12 learning about this, and trying to know the
13 basics of it, but I don't recall that if
14 there was actually death or if there was a
15 change where there was scar. The word does a
16 cell die though, I'm hesitating here because
17 that could mean so much. Die might mean it
18 doesn't work the way it worked before,
19 therefore it isn't functioning. Die might
20 mean that it's gone and disappears totally, I
21 don't believe that it's gone and disappears
22 totally, but I believe it's so altered it

1 doesn't function and that's its irreversible.
2 This word "die," as it relates to tissue,
3 that would be something that I think someone
4 looking at biopsies, seeing what is the
5 process and what happens to those cells and
6 whether there is a pathologic definition of
7 cellular death, that's not something I
8 personally did.
9 Q I see. But it at least disables it so
10 it couldn't function the way it was before?
11 A That's correct.
12 Q And that would result in tissue
13 shrinking; is that right?
14 A That is correct.
15 Q Okay. All right. Are you familiar,
16 because there's a lot of terms that have been
17 thrown around in these proceedings, are you
18 familiar with the term cauterize?
19 A Yes.
20 Q What is cauterizing?
21 A Cauterize and I used the term cautery
22 earlier when I mentioned the Bovie device, it

1 is using of heat to alter tissue, to destroy
2 tissue, to seal tissue, to seal blood
3 vessels, to ablate tissue, to remove tissue.
4 It's a -- I'm sure those who created cautery
5 and Bovie would not like what I'm about to
6 say, but I will say it any way. My view of
7 that since I'm not someone who ever created
8 this was that it would be more like a burning
9 of tissue. It's through that heat element
10 that those tissues are altered.
11 Q Do you consider cauterizing different
12 from the ablation with the somnoplasty device
13 that we were talking about earlier?
14 A Yes.
15 Q If I understood you correctly, you said
16 that the cauterizing does produce heat to
17 burn cells?
18 A Yes.
19 Q If I wanted -- if there was a particular
20 portion of tissue in the nose that I wanted
21 to cauterize, where would I need to apply the
22 energy?

1 MR. BRIGGS: Objection. Form.
2 A You'd have to apply it directly to the
3 tissue.
4 Q You couldn't cauterize tissue by apply
5 energy somewhere else?
6 MR. BRIGGS: Objection. O form.
7 A That's not something typically done.
8 And let me be clear at least about this. One
9 reason I used cautery early on in my career
10 is it was all that was available. My
11 understanding of cautery, which is why it was
12 effective, it also the energy would travel
13 along blood vessels in the region and the
14 zone of injury created by cautery was not
15 controllable and beyond what I as a clinician
16 wished.
17 Q I see.
18 A The thing that intrigued me about
19 Somnus, was that the zone of injury that
20 occurred was controllable, through what I've
21 already said by virtue of energy and time.
22 And therefore, at least in laboratory

1 testing, made sense to me because I would be
2 able to have greater control over my outcome.
3 Q Okay.
4 A And I should mention 'cause you -- I'm
5 using the term cautery and you're asking me
6 about it. Another kind of cautery, just to
7 be complete, is chemical cautery and just to
8 state this very quickly, that's typically
9 used in the nose when someone has a nosebleed
10 comes to a physician we take silver nitrate,
11 which is a chemical, we can see the place of
12 bleeding usually in the front part the nose,
13 we apply the silver nitrate. So the cautery
14 is electrical, but there's a chemical cautery
15 too. I just wanted make sure that I didn't
16 limit my use of that term for you.
17 Q You said it's helpful as a clinician to
18 have greater control over the outcome; is
19 that right?
20 A Yes.
21 Q For that you were referring to the --
22 being able to control the particular location

1 where energy is being applied to?
2 A Yes.
3 Q And you said that the somnoplasty device
4 did that for you?
5 A It did.
6 Q So in general, if you're trying to
7 target particular tissue, as a clinician it
8 would be desirable to be able to control the
9 precise portion of tissue that you're
10 applying energy to; is that right?
11 A That is correct.
12 Q So before --
13 A I actually call that the zone of injury
14 because this is injury, but it's a controlled
15 injury.
16 Q And you want to be able to control both
17 the location of the injury and how much
18 energy your applying to that location?
19 A I would say it differently. I want to
20 control the location of the injury and the
21 extent of that injury beyond the location
22 where it is being applied beyond those

1 boundaries.
2 Q I see. So it's sort of physical control
3 over the location?
4 A Yes.
5 Q All right. I know we started this
6 conversation here about cauterization, but I
7 just want to bring us back to heating tissue.
8 If you wanted to heat tissue whether with
9 cautery or with ablation, where would you
10 apply that energy to?
11 A I would apply it directly to the tissue.
12 Q The tissue that you want to heat?
13 A Yes.
14 Q Okay. Now, we've been talking a lot
15 about the somnoplasty device and your
16 experience is dating back to 1997 or so?
17 A Yes.
18 Q Before 2006, were there any other
19 ablation devices that you used?
20 A Yes.
21 Q Which ones?
22 A Laser. Cryotherapy, freezing.

1 Q Were there any other electrical ablation
2 devices?
3 A Cautery, Bovie.
4 Q And what about radio frequency energy
5 devices?
6 A I don't recall having a radio frequency
7 energy prior to that time.
8 Q Prior to Somnus?
9 A That's what I meant, prior to Somnus. I
10 don't recall having any type of radio
11 frequency energy.
12 Q Understood. And could you use laser,
13 cryo, or cautery for similar purposes to what
14 you use the somnoplasty device for?
15 A I could.
16 Q So as a clinician how did you pick
17 between those?
18 A It really was back to what I said
19 before. I needed to manage the patients
20 problem where they had failed medical
21 management, specifically this was around the
22 nasal turbinates, that was the big issue.

1 Many of these individuals had lot of medical
2 treatment, still had nasal obstruction that
3 was disturbing for many, many different
4 reasons.
5 I knew I believed that if I could reduce
6 them, that I could get rid of the problem.
7 And I used pretty much whatever became
8 available and that began with cautery, as I
9 said it had been there -- beginnings of my
10 own surgical career then moved to cryo
11 surgery, freezing, and used tools that could
12 do exactly that, shrink, freeze the tissue.
13 And they weren't ideal, for lots of reasons
14 they weren't ideal, I've alluded to them
15 already and that was the inability to control
16 the outcome. An inability to control the
17 injury, but they were effective.
18 I think at times they removed more
19 tissue than I wanted and that was not a good
20 thing. It was too much variability. So I
21 always was looking, trying to find what else
22 could be out there. And I would continue to

1 scour the literature and try to pay attention
2 when I traveled around the world teaching
3 many of these things, and be aware of any new
4 technology or any new device that might be
5 out there. And the only thing that I then
6 became aware of during those years at the end
7 of 1990s and early 2000s was the radio
8 frequency Somnus device.
9 Q As a clinician did you understand how
10 the Somnus device achieved that greater
11 control over the outcome that you were
12 looking for?
13 A I'm glad you say as a clinician,
14 clinician meaning I'm someone treating versus
15 someone developing. In this instance, well,
16 I've developed many, many instruments and we
17 can talk about that if you so wish, this was
18 developed by electrical engineers. It's what
19 I've already said the data, the histological
20 data, where work was done on animals, which
21 showed with different energy and time
22 parameters the kind of creation of zone of

1 injury that then would permit me as a
2 clinician to be instructed as to how long,
3 and what energy this would be used. The
4 histologic images that I saw, I believed and
5 believed them to be transferable as a
6 clinician that it then could apply to my
7 patients.
8 What was so beautiful about it, there
9 are many slides in the literature, it's
10 really sort of oblong, three-dimensional
11 oblong zone around the tip of the needle.
12 Q I see. Okay, that's helpful. All
13 right, taking a step back. Taking a step
14 back, we've been talking specifically about
15 the devices. I'd like to talk about sort of
16 the procedure that goes into one of these
17 nasal treatments; is that okay?
18 A Sure.
19 Q All right. So let's assume that you
20 have a patient who's coming in for a
21 procedure, let's say on the nasal turbinates,
22 do you have that in mind?

1 A Yes.
2 Q I'd like to just focus on how you used
3 to do this before 2006; is that all right?
4 A Yes. Before 2006, I want to be clear
5 about that.
6 Q Correct. Before 2006, early on I think
7 you testified that you began doing these in
8 1997 with the somnoplasty device?
9 A Correct.
10 Q Keeping that time period in mind, what
11 were some of the steps that you would take to
12 get the patient ready before the operation,
13 did you give them any operation day
14 instructions?
15 A So the patients that I did early on, and
16 that's why I wanted to clarify before 2006,
17 these were done in the operating room. Some
18 might have had a general anesthetic. Some
19 might have sedation because these were the
20 procedures by the virtue of the size of
21 instruments, what we had to do in the nose,
22 it was not comfortable. So for sure, at

1 least there was some degree of sedation, if
2 it was being combined with another nasal or
3 sinus procedure would be under general
4 anesthetic.
5 However, the preparation of the patient
6 was mostly the same. Let me try to clarify
7 that for you. That is that the patients once
8 they were either asleep or sedated, the nose
9 would be decongested. That decongestant was
10 a liquid. It would be either the generic
11 name is oxymetazoline, which could be bought
12 today over-the-counter at any pharmacy, one
13 of brand names Afrin it is a topical,
14 valuable, powerful decongestant. There were
15 times in those early days that cocaine was
16 actually used and cocaine is a powerful
17 decongestant. And what is a vasoconstrictor,
18 meaning it will shrink and constrict the
19 blood vessel.
20 And ear, nose and throat physicians
21 for -- I don't know, I would have to say,
22 decades, generations, probably, would have

1 cocaine in the office and would use it to
2 anesthetize and decongest the nose. We
3 stopped using it -- I don't need to go into a
4 lot of detail here -- only because it became
5 difficult managing it, the regulatory issues
6 around it. And there were other medications
7 other than cocaine that substituted it, which
8 made all of the administrative aspects of
9 what we needed to do so much easier.
10 But let me go back to this: I only was
11 trying to emphasize that there were fluids
12 and secretions -- fluids used, whether it
13 be -- to decongest the nose. That, I think,
14 is the key part that is important -- I
15 believe important to you.
16 After the nose was decongested with
17 spray, I would take cottonoids, cottonoids
18 being long pieces of cotton sometimes having
19 a string attached to it, putting a
20 decongestant and topical anesthetic on that,
21 placing that into the nasal cavity. So
22 again, fluid placed upon a cotton material

1 that would allow me to anesthetize and
2 decongest the nose.
3 Next, what I would do, depending upon
4 the area where I was working or looking, if
5 it was in the front of the nose, like the
6 front tip, anterior tip of the nasal
7 turbinate, I might use a headlight and a
8 nasal speculum, a nasal speculum being a
9 medical tool which merely opens the nostril
10 of the nose so I can see in the nose.
11 If I was working further back in the
12 nose, I would use a nasal endoscope with high
13 definition imaging, either looking through
14 the endoscope or looking on a television
15 monitor. Early on, we didn't have television
16 monitors. I looked through the endoscope.
17 But now I -- and I think a majority of
18 people -- but I'll speak to my practice --
19 will use a high-definition television to be
20 able to see and visualize the area.
21 At that point in time, if I'm working
22 back in the nose, I will inject another

1 fluid; I will inject a local anesthetic,
2 usually Xylocaine, or lidocaine -- the same
3 thing, just trade name and generic name --
4 with epinephrine, epinephrine being an
5 adrenaline compound to decongest the nose.
6 So that -- that's a long process. And
7 for all practical purposes, the anesthetic
8 took longer than the procedure because if you
9 were the patient, you would wish to have good
10 anesthesia before I, as the surgeon, went
11 ahead. I, as the surgeon -- it is my
12 responsibility to make sure my patient is
13 comfortable. And if they're not comfortable,
14 they're -- patient's going to be moving
15 around, and we never achieve a good result.
16 It is the time and patience needed in
17 getting these various fluids in different
18 forms back into the nose to get good
19 anesthesia.
20 Q Understood.
21 So that was a lot. And thank you for
22 walking --

1 A That maybe more information than you
2 wished to have, but you asked for what are
3 the steps and phases of this, and I'm not
4 sure how you wish to use that information,
5 but I wanted to be complete and clear for
6 you.
7 Q Yeah, of course. And there's just a
8 couple questions I have about that. Just if
9 I can try to summarize -- I know you talked
10 about a lot of different applications of
11 medicines and things like that.
12 But if I understand it correctly, you
13 had three goals before the operation. One of
14 those goals was to apply some form of
15 anesthetic in order to make the patient more
16 comfortable?
17 A Yes.
18 Q Another one of those goals was to
19 decongest the nasal cavity?
20 A Yes.
21 Q And that means to reduce the amount of
22 mucus in the nasal cavity?

1 A No, not really. Decongesting the nose
2 was really shrinking these nasal turbinates,
3 the erectile tissue, as I will describe them,
4 in the nose 'cause they're -- it's similar
5 erectile tissue to other parts of the body.
6 And the purpose of that shrinking was so that
7 I could see.
8 Q I see.
9 A That I had visualization. Because so
10 many of these individuals who had turbinate
11 hypertrophy, hypertrophy meaning enlargement
12 of a structure, it was -- the nose was
13 completely filled, and I could barely see
14 into the nose. I needed to shrink that so I
15 could see the whole length of the nose.
16 The issue of the mucus in the nose -- I
17 didn't have to get rid of the mucus in the
18 nose. There were some rare and unusual
19 instances when mucus would be thick and
20 sticky and I'd have to suction and get that
21 out. But my goal was not removing the mucus.
22 That was not the issue.

1 Q Okay.
2 A Mucus was in the nose.
3 Q Okay. Would you do anything to clear
4 out the mucus?
5 A If it was obstructing my view. If it
6 was this thick, tenacious secretion, I might
7 have to mechanically remove it with forceps,
8 I might have to suction it, I might have to
9 irrigate the nose with a saline solution to
10 wash out the nose. And again, that's really
11 in the instance of this thick, sticky mucus
12 that forms a thing that we called biofilms,
13 which is whole nother thing that happens to
14 mucus in the nose.
15 But generally speaking, the mucus isn't
16 the issue.
17 Q Okay.
18 A It's there, and it's fine.
19 Q All right. When you would irrigate the
20 nose, what would happen to the fluid that you
21 irrigated the nose with?
22 A It would stay there.

1 Q Stay there?
2 A It would stay there. Sometimes a
3 little -- if there was a little bit there,
4 patient would either swallow it. Or if there
5 was a large volume I needed, for comfort of
6 the patient, I would suction it out.
7 Q Okay. Understood.
8 And just focusing on if you were
9 treating, for example, the turbinates, if you
10 were to irrigate the turbinates, those are
11 sitting above the nasal floor?
12 MR. BRIGGS: Objection. Form.
13 A The -- let me -- I need to clarify this.
14 Q Sure.
15 A The turbinates have nothing to do with
16 the nasal floor. There are three or four
17 turbinates that are on the side or what we
18 call lateral walls of the nose. They are the
19 lower middle superior and on occasion
20 supreme. We actually call them inferior,
21 middle superior and supreme.
22 I always worry when I use with a patient

1 or someone, with all due respect, who is not
2 necessarily sophisticated in the anatomy, and
3 I use the word "inferior," they think that
4 means it's bad, it doesn't work very well.
5 But it's an anatomic term meaning lower. So
6 I interchange the words -- and I might do so
7 today -- between "lower" and "inferior."
8 But they -- their only relationship --
9 perhaps this is what you're asking -- to the
10 nasal floor might be that if the lower,
11 inferior, turbinate is very large, it could
12 touch the nasal floor, not be attached to but
13 merely by virtue of its size be touching the
14 nasal floor and obstructing the nose, the
15 thing that we're trying to treat.
16 Q I see.
17 So normally, the turbinates would sit
18 above the nasal floor and wouldn't touch
19 the --
20 A That is correct. And they're off on the
21 sides of the nose rather than the roof or the
22 medial, middle portion of the nasal cavity.

1 Q I see.
2 And so if you were to irrigate that
3 area, the irrigation fluid would then flow
4 down to the nasal floor?
5 A Well, most of -- yes and no. If I'm
6 working in my office, which I would on some
7 of these patients, patient would be sitting
8 in an examination chair. Virtue of gravity,
9 that fluid would fall to the bottom.
10 Q Okay.
11 A There are times, again, doing an office
12 procedure, much like a dentist office, the
13 patient would be reclined slightly. And then
14 rather than the nasal floor, it might flow to
15 the back of the nose, the posterior part of
16 the nose.
17 If I were working under general
18 anesthesia, I would say every single one of
19 those patients is laying almost flat, perhaps
20 the head evaluated a little tiny bit to
21 maintain their airway, to help with
22 congestion and swelling. And there, the

1 fluid would go towards the back part of the
2 nose, posterior part of the nose.
3 Q I see. So --
4 A I keep using those terms to make sure
5 that we're clear to any -- to you or to
6 anyone else who might need to look at this in
7 those terms.
8 Q Yeah, understood.
9 So the location that the irrigation
10 fluid would flow to depends on whether the
11 patient is seated or laying on their back or
12 somewhere in between?
13 A That is correct. But I would also even
14 say with that the nose is such that mucus and
15 fluids flow normally when the nose is healthy
16 and functioning from the front of the nose to
17 the back of the nose.
18 The normal -- a normal -- this may be
19 beyond what you wish to know, but I'll say it
20 anyway. A normal person's nose makes
21 2 quarts of mucus a day. I mean, I think --
22 while we cannot put into the record that

1 picture, we can envision 2-quart jars filled
2 with mucus.
3 Now, all day long that mucus is not
4 sitting on the floor of the nose. That mucus
5 in general health and wellness is not coming
6 out of the front of the nose. The mucus is
7 in the back of the nose, back of the throat
8 and is being swallowed.
9 So it is the natural function of the
10 cilia, the little hairlike microscopic areas
11 on top of the cells, for mucus and secretions
12 to flow and be pushed from front to back.
13 That would include medications; that would
14 include saline; that would include the
15 anesthetic that I put in there. All of these
16 things, that's the nature of how the nose
17 works.
18 And again, that may be far beyond what
19 you need, but I -- it seems important in what
20 you're trying to get at.
21 Q I'm just trying to get an understanding
22 of how these procedures --

1 A Yeah, and I hope I'm not giving you more
2 than you need, but I'm trying to be complete
3 for your sake.
4 Q No, I appreciate all of the details.
5 So earlier you were talking about
6 suction. So if there was too much of this
7 mucus or it had solidified -- I apologize for
8 not recalling the term -- or if there was too
9 much of this irrigation fluid, you could just
10 use suction to get rid of it?
11 A That is correct.
12 Q Okay. Understood.
13 And now I want to go earlier when we
14 were discussing sort of the preoperative
15 procedures and things like that.
16 Do you recall when you mentioned that
17 sometimes one of these procedures would be
18 combined with another procedure?
19 A Yes. I recall saying that.
20 Q Okay. And so what are types of
21 procedures that you might perform
22 concurrently?

1 A There are many. It could be provide
2 with correction of a deviated nasal septum,
3 the septum being the wall that separates the
4 two sides of the nose. That can be deviated
5 from trauma or just the way the nose grew.
6 And that is not at all uncommon to combine
7 turbinate with that.
8 There could be surgical procedures on
9 the sinuses where the outflow of the sinus --
10 sinuses are air-filled spaces in the head
11 that drain into the nose. Those outflows can
12 become obstructed for different reasons.
13 Where I and other surgeons will open those
14 sinus outflows, on some occasions go into the
15 sinus to remove whatever might be there, all
16 kinds of different things. We could talk
17 about it if you so wish.
18 There are times that the other
19 turbinates, not just the inferior turbinate,
20 but the middle turbinate, which has different
21 kind of structure, slightly different kind of
22 structure and has different problems. That

1 middle turbinate might need to be altered in
2 its size.
3 So there are many things that need to be
4 done, and that really comes down to proper
5 diagnosis, evaluation and then doing what
6 needs to be done for that particular patient.
7 But it's not unusual to combine several
8 procedures.
9 Q I see. Okay.
10 MR. BRIGGS: Counsel, if we're moving
11 to a new topic, I could also use a
12 break. But if this is in the same
13 topic, I can wait for a little bit.
14 MR. NEMTZOW: I think I've just got a
15 couple more questions on that if
16 that's okay.
17 MR. BRIGGS: Sure.
18 MR. NEMTZOW: Thank you.
19 Q All right. So if I understood your
20 testimony just now, if a patient had multiple
21 different problems in the nose that you
22 needed to fix, you would typically try to fix

1 all of them in the same time, rather than
2 doing --
3 A If possible.
4 Q -- separate procedures?
5 A Yes, yes.
6 Q Okay.
7 A That's most efficient.
8 Q All right. And just one more set of
9 questions here.
10 So you had mentioned before that in some
11 circumstances you would use a head lamp and a
12 speculum, and in others if you needed to
13 reach back further into the nose, you would
14 use an endoscope; is that right?
15 A Yes.
16 Q Okay. And which procedures, again,
17 thinking prior to 2006, would you need an
18 endoscope for?
19 A Any -- most all of the sinus surgical
20 procedures I would need an endoscope so I
21 could see the outflow of the sinus, safely
22 and effectively get into those sinuses to

1 alter whatever I -- may need to be done.
2 That's typically removing mechanical
3 obstructions in those early days, using rigid
4 surgical instruments, forceps, drills of
5 different kinds. But I needed to be able to
6 see accurately with those rigid instruments
7 in those days of 2000 -- before 1996 -- you
8 said 19 --
9 Q 2006.
10 A Yes, before 2006. So I would have to
11 see accurately.
12 Prior to endoscopes, I'm not even sure
13 how I did it and did it safely, but we did,
14 and that was with a headlight and with a
15 nasal speculum. And we did sinus surgery,
16 and we did it effectively, as did generations
17 of people before me.
18 The -- I don't think the outcomes were
19 as good. I think the destruction of tissue,
20 the amount of bleeding that occurred, was far
21 greater. And I think the recurrence rate for
22 me and for my colleagues was far greater

1 prior to the use of endoscopy and with the
2 tools that we melded with the endoscope to go
3 ahead and do those surgical procedures.
4 Q I see.
5 And is that because inserting those
6 tools would cause trauma to the nose?
7 A The tools that we had, as I've already
8 alluded, were rigid tools. I've already said
9 to you that a lot of these structures, like
10 the sinuses, drain into the nose from the
11 side walls of the nose.
12 Taking a rigid instrument and trying to
13 make it go sideways into the side wall of the
14 nose up into the sinuses was not easy. Some
15 of these curved instruments, varying angles
16 of all kinds, 45 degrees, 70 degrees,
17 90 degrees, 120 degrees. I, as a surgeon and
18 those that I taught -- that took discipline,
19 patience. And I will be -- and I will say
20 skill to work at those angles with those
21 instruments.
22 The -- to just embellish it even

1 further, the eye itself is located around --
2 the sinuses are located around the eye. The
3 maxillary sinus in the cheek, the eye sits on
4 that. The ethmoid sinus between the eye and
5 the nose, the eye sits next to that. The
6 brain is above the sinuses.
7 And you know, our goal is to get the
8 patient better, and our goal is not to have
9 critical, serious complication and injury.
10 Q Understood.
11 A So again, that's -- those are the tools
12 we use.
13 Q Thank you.
14 MR. NEMTZOW: Now would be a good time
15 for a break.
16 MR. BRIGGS: Five minutes unless
17 people need --
18 MR. NEMTZOW: Can we do ten?
19 MR. BRIGGS: Ten, sure. Off the
20 record.
21 (Whereupon, a recess was taken
22 from 10:41 AM until 10:56 AM.)

1 Q Before we get started, did you speak
2 with counsel during the break?
3 A I did.
4 Q Did you speak about the substance of
5 your testimony?
6 A No.
7 Q Thanks.
8 All right. So we've been talking a lot
9 about instruments and tools so far. I'd like
10 to talk a little bit more about rhinitis,
11 specifically and particularly diagnostic
12 criteria for rhinitis before 2006.
13 So what diagnostic criteria would you
14 have used to diagnosis rhinitis before 2006?
15 A Well, rhinitis is a broad term, and
16 there's several different kinds of rhinitis.
17 There's allergic and nonallergic rhinitis,
18 and the nonallergic, there's nasal motor, and
19 there's a whole bunch of subcategories of the
20 nonallergic rhinitis.
21 In my assessing and evaluating a
22 patient, history was always the most

1 important thing. And so I could learn a lot
2 about when a person's rhinitis occurred, were
3 there triggers, was it seasonal. And also
4 what they may have done for that. So a lot
5 of diagnosis was in history, rather than
6 testing.
7 Q Okay.
8 A If I suspected or was unsure of the
9 cause, I would typically send the patient to
10 an allergist. I am not an allergist. I
11 don't practice allergy. I do give medication
12 to treat some patients for allergic rhinitis.
13 But I would send them to an allergist and
14 some allergists would do skin testing. Some
15 allergists would do a scratch testing on the
16 back. I mean, a whole host of things.
17 And I really can't speak to exactly all
18 the things that were available. Blood tests
19 were used. I don't recall exactly when those
20 blood tests came into being that allergists
21 used. They weren't things that I did.
22 Q Are you familiar with an IGE panel?

1 A Yes.
2 Q What's an IGE panel?
3 A It is a group of blood tests where they
4 are looking at various immune factors within
5 the blood to determine is there allergic
6 rhinitis or not.
7 Q So that could be relevant for
8 determining if there is rhinitis?
9 A But I never ordered it. But other
10 physicians that I sent patients to did.
11 Q But the results of that IGE could be
12 relevant to your rhinitis diagnosis?
13 A The interpretation of those results by
14 someone skilled who knows allergy would be
15 something I would look at, their opinion.
16 Q So we talked about how the first thing
17 you'd look to would be the patient's history.
18 MR. BRIGGS: Object to form.
19 Q Would you also look to any symptoms?
20 A That's part of the patient's history,
21 are symptoms. Symptoms is history.
22 Q Pardon me.

1 A Symptoms are the history, what is the
2 patient being troubled by, what information
3 do I elicit from them that are the symptoms.
4 Versus signs that are physical signs of
5 disease. We differentiate symptoms and
6 signs.
7 Q So what symptoms would you be looking
8 for in the patient's history?
9 A They would be things of nasal
10 obstruction, nasal congestion, secretions,
11 various triggers, were there foods, were
12 there environmental factors that were
13 present, were there exposure to animals,
14 industrial factors. Where they're working,
15 occupational, things of that kind.
16 Or, if those were negative, I go
17 further, because I mention there's these
18 nonallergic rhinitis or what we call
19 vasomotor rhinitis. There are -- we don't
20 have itchy eyes, itchy nose, watery eyes,
21 sneezing fits, sometimes asthma, wheezing,
22 that is associated with the allergic.

1 So I will go further and try to find out
2 about that. And sometimes the nonallergic is
3 related to temperature change. In other
4 words, going from a warm room to a cold room,
5 change in illumination, a dark room to a
6 brightly lit room. Pregnancy can cause
7 rhinitis of pregnancy, there's geriatric
8 rhinitis, where there's rhinitis, as people
9 get older and the nose just doesn't function
10 the same.
11 So there are many things in that
12 history, and I'm sure there's many, many
13 other things that I've even not touched upon
14 here that I just haven't recalled.
15 Q That's helpful. You had mentioned --
16 because there's a lot of technical terms in
17 this case. You mentioned obstruction and
18 congestion.
19 Is that -- would that be sort of mucosal
20 swelling in the nose?
21 MR. BRIGGS: Objection to form.
22 A It can be.

1 Q Okay. So is mucosal swelling an example
2 of obstruction that you would look for when
3 diagnosing rhinitis?
4 A That would be one of the things that I'm
5 looking, when I look in the nose, that is one
6 of the clinical signs that I look for. And
7 that is, what does the mucus membrane look
8 like.
9 Q Would that also be relevant to
10 determining if the patient has congestion
11 that would be indicative of rhinitis?
12 MR. BRIGGS: Objection, form.
13 A Congestion can be part of rhinitis, but
14 I really think of them as different. I
15 separate those.
16 Q Okay. All right.
17 So once you've diagnosed a patient with
18 rhinitis, then I presume you might try to
19 apply some sort of a treatment; is that
20 right?
21 A Yes.
22 Q And how would you gauge whether that

1 treatment is effective?
2 A By response from the patient, that would
3 be first, do they -- have their -- have their
4 symptoms improved, are they any better, are
5 they gone, and for how long. The other might
6 be by looking in the nose itself. So one is,
7 what the patient tells me their symptoms, the
8 other are the signs of less swelling within
9 the nasal cavity, swelling and obstruction
10 from the tissue.
11 Q So, for example, would you ask a patient
12 to score one of their symptoms from one
13 number to another before and after the
14 treatment?
15 A I don't typically do that. It
16 doesn't -- there are many of my colleagues
17 who do and who will have forms of one kind or
18 another where they will do that. I will use
19 more verbal cues and try to get the patient
20 versus a number, 'cause I find a lot of
21 variability, but I will ask the patient how
22 their symptoms are and whether they are

1 better or worse.
2 If I were -- that's on my clinical
3 setting. And to differentiate this, I've
4 been involved in countless research projects
5 and I have overseen them, and I have put
6 protocols together. That becomes a very
7 different kind of a thing, where we do use
8 scoring systems and accepted, clinically
9 validated worldwide accepted scoring tables.
10 There I use that when I am determining
11 outcome as it relates to clinical work.
12 Q Okay.
13 A And that's different from what I do just
14 in the trenches day-to-day in managing my
15 patients.
16 Q Understood. And for those more for
17 research purposes, focusing in on those,
18 would you look to more observations in the
19 nose rather than subjective criteria from the
20 patient?
21 A We do both.
22 Q You do both?

1 A Yes. There's several validated
2 instruments that we use, that patients are
3 given, and where we have a scoring system.
4 Things called the Snot 20, sinus and nasal
5 outcome test, the term snot. Or the Snot 22,
6 or the nose, N-O-S-E, test, these are
7 acronyms used to describe what the testing
8 is.
9 Q That's a pretty clever acronym.
10 A Someone gave some thought to it.
11 Q All right. So thinking about the Snot
12 20, I'm not familiar with those, so can you
13 walk me through what some of those are.
14 A Yeah. And I can't give you all of them
15 off the top of my head. But they would be
16 things like nasal obstruction, nasal
17 drainage, breathing, sleep issues because of
18 nasal obstruction, snoring. There's a whole
19 host of these things, easily found on -- you
20 can easily find what that document is. I
21 don't have that off the top of my head right
22 now.

1 Q Understood. Could some of the criteria
2 for determining if a rhinitis treatment was
3 successful include measuring the size of
4 certain distances in the nose to determine if
5 the swelling was reduced?
6 MR. BRIGGS: Objection, form.
7 A That's different. So on one hand we
8 have the patient's perception through these
9 validated measurements that they complete.
10 Then we have the -- what we try to have as
11 objective data, where, as a clinician, I try
12 to observe what improvement there has been.
13 I emphasize that the word try for a
14 reason. And that is that, this is difficult.
15 The nose is changing all day long. And
16 there's what we call the nasal cycle. Some
17 parts of the day the nose is very congested,
18 and other parts it's not. People have used
19 things like rhinomanometry which measures the
20 pressures in the nose.
21 That's never been popular in the United
22 States other than a few selective places like

1 Mayo Clinic. It's been more of a European
2 tool that's used to measure obstruction. It
3 hasn't really been used here because of what
4 most clinicians believe is a lot of
5 variability.
6 We've talked about imaging, MRI or CT
7 scanning, that is also variable because of
8 the variability of the nose as it changes
9 throughout the day.
10 Nasal endoscopy is good, but we're only
11 catching the nose at some point in time, at a
12 moment in time. And, therefore, we put a
13 great deal on what the patient says and tells
14 us.
15 Q I see. Understood.
16 Is this why, sometimes when you're sick,
17 you start feeling worse at night?
18 A I'll explain that very simply because it
19 may be pertinent here.
20 As I mentioned, these turbinates are
21 erectile tissue, they become congested. As
22 all of us in this room sit here all day, it

1 is possible that our ankles and legs could
2 become swollen. That is because there's
3 dependent swelling in the legs. When we put
4 our head down at night, typically we sleep
5 lying flat in our culture. The nose and the
6 turbinates can fill with fluid and can become
7 congested. And it's not unusual for someone
8 to say, I sleep on one side, that side
9 becomes congested, I flip over in bed, the
10 other side becomes congested and we get this
11 alternating nasal obstruction relative to
12 fluids accumulating within the turbinates.
13 Q I see. Okay. You had mentioned earlier
14 that there's some criteria that they use in
15 Europe that the United States doesn't use
16 them; is that right?
17 MR. BRIGGS: Objection, form.
18 Q Strike that. I'll rephrase the
19 question.
20 You had mentioned earlier that there are
21 some criteria that's more popular to use in
22 Europe for evaluating rhinitis and less

1 popular in the United States, correct?
2 A No. I really -- I didn't say that. So
3 let me clarify that. I'm sorry if I created
4 confusion.
5 Generally speaking, around the world,
6 these patient validated quality of life nasal
7 sinus assessments are used. That's pretty
8 much -- if I pick up a piece of literature
9 from anywhere in the world, I'm going to see
10 snot 20, snot 22, and several other scoring
11 tests like that.
12 When I mentioned that is used in Europe
13 in some areas is rhinomanometry, a mechanical
14 device by which nasal obstruction can be
15 measured by determining pressure and air
16 flow. And I didn't really embellish and give
17 you that information.
18 That is the thing that's rhinomanometry
19 that has never been popular, except in, I can
20 count on one hand the centers where it's used
21 in the United States.
22 Q I see. All right. Thank you.

1 Okay. I'd like to go back to your
2 background in working for various medical
3 device companies, if that's all right.
4 A Yes.
5 Q So I think in your declaration you had
6 mentioned a few different companies that you
7 worked for aside from Acclarent, which we've
8 already talked about, and Somnus, correct?
9 A Yes.
10 Q One of those companies is Rhino Systems,
11 Incorporated?
12 A Yes.
13 Q They sold or sell a nasal irrigator that
14 uses suction?
15 A Powered suction and irrigation.
16 Q Okay. And what has your work for Rhino
17 Systems involved?
18 A I'm the medical director of that
19 company. I've been involved in overseeing
20 some of the research that has been done to
21 show clinical efficacies of saline irrigation
22 for the nose. That was published, not by me,

1 but I oversaw that, and that related to COVID
2 and the relationship of COVID and the impact
3 of saline irrigation.
4 I was involved in the development of the
5 device itself. It is called Navage,
6 N-A-V-A-G-E, and it's powered suction, and
7 has -- just to provide a little bit of
8 background. Distilled water is placed into
9 an upper tank, a salt pod of concentrated
10 saline is placed in. It is placed up to the
11 nose, and the powered suction pulls the
12 saline from one side of the nose to the
13 other.
14 Now, specifically to your question. My
15 involvement in this, on the medical physician
16 side, was the interface between this device
17 and the nose itself. We call it a nasal dock
18 or nasal pillows that are placed into the
19 nostrils through which the suction draws the
20 saline from one side to the other. That was
21 important as we thought about what is a good
22 seal. What other devices or technologies are

1 already out there that we might be able to
2 use in creating comfort. And one of the
3 areas that we went was to a CPAP, Continuous
4 Positive Airway Pressure for sleep apnea,
5 people have nasal devices, nasal pillows,
6 that are called, that they wear, and what
7 were the materials used. So they are in the
8 design of that. I was involved with that.
9 Separate or in addition, the amount of
10 suction that would be used. So I provided
11 input as to what would that suction be that
12 might not affect the sinuses or the
13 eustachian tube, the tube from the ear to the
14 back of the nose, creating ear issues.
15 Q Okay. And you mentioned the Navage
16 device, correct?
17 A That's the device we're talking about,
18 yes.
19 Q Does the Navage device deliver energy to
20 the tissue in the nasal cavity?
21 A None. Unless one wishes -- I don't
22 think of suction really as energy. Although,

1 there are some physicists who will talk about
2 the Bernoulli effect and all, but I don't
3 think that's what we're talking about here.
4 Q Okay. Thank you.
5 So another company that you mentioned in
6 your declaration is company call Entellus?
7 A Yes.
8 Q They also sell a balloon somnoplasty
9 device like Acclarent?
10 A Similar, but different.
11 Q What has -- what is the nature of your
12 work been for Entellus?
13 A I worked for only a short period of
14 time, after I left my work at J and J the
15 people from Entellus came to me to see if I
16 can provide some consultation and advice on
17 the development of tools that would relieve
18 mechanical obstruction in the nose and
19 sinuses. Tools that would dilate and expand
20 structure where the outflow of the sinus
21 should occur.
22 Q Does the device that Entellus makes

1 deliver energy to tissue?
2 A They may have an energy delivery device,
3 Entellus was subsequently sold to Stryker by
4 the way, so I cannot speak to whether they
5 have other tools and devices that are energy,
6 but at that time these devices did not
7 involve energy.
8 Q So you didn't work on a device for
9 Entellus that delivered energy to the tissue?
10 A I did not.
11 Q Then I think you also mentioned doing
12 some consulting work for Meril Life?
13 A Yes.
14 Q What did that work entail?
15 A Meril Life is an international company,
16 they're based in India, actually a
17 multispecialty company.
18 They have orthopedic technology, cardio
19 vascular technology, they were looking to be
20 involved in the nasal sinus space, and looked
21 to me to provide some knowledge, again, as it
22 related to these tools that would move from

1 rigid implementation to minimally invasive
2 tools, but mostly balloon technology, things
3 that would be inserted into a space, dilate,
4 open the outflow. I did some work for them,
5 it wasn't a long relationship for a lot of
6 different reasons. They were in India, I was
7 in the United States, I put them in touch
8 with colleagues that would be more efficient
9 for them that I knew from my engagement with
10 people in India that I thought would be more
11 effective to achieve their outcomes.
12 Q And the devices that you worked on for
13 Meril Life, did any of those deliver energy
14 to tissue?
15 A They may have some now, the ones I
16 worked on did not.
17 Q Finally, I think you mentioned in your
18 declaration, the Dianosic?
19 A Dianosic on sick.
20 Q Dianosic. Thanks for the clarification.
21 A That's okay.
22 Q So you've performed consulting work for

1 Dianosic?
2 A I'm one of their senior medical
3 advisories, still am today. And during break
4 there were some messages from that company
5 for me, it's active.
6 Q What has the nature of your work with
7 Dianosic included today?
8 A Dianosic is a Paris-based company. The
9 information is public, although at one time
10 it was of course, it was proprietary because
11 it was a start-up. We are looking at
12 implantable devices placed in the physician
13 office in the nose and/or sinus area that
14 will dilute drug medications over a period of
15 time. Period of time being over six months
16 to manage allergic rhinitis or chronic rhino
17 sinusitis. The possibilities of even using
18 the nasal cavity as an avenue to deliver
19 drugs from -- to the brain, nose to brain,
20 getting drugs into the intracranial space for
21 management of various neurologic disorders.
22 Q In your work with Dianosic have any of

1 the devices you worked on delivered energy to
2 tissue in the nose?
3 A None.
4 Q Thank you. I think we've talked about
5 your work for Acclarent, Rhinosystems and
6 Entellus, Meril Life and Dianosic, are there
7 any other companies that you've provided
8 consulting services for?
9 A I have and this goes back a bit. There
10 was Ethicon Surgical, quite a long time ago,
11 that was more on the -- when I was doing
12 reconstructive -- had cancer reconstructive
13 surgery. It involved really sutures,
14 suturing, kinds of suture material, wound
15 closure materials that was -- those were not
16 energy related. I did some work and
17 developed and created some tools for what was
18 Xomed that then became Medtronic Xomed. That
19 then became Medtronic, you know, as these
20 companies have various iterations in their
21 life. That was in the creation and
22 development of what were drills and drill

1 bits that were rigid instruments to
2 specifically reach the frontal sinus, the
3 sinus above the eyes in the forehead because
4 that was an extremely challenging area and as
5 I mentioned earlier, we had to have
6 instruments of various angles and everything,
7 the bone was sometimes hard, we had to drill
8 to remove and I created some instruments for
9 that. Additionally, there were some specific
10 operations that were being performed for
11 people with thyroid disorders where they have
12 what we call exophthalmos, meaning their eyes
13 are bulging outward by the nature of
14 chemicals being accumulated within the fat
15 around the eye. Those individuals would
16 sometimes go blind because of the pressure of
17 that upon the optic nerve and I created a set
18 of tools that were used for surgical
19 procedures to decompress the bone around the
20 eye. Removing the bone of the sinuses to an
21 obstructive procedure but done at the expense
22 of giving an area to expand the tissue that

1 was swollen within the eye, the orbit, to
2 relieve the pressure on the optic nerve and
3 get rid of the blindness and successfully in
4 large number of individuals.
5 I actually had the only set of
6 instruments that Medtronic had and maybe
7 someone else had, so that was my set of
8 instruments that I created and developed.
9 Q Did those instruments that you developed
10 with Xomed deliver energy to tissue?
11 A None.
12 Q So we've also talked about Ethicon
13 Surgical, Xomed or Medtronic Xomed, have you
14 consulted for any other medical device
15 companies?
16 A Yes, I have. There are several
17 start-ups that I have been involved in. That
18 are still in the start-up phase. Those I
19 will have to say I don't know, I don't know
20 if anyone can advise me, but let me direct it
21 to you, I have nondisclosures with those
22 companies at this point in time for the work

1 that I do. I share my expertise with only
2 them, and our dialogues back and forth as any
3 start-up where I try to honor and be ethical
4 in the nondisclosure and the work I do and
5 not mix that with any work I do for anyone
6 else or any other purpose.
7 Q Understood. I don't have any intention
8 of getting into any of that confidential
9 info.
10 I'd like to stay on medical devices, but
11 focus a little bit more on another device
12 that you spoke about working on, and that's
13 a -- I believe that you helped work on a
14 laser device; is that right?
15 A Yes.
16 Q Okay. So could you tell me a little bit
17 more about what that device was?
18 A That device was a -- the energy was the
19 KTP 532 laser, that is merely the wave length
20 of the laser energy, the commercial name of
21 the device and the company was Laserscope. I
22 alluded to this tangentally before, the

1 founder of that was Rodney Perkins who was
2 the otologist, who then founded and created
3 this Earlens that I wear and have provided
4 some more advice more as a user, Bill Facteau
5 who you mentioned is the CEO.
6 The Laserscope itself had been approved,
7 FDA approved for use in the ear, initially,
8 that was Dr. Perkins area of expertise and
9 interest, as I mentioned, in which he would
10 use laser energy to create holes in the bone
11 of a part of the ear to manage hearing
12 issues.
13 We at the Cleveland Clinic received the
14 second Laserscope device 002 and we used and
15 it was approved for use in the larynx, the
16 voice box, mouth, and throat. And we used it
17 extensively there. These were flexible
18 fibers and thin and permitted use of energy
19 in various places that we could not use it
20 before.
21 I as the nose and sinus physician at the
22 Cleveland clinic had this idea let's try to

1 use it and get approval through the FDA for
2 use and see if there are any indications for
3 the nose and sinus. The challenge I had was
4 this flexible fiber, as I've mentioned a few
5 times already, to make it go at a right
6 angle, I couldn't do. So I created some
7 little devices, a cannula, one would wish to
8 say that, through which the laser fiber could
9 be placed. I had various angles. I could
10 direct it into the places where I need it. I
11 found, unfortunately, that the laser energy
12 didn't add very much to management of the
13 nose and sinus.
14 However, it did help in manage nasal
15 turbinates. I ended up publishing several
16 articles about its role in shrinking the
17 enlarged nasal turbinates and what its
18 efficacy was and safety was. That became a
19 popular place, but when all said and done it
20 was a very expensive tool to manage that one
21 thing.
22 One wouldn't be acquiring that piece of

1 equipment for their operating room unless
2 they were going to use it for many, many
3 other things.
4 Q I see. Were there other clinicians who
5 did use the device that you designed?
6 A Yes.
7 Q Would those clinicians have understood
8 how to use that device safely?
9 A I cannot speak to what a clinician would
10 do or what knowledge they would have prior to
11 that. I can only tell you that I have given
12 lectures during which time I would provide to
13 them my criteria of how to do this and then I
14 would -- and I know that salespeople and
15 clinical teams would go to those operating
16 rooms to instruct people, what they took from
17 that and how they used it is beyond anything
18 I can control.
19 Q Understood. But you at least expected
20 that they could learn how to use the device
21 safely and correctly?
22 A Absolutely.

1 Q And one of things I imagine when you're
2 dealing with one of these laser devices is
3 figuring out what dosage you need to apply to
4 the tissue; is that right?
5 A Yes.
6 Q It was your understanding at that time
7 that clinicians would be able to garner an
8 understanding of the energy dosage that they
9 would need for their clinical applications?
10 A Yes.
11 Q Would a surgeon know how to calculate
12 energy dosage at that time?
13 A The piece of equipment was very user
14 friendly. And it wasn't like you had to dial
15 in a whole bunch of things, the energy was a
16 certain energy, it was more the wavelength,
17 and it was more the interface between the end
18 of the laser fiber and the tissue. And that
19 was something through videos that I created
20 through my going and teaching and watching
21 people, through assisting people didn't take
22 much for a surgeon to see that by the

1 distance between the end of the fiber and the
2 tissue itself that you can have a different
3 affect on the tissue itself.
4 Q I see. And that's because it's a
5 broader coverage area, so it's spreading
6 energy out over a larger range?
7 MR. BRIGGS: Objection. Form.
8 A A laser is coherent light. It's not
9 like an incandescent lightbulb where the
10 light will go in several different directions
11 where it is diffused. Laser by virtue is
12 coherent meaning that the laser beams are in
13 alignment. Therefore, it could be -- you're
14 really focusing and concentrating it. There
15 is a little bit of difference in how that
16 energy would be absorbed by the tissue
17 whether you place the energy into direct
18 contact versus held a distance away.
19 Q Understood. You were talking a little
20 bit earlier about the inception for this
21 laser device that you help develop; is that
22 right?

1 A I didn't develop the laser. I didn't
2 develop the laser device. Rodney Perkins
3 developed the laser device. What I did was
4 to try to see another place that it could be
5 used different from its early use and see if
6 the there was an indication. By indication I
7 mean, did I, as a clinician, see value and
8 then was there safety, was there durability,
9 and then would a regulatory body agree if I
10 could meet those criteria. What I created
11 wasn't the laser or the energy, it was a tool
12 used to deliver it into a place that was
13 difficult to get to.
14 Q Okay. And you mentioned that safety is
15 one of things that you had to consider when
16 evaluating whether it could be used in the
17 nose, correct?
18 A Yes.
19 Q Would you agree that some of the safety
20 concerns that would be relevant to use in the
21 laser in other parts of the body were
22 relevant to its use in the nose?

1 MR. BRIGGS: Objection. Form.
2 A Could you repeat that, please?
3 Q Sure. Would you agree that some of the
4 safety concerns that would be relevant to
5 using the laser in other parts of the body
6 were also relevant to using the laser in the
7 nose?
8 MR. BRIGGS: Same objection.
9 A Yes, yes.
10 Q All right. And so what procedure did
11 you ultimately determine that the laser
12 device that you helped to develop would be
13 useful for?
14 MR. BRIGGS: Objection. Form.
15 A As I said, the turbinates.
16 Q Okay.
17 A Most useful for the turbinates.
18 Q What specifically did your -- strike
19 that.
20 What indication specifically was your
21 laser device used for?
22 MR. BRIGGS: Objection. Form.

1 A The indication was the nasal obstruction
2 that would be, as I've said the symptom, then
3 the sign would be my visually seeing the
4 nasal obstruction and it was coming from the
5 turbinates, it was a combination as we talked
6 about signs and symptom.
7 Q Could that laser device have been used
8 the treat rhinitis?
9 MR. BRIGGS: Objection. Form.
10 A I have no information to know if it
11 would be able to be used for rhinitis.
12 Q As you sit here today, you have no
13 recollection as to whether the laser device
14 that you mention in your declaration was used
15 to treat rhinitis?
16 A I never used it to treat rhinitis. I
17 cannot speak to what anyone else would do,
18 but in my writing, my teachings, my
19 lecturing, rhinitis was not what the focus
20 was. It was mechanical obstruction.
21 Q Would you agree that one way to treat
22 rhinitis is through turbinate reduction?

1 A I would not agree. I think those are
2 different things, okay.
3 Q When you performed the turbinates
4 reduction with the laser device we've been
5 discussing that would produce scar tissue in
6 the turbinates, correct?
7 MR. BRIGGS: Objection. Form.
8 A It would produce scar tissue, but I
9 tried to mitigate the scar tissue by how I
10 used it by at least a concepted theory that I
11 had.
12 Q What do you mean by "mitigate scar
13 tissue"?
14 A Well, I didn't want to have a huge, I
15 wanted just enough scar tissue and I knew
16 that the mucus membrane of the nose was
17 important, so rather than destroying all of
18 the mucus membrane, what I did and shown in
19 the articles that I wrote, is I conceived of
20 what I called a cross-hatching methodology.
21 Where rather than taking the laser fiber and
22 putting it within the turbinates as I did

1 with cautery or other things, I would go over
2 the surface of the turbinates and create kind
3 of like a checker board, cross-hatching. The
4 concept being that the -- those cross-hatched
5 areas would heal and would be scar tissue,
6 that scar tissue, as I've mentioned would
7 hold in check by virtue of a scar being a
8 tougher tissue and keep the turbinates from
9 expanding.
10 Additionally, what would happen would be
11 that there would be some mucus membrane that
12 would be left intact that would function.
13 Q Understood. So in this cross-hatching
14 procedure that you were just describing --
15 strike that.
16 We've been discussing how to perform
17 turbinate reduction with the laser device
18 that you worked on, correct?
19 A Yes.
20 Q And that turbinate reduction can also
21 decrease the autonomic innervation of the
22 turbinates, correct?

1 MR. BRIGGS: Objection. Form.
2 A I don't know that to be true. I never
3 looked at that. I never studied that it
4 would change that autonomic nervous system.
5 I never had criteria where I tried to
6 determine what were the autonomic functions
7 of the turbinates. Nor did I have criteria
8 to determine what would be the outcome for
9 that. My criteria for choice of patient was
10 nasal obstruction. My end goal was, could
11 the patient breathe better.
12 Q And again, focusing on the turbinates
13 reduction procedures we've been talking about
14 with relation to the laser device you worked
15 on --
16 A Um-hmm.
17 Q -- can those turbinate reduction
18 procedures also reduce mucus production?
19 A It wasn't anything I ever measured, so I
20 don't know. As I said to you, what I was
21 trying to do by leaving these islands of
22 mucosa was to maintain mucus production. But

1 I can't speak to it. It's not something that
2 I ever measured to determine whether it did
3 or didn't.
4 Q Okay. Can the turbinate reduction
5 procedures with the laser device you worked
6 on improve the patient's airway?
7 MR. BRIGGS: Objection. Form.
8 A Improving the airway is exactly what
9 we're talking about. The airway is
10 compromised when there is obstruction. So if
11 I can reduce the turbinate, I have opened the
12 airway, there is more air space; therefore,
13 the airway is improved.
14 Q Okay. All right. I'd like you to open
15 your '077 declaration at Paragraph 13, which
16 is on Page 5 of the declaration.
17 A I have that.
18 Q Okay. And is this paragraph describing
19 the laser device we've just been discussing?
20 A It does.
21 Q And is the figure that appears at the
22 bottom of Page 5 of your '077 declaration an

1 image of the laser devices that you've helped
2 design?
3 A That's an image of the hand pieces into
4 which the flexible fibers were inserted.
5 Q Understood.
6 And do you see in Paragraph 13 of your
7 declaration where you say the device is
8 described in the article "Lasers and
9 Endonasal Surgery" from 1997.
10 A Direct me to that again.
11 Q The second line down in Paragraph 13.
12 A Yes. I see that. Yes.
13 Q Okay. Did you review -- strike that.
14 Are you familiar with the article
15 referenced in Paragraph 13 of your
16 declaration?
17 A I am.
18 Q Did you review that article when
19 preparing your declaration?
20 A I looked at it. I did not look at it in
21 great detail.
22 Q Okay. Did you rely on that article in

1 the opinions that you presented in your
2 declaration?
3 A I did.
4 Q You did, okay.
5 A I relied on it as it related to -- to --
6 I want to go back here -- really in two
7 parts, one, the use of radio frequency energy
8 and lasers, which is -- that is in the
9 subsection. That paragraph is in the
10 section. So I relied on it on that -- for
11 that. But also relied on it tangentially
12 about my work in accretion and development of
13 tools.
14 Q Okay.
15 A And my role in that.
16 Q And when you were reviewing the article
17 mentioned in Paragraph 13 of your declaration
18 when preparing it, did you notice anything in
19 that article that was inaccurate?
20 A I didn't review it in that depth to try
21 to see the complete accuracy of the article
22 itself and whether there was something I

1 stated then that I might have stated
2 differently now.
3 Q Okay. And would a POSITA -- sorry.
4 Strike that.
5 Would a person of ordinary skill in the
6 art in 2006 have considered your article as
7 relevant when evaluating the patentability of
8 The Foundry patents at issue in this case?
9 MR. BRIGGS: Objection. Form.
10 A I don't see where that would be related.
11 Q Understood.
12 MR. NEMTZOW: And I think now would be
13 a good time for a break.
14 (Whereupon, a recess was taken
15 from 11:35 AM until 11:49 AM.)
16 Q Welcome back. Did you speak with
17 counsel during the break?
18 A I did not.
19 Q Okay. All right. I'd just like to
20 return very quickly to the laser device we
21 were talking about before.
22 Okay. So let's turn back to Page 5 of

1 your '077 declaration at Paragraph 13.
2 A I have it.
3 Q Okay. And we were talking about the
4 image that appears on the bottom of Page 5 of
5 your '077 declaration.
6 A Yes.
7 Q And so I think you were talking about
8 this earlier, but it looks like there's some
9 bends at the end of the devices there; is
10 that right?
11 A Yes.
12 Q Okay. And what is the reason for the
13 bend at the end of those devices?
14 A The bend is to direct the flexible laser
15 fiber into the direction I wish it to go,
16 such as the outer lateral wall of the nose or
17 up into the sinus.
18 Q I see.
19 Okay. And when these devices were sold,
20 were they sold with those bends already
21 formed?
22 A Yes.

1 Q Okay. And it looks like there is
2 varying degrees of bends there; is that
3 right?
4 A Yes.
5 Q Okay. And what's the reason for that?
6 A The different degrees are because
7 they're different places that need to be
8 reached, and those have different angles and
9 entrances and -- so we needed to have a
10 variety of choices to get into a specific
11 sinus or nasal area. And in addition, every
12 patient is different, so it wasn't like one
13 device for the frontal sinus, one for the
14 maxillary sinus. It would just depend on the
15 angle and what the pathology was and what we
16 had to use.
17 Q Okay. I see.
18 And you spoke earlier about using these
19 devices on the turbinates specifically; is
20 that right?
21 A Yes.
22 Q Okay. And would you use one of the ones

1 with a bend in order to use laser energy on
2 the turbinate?
3 A Yes.
4 Q Okay. And it looks like the one all the
5 way over to the right does not have a bend at
6 the end; is that right?
7 A That is correct.
8 Q Okay. Could you apply energy to the
9 turbinate with the one on the end that
10 doesn't have a bend?
11 A I could.
12 Q Okay. So is it fair to say that you
13 could use the one without a bend in some
14 cases; you'd use the one with a bend in other
15 cases?
16 A Yes.
17 Q Okay. Are there any areas of the nasal
18 anatomy that you can't reach without a bent
19 device?
20 MR. BRIGGS: Objection to form.
21 A There -- yes. There are places that I
22 cannot reach without a -- let me say it more

1 clearly. There are places in the nasal
2 cavity where I need a bend to reach it
3 accurately and safely.
4 Q Okay. And what would those place be?
5 A Many places on the lateral nasal wall,
6 only because I'm working into the nose and
7 trying to work off to the side.
8 Q Okay.
9 A And it could be any one of -- anything
10 in any of those areas.
11 Q Understood.
12 And I'm certainly not a person who would
13 perform these procedures, but I imagine that
14 if you have a bend at the end of the device,
15 it makes it easier -- it gives you a better
16 insertion angle into the nose?
17 MR. BRIGGS: Objection. Form.
18 A It's not about inserting into the nose.
19 I can put any of these into the nose through
20 the nostril. It's about getting the energy
21 to where it needs to be.
22 Q I see. Understood. Okay. And I think

1 we can put that aside.
2 All right. So I'd like you to take a
3 look at the three declarations that you
4 brought with you today.
5 I think you have the '077 in front of
6 you, correct?
7 A I do. I have all three in front of me.
8 The '077 is the one that's open.
9 Q Yep. And you also with you the '011
10 declaration and the '675 declaration?
11 A I do.
12 Q Okay. And are all three of these
13 declarations a complete description of the
14 opinions that you have given in this matter
15 to date?
16 A They are.
17 Q Okay. And your three declarations all
18 include the materials that you considered in
19 order to form your opinion in this matter; is
20 that right?
21 A Yeah.
22 MR. BRIGGS: Objection. Form.

1 A Yes.
2 Q Is there anything that you need to add
3 to that list?
4 A I can't think of anything.
5 Q Okay. And you reviewed your
6 declarations since you've submitted them?
7 A I have.
8 Q Okay. And when did you review them?
9 A I've reviewed them several times. I've
10 read them. I last reviewed them yesterday.
11 Q Okay. And did you review all three of
12 your declarations yesterday?
13 A I did.
14 Q Okay. Did you read all three of them
15 completely yesterday?
16 A I did.
17 Q Okay. Is there anything in your
18 declarations that is incorrect?
19 A I found a couple of spelling typos, but
20 the information is correct.
21 Q Okay. Would you like to make any
22 corrections today?

1 A I don't. It doesn't change the
2 substance of what needs to be said.
3 Q Understood.
4 A And I did not make any notation of where
5 those very minors typos were.
6 Q Understood.
7 Can you describe the process by which
8 your declarations were prepared?
9 MR. BRIGGS: Objection. May call for
10 attorney-client privilege.
11 The witness can answer to the extent
12 the answer does not reveal any
13 attorney-client privileged
14 information.
15 A I had a dialogue with the attorneys in
16 which I presented my views of the issues at
17 hand. There were, in that dialogue,
18 questions that were asked of me. I tried to
19 provide answers to those. And out of that
20 came a draft of a declaration, based upon my
21 information I provided. I edited that draft.
22 We wrote sections along with the attorneys.

1 Q Okay. Did you write your declarations?
2 MR. BRIGGS: Objection. Form.
3 A What do you mean when you say did I
4 "write them"?
5 Q Did you write the words that appear in
6 your declarations?
7 MR. BRIGGS: Objection. Form.
8 A I did write some of it. Most of it, the
9 words came from the attorneys putting in some
10 of the legalese that I'm not capable -- I'm
11 not an attorney. That went into it. Many of
12 the initial draft came from the words that I
13 gave to the attorneys. There were then parts
14 that I edited and wrote sections that then
15 were incorporated into the earlier drafts.
16 Q And you said that the attorneys put in
17 some of the legal portions of your
18 declaration; is that right?
19 A Yes.
20 Q Okay. And if we turn in the '077
21 declaration to Page 6.
22 A Yes.

1 Q Starting at Paragraph 16, going through
2 Page 10, the first line.
3 A Yes.
4 Q Is that the legal portions that you were
5 referring to?
6 A That and even the part about prior
7 testimony. I didn't write that. I gave
8 information about those cases, but I could
9 not have found -- and those numbers and all
10 of that.
11 Q Okay. But you understand everything
12 that was put in the legal standard section of
13 your declarations, correct?
14 A I do.
15 Q Okay. Now, there are a few annotated
16 figures in your declarations; is that right?
17 A Yes.
18 Q Okay. And did you create the
19 annotations in the figures in your
20 declarations?
21 A I did not.
22 Q Okay. Did counsel create the

1 annotations in the figures in your
2 declarations?
3 A Can you -- can we look at one of those
4 and I -- so I can be certain about which part
5 you mean when you say "annotated." I want to
6 be clear as I answer it.
7 Q Sure. Happy to.
8 Maybe if we go to Page 61 of your
9 declaration.
10 A Six-one?
11 Q Six-one, yep.
12 And when you're there, there's an
13 annotated Figure 1 from the Imran patent
14 above Paragraph 109 of your '077 declaration.
15 Do you see that?
16 A I do.
17 Q And do you see that there are some
18 annotations in red on that figure?
19 A I do.
20 Q Okay. And did counsel provide those
21 annotations for you?
22 MR. BRIGGS: Objection. Form.

1 A I was provided the illustration. I
2 don't know who created the annotations.
3 Q Okay.
4 A I -- but I was given them and used them
5 in my -- in forming my opinions as a person
6 with skill in the art.
7 Q Okay. And if we go to back to Page 53
8 of your declaration. There's what appears to
9 be an annotated version of Figure 5H of the
10 Makower reference --
11 A Yes.
12 Q -- above Paragraph 93.
13 Do you see that?
14 A I do.
15 Q And did counsel provide you the
16 annotated figure that appears in that portion
17 of your declaration?
18 A I was provided that figure. I don't
19 know who put in the annotation.
20 Q Okay. But when you received it, you
21 receive it from counsel?
22 A I did.

1 Q Okay. How many hours did you spend
2 preparing your declarations?
3 A I don't have an exact number. The
4 preparation was the conversations; it was the
5 drafting; it was the reading, the rewriting.
6 But it could have been 20, 30 hours. I --
7 guessing, estimating. I don't know. I don't
8 have that number with me right now.
9 Q Understood. Between discussing with
10 counsel, reviewing materials, and editing
11 your declaration, you spent somewhere between
12 roughly 20 to 30 hours?
13 A I believe so. I don't know if that's an
14 accurate number.
15 Q Okay. You did not state your hourly
16 rate in your declaration, did you?
17 A It is not in there.
18 Q What is your hourly rate for this
19 matter?
20 A $800 per hour.
21 Q Is it different when you're sitting for
22 a deposition?

1 A A deposition is different. At least
2 those who oversee this part of my practice
3 have a fixed fee for deposition time.
4 Q And what is your fixed fee for
5 deposition time?
6 A I honestly don't know. I haven't looked
7 at it. I have not looked at what the 2025
8 fee is and whether that's changed. I haven't
9 been available to look at that or discuss
10 that with those who oversee that. This is my
11 medical practice management financial group.
12 Q Understood. So you don't know how much
13 you're being compensated for your testimony
14 today?
15 A I don't.
16 Q All right. What did you do to prepare
17 for your deposition today?
18 MR. BRIGGS: Again, may call for
19 attorney-client privileged
20 information. The witness can answer
21 to the extent the answer does not
22 reveal any attorney-client privileged

1 information.
2 A I reviewed the documents that are listed
3 in the declaration. I reviewed the
4 declaration. I want to look at that list
5 just to be sure if there's anything else in
6 that list.
7 In addition to reviewing all of those
8 materials in my declaration, I had
9 conversations with the attorneys about the
10 process.
11 Q And was that with the attorneys sitting
12 here today?
13 A Yes.
14 Q And did you speak with anybody else?
15 A I did not.
16 Q For about how long -- when did you meet
17 with counsel to prepare for your deposition
18 today?
19 A I almost feel that we've been meeting
20 all along, every time I've spoken to them,
21 whether it's creating the document, it's all
22 about preparing for this.

1 The declaration is part of that, I
2 believe, but then again I'm not an attorney
3 who can say what part is prepared for the
4 deposition and what is not.
5 Q Understood. So when have you met with
6 counsel after you signed your declaration?
7 A Again, I don't have that timetable in
8 front of me. There certainly may have been a
9 couple of Zoom calls where we met. And then
10 there was a time yesterday that we met
11 together.
12 Q For about how long did you meet
13 yesterday?
14 A I would say roughly about six hours.
15 Q Okay. And did you speak with anyone
16 besides the attorneys present today to
17 prepare for today's deposition?
18 A I did not.
19 Q Did you speak with Dr. Vixen?
20 A I have.
21 Q Did you speak with Dr. Vixen after you
22 submitted your declaration?

1 A I have not.
2 Q Did any documents that you reviewed in
3 preparation for your declaration -- strike
4 that.
5 Did any of the documents that you
6 reviewed in preparation for your deposition
7 today refresh your recollection?
8 MR. BRIGGS: Objection, form.
9 A My recollection of what?
10 I mean, reviewing everything, of course,
11 helps in my recollection, but I'm not clear
12 as to what you're asking me as it related to
13 my recollection.
14 Recollection of what?
15 Q Were there any specific facts that you
16 did not recall and reviewing a document
17 helped to refresh your recollection of those
18 facts?
19 MR. BRIGGS: Objection, form.
20 A No.
21 Q Do you know who the inventors are, the
22 named inventors are of The Foundry patents at

1 issue in this case?
2 A Can I see The Foundry patents so I can
3 see those names to be sure in my answer.
4 Q I can just list them off. I have them
5 here.
6 Are you familiar with Mark E. Deem?
7 A No.
8 Q Are you familiar with Hanson Gifford?
9 A No.
10 Q Okay. I think, as we spoke earlier, you
11 are aware that Aerin Medical has also
12 asserted some patents against Neurent, and
13 that Neurent has challenged those patents in
14 other IPR proceedings; is that right?
15 A I've learned that.
16 Q Are you familiar with Scott Wolf?
17 A I am.
18 Q How do you know Scott Wolf?
19 A Scott Wolf is the medical director of
20 Aerin Medical, and I've known him for many
21 years. He sits on the quality team. Any of
22 the clinical quality meetings, he is present

1 and I am present.
2 Q And did you first encounterer
3 Mr. Wolf -- apologies. Is it Mr. or Dr.?
4 A Doctor. He's an ear, nose and throat
5 physician, Dr. Wolf.
6 Q Thank you. Did you first encounter
7 Dr. Wolf in your capacity as a consultant for
8 Aerin Medical?
9 A No.
10 Q When did you first meet Dr. Wolf?
11 A I encountered him many, many years ago
12 in the work that I was doing at Acclarent.
13 And he was in that area, I was in that area,
14 because of our common interests in medical
15 devices, we spoke, he did talk with me at
16 that time about ideas that he had for use of
17 radio frequency, but it was very high level,
18 where it might occur, I can't even speak to
19 what the details were of that.
20 Q Were the discussions you had
21 specifically about the use of radio frequency
22 energy in the nose?

1 A Yes.
2 Q Do you recall approximately at what time
3 those conversations were?
4 A It was many, many years ago. I don't.
5 And I can't even recall the details, other
6 than because of common interest that we had
7 in medical devices, we would talk about
8 things that we were doing. Without
9 disclosing any of -- anything that was
10 proprietary or which was protected under a
11 nondisclosure agreement.
12 Q Did you have a nondisclosure agreement
13 with Dr. Wolf?
14 A No. Not at that point in time.
15 Q And Dr. Wolf didn't work at Acclarent,
16 did he?
17 A He did not.
18 Q Did you speak with Dr. Wolf about using
19 radio frequency energy to treat rhinitis?
20 MR. BRIGGS: Objection, form.
21 A At what point in time?
22 Q Prior to your work consulting with Aerin

1 Medical.
2 A I don't recall speaking about that at
3 that time.
4 Q Going back to these conversations we've
5 just been discussing. You said that those
6 discussions were while you were working for
7 Acclarent; is that right?
8 A Yes.
9 Q And what time were you working for
10 Acclarent?
11 A What time period?
12 Q Yeah. Time period.
13 A So I was a consultant for Acclarent from
14 2007 until 2010. By consultant, I was at
15 Acclarent several days a week, commuting
16 there for consulting work. And then became a
17 full-time employee of when the company was
18 acquired by Johnson & Johnson. That was
19 in 2010.
20 Q Okay. And do you recall if your
21 conversations with Dr. Wolf about radio
22 frequency energy in the nose occurred while

1 you were a consultant for Acclarent?
2 A They probably did because that was my
3 reason for being out in the Menlo Park Bay,
4 San Francisco bay area.
5 Q All right. Could you describe the
6 nature of your work with Dr. Wolf at Aerin
7 Medical?
8 A At this time?
9 Q Yes.
10 A At this time?
11 Q At any time.
12 A We are both physicians. He's the
13 medical director, I'm an independent
14 consultant. As I mentioned, we sit on
15 committees that relate to clinical trials,
16 clinical development. Sit on committees
17 together where there is discussion of new
18 product development. We sit on quality and
19 safety together.
20 So the engagement is more of being part
21 of the same committee and team. There are
22 times when there is a medical -- where

1 there's an adverse event with one of the
2 Aerin Medical devices. And because we are
3 both the physicians, we will have
4 conversation, dialogue, about the
5 significance of that event, whether it needs
6 to be reported to the FDA, what implications
7 it might have as it relates to design and
8 improvement of any part of that device.
9 Q Okay. Aside from your consulting work
10 with Aerin Medical and the conversations you
11 had with Dr. Wolf while you were at
12 Acclarent, have you had any other
13 interactions with Dr. Wolf?
14 A None that I can recall.
15 Q Okay. All right. And are you familiar
16 with Andrew Fraser?
17 A Andrew Fraser, yes, that's a name I
18 recollect, but I cannot tell you the details
19 of how I know Andrew Fraser. And please
20 don't report that to him that I could not
21 remember how I might recollect it.
22 Q I won't specifically report that to him.

1 A Okay.
2 Q Just a few more questions. I know we
3 want to have a break shortly.
4 I'd like to just talk about your
5 experience again a little bit.
6 You have not -- are you familiar with
7 the concept of electroporation?
8 A I am.
9 Q And you're familiar with the concept of
10 irreversible electroporation?
11 A I am.
12 Q You have not designed a device that
13 causes irreversible electroporation, have
14 you?
15 A Not that I know of.
16 Q And you've never designed a device that
17 ablates tissue using electroporation, have
18 you?
19 A I have not.
20 Q And you've never designed a device that
21 will cause electroporation in the nasal
22 pharyngeal passage, right?

1 A I have not.
2 Q And you have not designed devices that
3 use radio frequency energy?
4 A I have not.
5 Q And you have not designed devices that
6 have electrodes that deliver energy to
7 tissue, have you?
8 A I have not.
9 MR. NEMTZOW: All right. I think we
10 can stop there.
11 Q You have not developed any devices that
12 cause irreversible electroporation, have you?
13 A I have not.
14 Q You have not developed any devices that
15 ablate tissue using electroporation?
16 A I have not.
17 Q And you have never developed a device
18 that will cause electroporation in the nasal
19 pharyngeal passage?
20 A I have not.
21 Q You've never developed any devices that
22 use radio frequency energy?

1 A I have not.
2 Q You've never developed devices that have
3 electrodes that delivery energy to tissue,
4 have you?
5 A I have not.
6 MR. NEMTZOW: I think we can close up
7 for now.
8 MR. BRIGGS: Off the record.
9 (Whereupon, a recess was taken
10 from 12:11 PM until 12:46 PM.)
11 Q Welcome back.
12 A Thank you.
13 Q Did you have a good lunch?
14 A I did. Thank you.
15 Q Did you speak with counsel during the
16 break?
17 A I did.
18 Q Did you speak about the substance of
19 your testimony today?
20 A I did not.
21 Q Okay. Let's get started.
22 All right. If you could take your '077

1 declaration, if it's not already in front of
2 you.
3 You have it there?
4 A Yes.
5 Q Let's turn to Page 6.
6 I think we already discussed this
7 section before, but this is your legal
8 standards section of your declaration?
9 A Yes.
10 Q And you applied the same legal standards
11 to your analysis in all of the proceedings,
12 of course, today?
13 A I did.
14 Q Okay. All right.
15 And if your legal understandings were
16 incorrect, that would affect your analysis
17 and opinion, correct?
18 A Yes.
19 MR. BRIGGS: Objection, form.
20 Q Please turn to Paragraph 20 of your '077
21 declaration.
22 A Which paragraph?

1 Q Paragraph 20. I can get you a page
2 number in just a moment. It's on Page 7.
3 A I have it.
4 Q Okay. And in Paragraph 20 you state,
5 that you quote:
6 "Understand as well that a prior art
7 reference should be viewed as a whole."
8 Do you see that?
9 A Yes.
10 Q And what do you understand that to mean?
11 A That if there is any prior art, I need
12 to understand every part of it. That it is
13 each part of the -- of what is written has to
14 be understood by me.
15 Q Okay. And do you understand that a
16 prior art reference must be considered for
17 all that it teaches and not just a preferred
18 embodiment?
19 MR. BRIGGS: Objection, form.
20 A Yes.
21 Q Okay. And you understand that a person
22 of ordinary skill in the art is a

1 hypothetical person that's presumed to have
2 known all of the relevant art at the time of
3 the invention, correct?
4 A I do.
5 Q Okay. And if you turn to Page 8 of your
6 '077 declaration, you have a series of
7 bullets.
8 A I see them.
9 Q Let's look to the second bullet here.
10 And you say, "When a device or technology is
11 available in one field of endeavor, design
12 incentives and market forces can prompt
13 variations of it, either in the same field or
14 in a different one."
15 Do you see that?
16 A I do.
17 Q And what do you understand that to mean?
18 A I understand this as if there is some
19 technology available in some area, that --
20 that there can be changes in that depending
21 upon what may be needed, what is stimulating
22 and triggering that, either in that field, in

1 which it was, or in a different field.
2 Q Is this like earlier when we were
3 talking about how the laser device that had
4 been previously used in other parts of the
5 body, like the ear, could be adapted for use
6 in the nose?
7 MR. BRIGGS: Objection to form.
8 A Yes.
9 Q Okay. And so you understand that just
10 because a prior art reference teaches
11 something in one field, it does not mean that
12 those teachings are limited to that field
13 alone?
14 A Yes.
15 Q Okay. And then if we go to the third
16 bullet on Page 8 of your '077 declaration.
17 Do you see that?
18 A I do.
19 Q And it says:
20 "If a technique has been used to
21 improve one device and a POSITA would
22 have recognized that it would improve

1 similar devices in the same way, using
2 the technique is obvious unless it's
3 actual application is beyond his or her
4 skill."
5 Do you see that?
6 A I do.
7 Q All right. And what do you understand
8 that to mean?
9 A That if we have a tool or device and we
10 make it better, change it, that -- that using
11 it would be -- if it improves it, using it
12 would be obvious.
13 Unless, it says, it's beyond the POSITA
14 skill or ability to determine that.
15 Q Okay. Let's turn to last sentence of
16 Paragraph 21 of your '077 declaration, which
17 goes across Pages 9 to 10.
18 A I see that.
19 Q Do you see that?
20 A I see that.
21 Q You see in the middle of that sentence
22 the term "in haec verba."

1 What does that mean?
2 A If my Latin is correct, "in these
3 words."
4 Q Okay.
5 A I think that's the correct translation I
6 used.
7 Q All right. Let's go to Paragraph 31 of
8 your declaration.
9 Okay. Do you see here where it says, "I
10 have been asked by counsel for The Foundry to
11 apply the 'plain and ordinary' meaning to the
12 terms in the challenged claims"?
13 A I see that.
14 Q How do you determine the "plain and
15 ordinary" meaning?
16 A I -- how do I determine that or how do I
17 interpret that?
18 Q Is there a difference?
19 A The way I interpret it, is that this
20 is -- should be clear, ordinary to any
21 individual who has the skill to understand
22 it.

1 Q And how would you go about analyzing
2 that?
3 A I would do that understanding what is
4 the background of the individual who's
5 reading and trying to interpret this, that
6 they would meet certain criteria, that they
7 could understand this, and understand what
8 are plain and simple terms, versus legal or
9 even engineering terms and could make some
10 comment about it.
11 Q And is that all?
12 MR. BRIGGS: Objection to form.
13 MR. NEMTZOW: I'll withdraw the
14 question.
15 Q How would you go about analyzing --
16 strike that.
17 Is there anything else that you would do
18 when analyzing what the plain and ordinary
19 meaning of a claim term is?
20 A No.
21 Q Let's do go to Section 3D of your '077
22 declaration, which begins at Paragraph 19 on

1 Page 7, and goes through the end of
2 Paragraph 20 on Page 9.
3 This explains your understanding of the
4 law of obviousness.
5 A Yes.
6 Q Okay. And I read through this, and
7 please correct me if I'm wrong, but I did not
8 see that you were informed about what a
9 reasonable expectation of success is, in this
10 section.
11 Do those word appear there?
12 A I don't see them.
13 Q Okay. And to be clear, you're not a
14 lawyer, are you?
15 A I am not.
16 Q Okay. So you have no independent basis
17 for an understanding of the law, outside of
18 what the lawyers in this matter have told
19 you?
20 A Yes. That is correct. I -- only what
21 I've been told.
22 Q And everything that the lawyers have

1 told you about the law is cataloged in
2 Paragraphs 16 through 21 of your declaration,
3 correct?
4 MR. BRIGGS: Objection to form.
5 A Yes.
6 Q What is your understanding of the
7 requirements to show that there would have
8 been reasonable expectation of success?
9 A Reasonable expectation of success for a
10 treatment? Or success for what? I'm not
11 understanding what you're asking me.
12 Q Sure. Let's go to Paragraph 99 of your
13 '077 declaration.
14 A I see that.
15 Q Okay. Do you see where it says, "I
16 understand the petitioner's assert a POSITA
17 would have a reasonable expectation of
18 success in using Makower's Figure 5H device
19 to treat targeted tissue in the nasal cavity
20 to treat rhinitis"?
21 A I see that.
22 Q And you disagree with that?

1 A I do disagree.
2 Q Okay. And what's your requirements to
3 show that there would have been a reasonable
4 expectation of success?
5 A Well, I go into detail as to why this
6 would not have been successful, but on a very
7 high level, would this device, as a person
8 with skill in the art, would I be able to
9 expect that it would function effectively and
10 safely, and I do not.
11 So I don't have that reasonable
12 expectation as it relates to the 5H device.
13 Q Do you know if the requirements for
14 reasonable expectation of success require
15 actual success?
16 A I don't know if it requires actual
17 success. I don't see where, in my
18 understanding reasonable success, that it has
19 to be actual success. To me there's a
20 difference between reasonable and actual.
21 Q Okay. All right. Let's turn to Page 20
22 of your '077 declaration.

1 A I have it.
2 Q Okay. And here, you're discussing the
3 nasal anatomy and physiology?
4 A Yes.
5 Q You cite specifically to Dr. Bu-Saba,
6 are you with me on that?
7 A I am.
8 Q Okay. And you say in Paragraph 41 that
9 you generally agree with him as relates to
10 his use of the Lane particle?
11 A Yes.
12 Q And you're aware of Dr. Bu-Saba's
13 credentials and experience?
14 A I am.
15 Q Okay. And you understand that he has
16 performed thousands of nasal procedures,
17 including RF ablation using the somnoplasty
18 device that we have discussed today,
19 including doing so before 2006?
20 A I know that from his declaration.
21 Q Okay. You don't dispute that he's an
22 expert on the anatomy of the nasal cavity and

1 the nasopharynx, do you?
2 A I do not.
3 Q I think we discussed this earlier
4 before, but have you read the '077 Patent
5 specification?
6 A Yes.
7 Q Okay. And have you read the
8 specifications of the other two Foundry
9 patent's in this matter?
10 A I have.
11 Q Okay. And those specifications contain
12 the same disclosure; is that right?
13 A Yes.
14 Q Okay. And so The Foundry patents
15 disclose using catheters; is that right?
16 A Yes.
17 Q Okay. And The Foundry patents actually
18 disclose using flexible catheters, correct?
19 A All right. Yes.
20 Q Okay. So the claimed invention of The
21 Foundry patents can be carried out using
22 flexible catheters?

1 A They state that they can.
2 Q Okay. The Foundry patents permit that
3 electroporation catheters were already known;
4 is that right?
5 A Yes.
6 Q Okay. And electroporation catheters can
7 have electrodes on them?
8 A Yes.
9 Q Okay. Flexible catheters can be used
10 with devices that have electrodes on them; is
11 that right?
12 A Yes.
13 Q A flexible catheter can be used with
14 electroporation devices?
15 A Yes.
16 Q And flexible catheters can be used with
17 ablation devices, correct?
18 A Yes.
19 Q Do The Foundry patents describe any
20 clinical trials that the inventors performed?
21 A I don't recall any.
22 Q Okay. Do you know what a single

1 variable trial is?
2 A I know of it. I couldn't go into the
3 details of what those criteria are.
4 Q Does a single variable trial involve a
5 trial where only one single variable is
6 varied between the control and test
7 populations?
8 A That's my understanding.
9 Q Okay. Do the patents describe any
10 single variable trials that the inventors
11 performed?
12 A I am not aware of that.
13 Q Do the patents disclose any single
14 variable trials performed by the inventors
15 where the single variable is the use of radio
16 frequence ablation?
17 A Not that I'm aware -- I recall.
18 Q Okay. I would like to take a look at
19 the '077 Patent, so if we can grab, I believe
20 it's Tab 7.
21 MR. NEMTZOW: And we're not going to
22 mark this as an exhibit.

1 Q Okay. I'm handing you a copy of
2 Exhibit 1001 from the '077 Patent IPR
3 reference.
4 Do you recognize this document?
5 A I do.
6 Q This is the '077 Patent we've been
7 talking about today?
8 A Yes.
9 Q If we can turn to the claims, which
10 begin on the very last page of Column 7.
11 A I see that.
12 Q Do the claims of the '077 Patent require
13 a particular level of treatment?
14 MR. BRIGGS: Objection to form.
15 A Can you clarify and help me with what
16 you mean when you say "level of treatment"?
17 Q Sure.
18 For example, if you look at the end of
19 the last limitation of Claim 1, it says, "And
20 thus, treat rhinitis."
21 A I see that.
22 Q Do the claims require a certain level of

1 treatment of rhinitis?
2 A Again, the use -- when you say level,
3 what do you mean by level, what does that
4 word mean in the question.
5 Q Would that word have meaning to you as a
6 practicing clinician?
7 A Would what word?
8 Q Level of treatment?
9 A I would interpret that word to mean
10 severity of treatment. I mean, severity of
11 the disease, severity of rhinitis.
12 Q Okay. Do the claims of the '077 Patent
13 require a particular amount of reduction in
14 the severity of rhinitis?
15 A They do not.
16 Q Do the claims require of the -- strike
17 that.
18 Do the claims of '077 patent require a
19 particular treatment outcome?
20 A They do not.
21 Q Okay. Actually, let's take a look at
22 the '011 Patent. I'm handing you

1 Exhibit 1001 from the '011 Patent IPR.
2 Do you recognize this document?
3 A I do.
4 Q All right. Let's turn to the claims of
5 the '011 Patent?
6 A I'm there, I see that.
7 Q Do the claims of the '011 Patent require
8 a particular treatment outcome?
9 A They do not.
10 Q If you look at the end of Claim 1, of
11 the '011 Patent, do you see where it says,
12 such that nasal congestion is reduced?
13 A I see that.
14 Q Do the claims of the '011 Patent require
15 a particular amount of reduction in nasal
16 congestion?
17 A They do not.
18 Q Do the claims of '011 Patent require a
19 particular degree of treatment outcome?
20 A They do not.
21 Q Okay. Let's look at Claim 23 of the
22 '011 Patent.

1 A I see that.
2 Q Okay. And if you look at the last
3 limitation again, here for Claim 23 it says,
4 such that nasal congestion is reduced?
5 A I see that.
6 Q Do the claims of the '011 Patent require
7 a particular amount of reduction in nasal
8 congestion?
9 A They do not.
10 Q And do you see before that in Claim 23
11 where it says, disrupt neural activity in the
12 target tissue?
13 A I do.
14 Q And do the claims of the '011 Patent
15 require a certain amount of disruption of
16 neural activity in target tissue?
17 A They do not.
18 Q Okay. If we look to Claim 1, again, in
19 the last limitation it says, alter
20 nasopharyngeal cells in the target tissue?
21 A I see that.
22 Q Did the claims of the '011 Patent

1 require a particular amount of alteration of
2 the nasopharyngeal cells in the target
3 tissue?
4 A They do not.
5 Q Do the claims of the '011 Patent require
6 a particular type of alteration of the cells
7 in the target tissue?
8 A They do not.
9 Q If you look at the preamble of Claim 1,
10 do you see where it says, by altering
11 function of a nasopharyngeal passage?
12 A Yes.
13 Q Do the claims require a particular
14 amount of alteration of a function of a
15 nasopharyngeal passage?
16 A They do not.
17 Q Does Claim 1 require that nasal
18 congestion is reduced?
19 A At the end of Claim 1 it says "such that
20 nasal congestion is reduced."
21 Q It doesn't require that a certain amount
22 of nasal congestion --

1 A Not a certain amount but that it is
2 reduced.
3 Q Okay. We can put the '011 Patent aside.
4 I'm going to hand to you the '675
5 Patent, which is Exhibit 1001 in the
6 '675 Patent IPR proceeding.
7 Are you familiar with this?
8 A I am.
9 Q Let's take a look at the claims, which
10 again are on the last page of the patent.
11 A I have it.
12 Q Okay. Do you see the preamble of
13 Claim 1?
14 A I do.
15 Q Do the claims of the '675 Patent require
16 treating a particular type of nasal
17 condition?
18 A I read this as reducing mucus secretion;
19 therefore, I understand this as a treatment
20 to reduce mucus secretion. That would be the
21 condition.
22 Q Okay. And you're getting that from the

1 second limitation?
2 A That is correct.
3 Q Okay. And so the second limitation says
4 "such that mucus secretion is reduced"?
5 A That is what I'm reading.
6 Q Do the claims of the '675 Patent require
7 a certain amount of reduction in mucus
8 secretion?
9 A It does not.
10 Q Okay. And before that it says, "so as
11 to disrupt neural activity"?
12 A Yes.
13 Q Do the claims require a certain amount
14 of disruption in neural activity?
15 A No.
16 Q Okay. And then in the last limitation
17 of Claim 1, it says "changing the temperature
18 of target tissue."
19 Do you see that?
20 A I do.
21 Q Do the claims require a particular
22 amount of temperature change in the target

1 tissue?
2 A They do not.
3 Q Okay. And before that it says,
4 "delivering energy to the target tissue"?
5 A Yes.
6 Q And do the claims of the '675 Patent
7 require delivering a certain amount of energy
8 to the target tissue?
9 A They do not.
10 Q If we go further up in the claim -- in
11 Claim 1 of the '675 Patent, do you see where
12 it says "target tissue in a nasopharyngeal
13 passage of a patient"?
14 A I see that.
15 Q Do the claims of the '675 Patent require
16 particular target tissue in a nasopharyngeal
17 passage of a patient?
18 A They do not.
19 Q If we go back to the last limitation of
20 the claim, do the claims require delivering
21 enough energy to the target tissue such that
22 neural activity is disrupted?

1 A I believe that it does.
2 Q Where do you get that from?
3 A Well, where it says that "administering
4 therapy to target tissue with the treatment
5 device so as to disrupt neural activity." To
6 disrupt neural activity, I will -- therefore,
7 I understand that there would have to be
8 enough energy for that to occur. It doesn't
9 tell me the amount, but it tells me that it
10 will occur. Therefore, an amount of energy
11 to cause that to happen is what I presume is
12 utilized.
13 Q Do The Foundry patents tell you how much
14 energy is enough to disrupt neural activity?
15 A They do not.
16 Q Okay. And you see where it says again
17 "delivering energy to the target tissue"?
18 A I do.
19 Q Do the claims require delivering enough
20 energy to the target tissue such that mucus
21 secretion is reduced?
22 A They do not.

1 Q Okay. Do The Foundry patents tell you
2 how much energy needs to be delivered in
3 order that mucus secretion is reduced?
4 A They do not.
5 Q Okay. Do the claims require that mucus
6 secretion is reduced?
7 MR. BRIGGS: Objection. Form.
8 A I believe they do.
9 Q Okay. But again, The Foundry patents do
10 not tell you how much energy needs to be
11 delivered such that mucus secretion is
12 reduced?
13 A Yes. That is correct.
14 Q Okay. And then you see again where it
15 says "changing the temperature of the target
16 tissue"?
17 A Yes.
18 Q Do The Foundry patents explain how much
19 of a temperature change is required to
20 disrupt neural activity?
21 A They do not.
22 Q Do The Foundry patents disclose how much

1 of a change of temperature is required to
2 reduce mucus secretion?
3 A They do not.
4 Q Okay. All right. Moving away from the
5 claims.
6 Do the patents define any efficacy
7 requirements for the treatment of rhinitis?
8 A Could you repeat the question, please?
9 Q Sure.
10 Do the patents define any -- pardon me.
11 Strike that.
12 Do the patents define any efficacy
13 requirements for the treatment of rhinitis?
14 A In the '077 Patent in the first claim,
15 it does say at the end that "radiofrequency
16 energy to multiple radiofrequency electrodes
17 to treat a target tissue in the nasal cavity,
18 thus treat rhinitis." That to me implies
19 efficacy that rhinitis is being treated, so I
20 would say yes, efficacy is stated there.
21 Q I understand that you believe that
22 efficacy is stated, but my question was: do

1 the patents define any efficacy requirements
2 for the treatment?
3 A They do not. They do not.
4 Q Okay. So they don't define any efficacy
5 requirements for the treatment of rhinitis?
6 A Not any parameters or requirements but
7 that it is treated.
8 Q Okay. Do the patents define what
9 efficacy requirements are for reducing mucus
10 production?
11 A They do not.
12 Q Okay. Do the patents define how to
13 measure a reduction in mucus production?
14 A They do not.
15 Q Okay. Do the patents define the
16 efficacy requirements for reducing
17 congestion?
18 A They do not.
19 Q And do the patents define how to measure
20 a reduction in congestion?
21 A They do not.
22 Q Do the patents describe any results from

1 experiments performed by the named inventors?
2 A They do not.
3 Q Okay. Do the patents provide any data
4 regarding the use of irreversible
5 electroporation energy without the use of
6 neurotoxins?
7 A They do not.
8 Q Okay. We can put -- strike that.
9 All right. We can put the patents
10 aside.
11 Let's take a look at your '011
12 declaration. Let me know when you have that
13 in front of you. And let's go to Page 58.
14 A I have that.
15 Q Okay. And do you see Paragraph 108
16 there?
17 A I do.
18 Q Above Paragraph 108 you reproduced a
19 figure from Imran as annotated by
20 Dr. Bu-Saba?
21 A I see that.
22 Q And Dr. Bu-Saba is Petitioner's expert

1 witness?
2 A Yes.
3 Q Okay. And you say here that the
4 electrodes in red in this figure don't
5 deliver energy laterally; is that correct?
6 A I say that.
7 Q Okay. And you don't think that Imran's
8 electrodes deliver energy laterally because
9 they are not surrounded by an insulating
10 material?
11 A I say that.
12 Q Okay. You said you say that; is that
13 your opinion?
14 A I agree with that sentence.
15 Q You agree that the electrodes in Imran
16 do not deliver energy laterally because they
17 are not surrounded by an insulating material?
18 A Well, they deliver energy laterally.
19 They also deliver energy in multiple
20 directions. And I do go ahead and state that
21 later, later on. So in 108 it is -- I agree
22 and it is accurate that they deliver some

1 energy laterally. But the question is how
2 much, if at all, and how much is delivered in
3 other directions. And I cannot say that
4 other than it's delivered in multiple
5 directions.
6 Q Okay.
7 A That I can understand and presume, as
8 someone who understands this information.
9 Q And in your view Imran's electrodes
10 don't teach delivering energy laterally
11 because of the way in which those electrodes
12 extend laterally from the distal portion of
13 the device?
14 A It's because they --
15 MR. BRIGGS: Objection. Form.
16 A It's really how they are positioned and
17 not insulated that would cause them to
18 deliver energy in multiple directions.
19 Q Okay. And you can tell they're not
20 insulated because they extend laterally from
21 the distal portion of the device?
22 A That is correct.

1 MR. BRIGGS: Objection. Form.
2 A That is correct.
3 Q Okay. And so in your opinion, Imran's
4 electrodes do not deliver energy laterally
5 because they extend laterally from the distal
6 portion of the device?
7 MR. BRIGGS: Objection. Form.
8 A Yes. That is correct.
9 Q Okay. Let's go to the chart -- I think
10 you were already looking at it -- on Page 60
11 of your declaration.
12 A Yes.
13 Q And in this chart you're comparing
14 Figure 5A from The Foundry patents to
15 Figure 1 from Imran; is that right?
16 A I am.
17 Q You believe that Figure 5A from The
18 Foundry patents does deliver energy
19 laterally, correct?
20 A I do.
21 Q And that's based on your understanding
22 of the field lines shown in Figure 5A?

1 A It's my understanding that an electrode
2 that is positioned that way and insulated
3 will cause those kinds of field lines;
4 therefore, the energy is delivered in that
5 direction.
6 Q Okay. And so you agree that the field
7 lines shown in The Foundry patents are
8 correct?
9 A Yes.
10 Q In you can pick up the '011 Patent
11 again, which is Exhibit 1001 in the
12 '011 Patent IPR.
13 A I have it.
14 Q And let's take a look at Figure 5B.
15 A I see that.
16 Q And again, you believe that Figure 5A
17 shows a device delivering energy laterally;
18 is that correct?
19 A Yes.
20 Q Do you believe that Figure 5B shows a
21 device delivering energy laterally?
22 A Could you ask that again, please?

1 Q Sure.
2 Do you believe that Figure 5B shows a
3 device that delivers energy laterally?
4 A Yes.
5 Could I take a look at where I describe
6 this in my declaration, please, before I
7 answer "yes." I'd like to look at the detail
8 of that before I answer that.
9 Q I believe you discuss Figure 5B on
10 Page 57 of your declaration.
11 A Let me take a look at that first before
12 I respond.
13 And this is where in my declaration I
14 describe that energy delivery, and that's why
15 I wanted to retract by saying it delivered it
16 laterally, in which I talk about how 5B
17 delivers really -- described uniformly around
18 that field.
19 Q So is it your opinion that Figure 5B
20 does not deliver energy laterally?
21 A So from what I can see and understand
22 from this, it's delivering it uniformly

1 around that surface.
2 Q I understand, but my question was: is it
3 your opinion that Figure 5B does not deliver
4 energy laterally.
5 A The information that I got -- and I
6 comment on this -- came from Professor
7 Bikson, who is an electrical engineer, and
8 that it was he who helped me understand and
9 differentiate this. And it's my
10 understanding that there was the -- it is
11 different for the energy to be delivered
12 uniformly around that space versus directly
13 laterally.
14 Q Let's go to Paragraph 104 of your
15 declaration.
16 A Yes.
17 Q And you see here where you discuss how
18 Figure 5B shows a device constructed to
19 create a more uniform electrical field about
20 the shaft of the catheter body?
21 A Yes.
22 Q And then the following sentence it says,

1 "I confirmed this opinion" --
2 A Correct.
3 Q -- "with Dr. Bikson"?
4 A Yes.
5 Q Okay. It does not say here that you got
6 your opinion from Dr. Bikson, does it?
7 A That is correct.
8 Q Okay. It doesn't say here that you got
9 your understanding of Figure 5B from
10 Dr. Bikson?
11 A I needed to confirm it, meaning I looked
12 at this and saw that there was a difference,
13 and I assumed that there -- that one was
14 direct lateral, the other one was more
15 uniform and circumferential. I asked that of
16 Dr. Bikson. He explained that to me and
17 validated my thinking.
18 Q Okay. And so looking at Figure 5B,
19 based on your review of The Foundry patents
20 and your discussion with Dr. Bikson, can you
21 tell me whether or not Figure 5B delivers
22 energy laterally?

1 A It may deliver it laterally, but it's
2 delivering it uniformly around a more
3 circumferential area versus one direction
4 directly laterally.
5 Q Figure 5B delivers energy laterally and
6 uniformly, correct?
7 A Yes.
8 Q Okay. All right. Is Figure 5B operable
9 to deliver energy to tissue?
10 A I don't know enough about 5B to respond
11 to that. I want to review and look back at
12 the patent and see that description of that.
13 Q Of course. I can point you to where
14 that is.
15 I believe in the '011 Patent it shows up
16 about midway through Column 16. And, just
17 for the record, are you looking at the '011
18 Patent?
19 A I'm at the '011 Patent.
20 Q Column 16, Line 30, discusses both
21 Figures 5A and 5B, and then 5B is again
22 discussed at approximately Line 56. And just

1 before we continue, I'll restate the
2 question.
3 A Thank you.
4 Q Is Figure 5B operable to deliver energy
5 to tissue?
6 A According to this description, yes.
7 Q Do you have any reason to doubt that
8 description?
9 A No.
10 Q And Figure 5B shows ring electrodes; is
11 that correct?
12 A Yes.
13 Q You've just reviewed the description of
14 Figure 5B in the '011 Patent; is that right?
15 A I have.
16 Q Does the '011 Patent disclose that there
17 are any challenges with applying energy to
18 nasal tissue using the device in Figure 5B?
19 A It does not.
20 Q Is Figure 5B within the scope of the
21 '011 Patent claims?
22 A Yes.

1 Q Okay. Is Figure 5B within the scope of
2 the '077 Patent claims?
3 A Yes.
4 Q Okay. Is Figure 5B within the scope of
5 the '675 Patent claims?
6 A Yes.
7 Q Okay.
8 MR. NEMTZOW: I think now would be a
9 good time for a break. Thanks.
10 TECHNICIAN: Go off the record.
11 (Whereupon, a recess was taken
12 from 1:33 PM until 1:47 PM.)
13 Q Dr. Levine, did you speak with counsel
14 during the break?
15 A I did not.
16 Q You did not. Okay.
17 I'd like to return to the topic of
18 electroporation. All right?
19 A Okay.
20 Q Have you performed any medical
21 procedures that involved electroporation?
22 A I have not.

1 Q You haven't identified any example of
2 anybody using irreversible electroporation
3 alone to destroy tissue to achieve a
4 therapeutic result before The Foundry
5 patents, have you?
6 A I have not.
7 Q You would agree with me that the role of
8 nerve cells in mucus production causing
9 rhinitis symptoms was known before The
10 Foundry patents?
11 MR. BRIGGS: Objection, form.
12 A Yes.
13 Q Are you familiar with Dr. Ira Sanders?
14 A No.
15 Q Let's take the '077 Patent out.
16 Do you have that there?
17 A I have it.
18 Q Let's go to Column 3. Starting at
19 line 31.
20 A Okay.
21 Q If you go down a little bit further in
22 that paragraph. It says:

1 "Dr. Ira Sanders has demonstrated
2 that introduction of an intact
3 botulinum toxin molecule enter the
4 nasal passage of canines can reduce
5 mucus secretion by a significant
6 amount."
7 Do you see that?
8 A I do.
9 Q And did you read this in preparing for
10 your declaration?
11 A I did.
12 Q Does this refresh your recollection as
13 to the work of Dr. Ira Sanders?
14 A I was familiar with his work. When you
15 ask was I familiar with him, I thought -- I
16 misinterpreted what you said in that
17 question.
18 Q I see. Were you thinking that I was
19 meaning do you know Dr. Ira Sanders?
20 A Exactly.
21 Q Okay. But you are familiar with his
22 work?

1 A I am.
2 Q And that includes the work described
3 here in the '077 Patent?
4 A I am.
5 Q And so Dr. Sanders had already used
6 neurotoxin in the nose to reduce mucus
7 secretion before the Foundry patents?
8 A Yes.
9 Q Were you familiar with his work before
10 your retention for this case?
11 A I was.
12 Q So Dr. Sanders had already used
13 neurotoxin in the nose to treat rhinitis
14 before The Foundry patents?
15 A Yes.
16 Q All right. And the effect of disabling
17 nerve cells on rhinitis was already known
18 before The Foundry patents?
19 A Yes.
20 Q You can put that down.
21 All right. I'd like to return just
22 briefly to your experience with Acclarent.

1 Do you have that in mind?
2 A Uh-hmm.
3 Q I know we talked about it a lot.
4 We were mentioning the balloon
5 somnoplasty device that Acclarent sold,
6 right?
7 MR. BRIGGS: Objection, form.
8 A Yes.
9 Q That balloon somnoplasty device was used
10 in the nose?
11 A Yes.
12 Q And that balloon somnoplasty device was
13 developed based on technology from other
14 endoscopic device and balloon catheters; is
15 that right?
16 MR. BRIGGS: Objection, form.
17 A Yes.
18 Q And those other devices included devices
19 that were used outside of the nose?
20 A Yes.
21 Q Okay. Would you agree that biomedical
22 engineers are highly educated people?

1 MR. BRIGGS: Objection, form.
2 A I'm not sure I could comment on that. I
3 respect them, I respect what they do and
4 their education.
5 Q Fair enough.
6 Do you agree that biomedical engineers
7 can hone their expertise by querying surgeons
8 about the problems encountered while using
9 surgical tools?
10 MR. BRIGGS: Objection, form.
11 A Yes.
12 Q Do you agree that it's the job of a
13 biomedical engineer to take in information
14 from clinicians?
15 MR. BRIGGS: Objection, form.
16 A Repeat how you asked that, please.
17 Q Sure. Yeah. I can repeat the question.
18 Do you agree that it's the job of a
19 biomedical engineer to take in information
20 from clinicians?
21 MR. BRIGGS: Objection, form.
22 A I don't know how you'd say it's their

1 job. I think it could be helpful to the
2 clinician, it can be helpful to the creation
3 of a device, it can helpful to what they're
4 trying to achieve. I don't know if I'd say
5 that is their job.
6 Q Do you think it's part of a biomedical
7 engineer's job to take in information from
8 clinicians?
9 MR. BRIGGS: Objection, form.
10 A If in fact, what they're trying to do is
11 create a medical device, yes.
12 Q Do you agree that it's the job of a
13 medical engineer -- strike that.
14 Do you agree that it's the job of a
15 biomedical device engineer to take in
16 information from clinicians?
17 MR. BRIGGS: Objection, form.
18 A Yes.
19 Q Okay. And do you agree that it's the
20 job of a biomedical engineer, working on a
21 medical device, to take in information from
22 clinicians to create better tools?

1 MR. BRIGGS: Objection, form.
2 A Yes.
3 Q Okay. All right. Returning back to the
4 Acclarent balloon somnoplasty device just for
5 a brief moment.
6 That device operates by exerting
7 physical pressure on tissue?
8 MR. BRIGGS: Objection, form.
9 A Yes.
10 Q And Acclarent didn't sell radio
11 frequency ablation devices when you were
12 working there?
13 MR. BRIGGS: Objection, form.
14 A They did not.
15 Q They didn't sell electroporation devices
16 when you were working there?
17 MR. BRIGGS: Objection, form.
18 A They did not.
19 Q They didn't sell devices that were in
20 conjunction with neurotoxins?
21 MR. BRIGGS: Objection, form.
22 A Did not.

1 Q The Acclarent company didn't sell
2 devices that treated nerve tissue, did they?
3 MR. BRIGGS: Objection, form.
4 A Did not.
5 Q Okay.
6 MR. NEMTZOW: And I think we'll just
7 need a quick five-minute break. Be
8 right back.
9 (Whereupon, a recess was taken
10 from 1:55 PM until 2:00 PM.)
11 MR. NEMTZOW: Pass the witness.
12 MR. BRIGGS: We have no questions.
13 MR. NEMTZOW: Okay.
14 COURT REPORTER: Do you want a rough
15 today?
16 MR. NEMTZOW: Monday for the final.
17 (Whereupon, this examination was
18 concluded at 2:00 PM)
19
20 DR. HOWARD LEVINE
21
22

1 Subscribed and sworn to
before me on this ____ day
2 of _____, _____.
3
4 _____
Notary Public
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1 I N D E X

2 WITNESS: DR. HOWARD LEVINE

3 EXAMINATION BY PAGE

4 NEMTZOW 4

5

6 E X H I B I T S

7 LEVINE DESCRIPTION PAGE

8 Exhibit 1 Printout from Openpaymentsdata.cms 23
9 .gov

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1 C E R T I F I C A T E
2
3 I, KIARA MILLER,, Certified Reporter,
4 do hereby certify:
5 That DR. HOWARD LEVINE, the witness whose
6 deposition is hereinbefore set forth, was duly
7 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 such
10 witness.
11 I further certify that the adverse party,
12 PATENT OWNER, was represented by counsel at the
13 deposition.
14 I further certify that the deposition of
15 DR. HOWARD LEVINE occurred at the offices of
16 GREENBERG TRAURIG, One Vanderbilt Avenue, New York,
17 NY, on Thursday, January, 9, 2025, commencing at
18 9:00 AM to 2:00 PM.
19
20
21
22

1 I further certify that I am not related to
2 any of the parties to this action by blood or
3 marriage, I am not employed by or an attorney to any
4 of the parties to this action, and that I am in no way
5 interested, financially or otherwise, in the outcome
6 of this matter.
7
8 Kiara Miller
9 _____
10 KIARA MILLER
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A
a-n-a-i-s 26:1
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