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Transcript of Nicolas Bu-Saba, M.D.

Date: October 17, 2024

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

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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

-----X

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

Petitioners,

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

-against-

THE FOUNDRY, LLC,

Patent Owner.

-----X

DEPOSITION OF

DR. NICOLAS BU-SABA

BOSTON, MASSACHUSETTS

October 17, 2024

REPORTED BY: KIARA MILLER

FILE NO.: 557128

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2 BEFORE THE PATENT TRIAL AND APPEAL BOARD

3 -----X

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

6 Petitioners,

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

8 -against-

9 THE FOUNDRY, LLC,

10 Patent Owner.

11 -----X

12
13
14 Deposition of DR. NICOLAS BU-SABA, taken on
15 behalf of PATENT OWNER, at 60 State Street,
16 Boston, Massachusetts, commencing at 9:03 AM,
17 October 17, 2024, before Kiara Miller.
18
19
20
21
22

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

2
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10 BY: JOSHUA L. STERN, ESQ.

11 GILBERT SMOLENSKI, ESQ.

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18
19 BY: HEATH BRIGGS, ESQ.

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

5 EXAMINATION BY

6 MR. BRIGGS:

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

9 A Yes.

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

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

18 Q Okay. Thank you. That is helpful.

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

1 Do you understand that?

2 A Yes, I do.

3 Q Okay. I see your attorneys are here.

4 Do these folks represent you?

5 A They represent, yes.

6 Q Okay. Can you state your full name for
7 the record?

8 A Nicolas Bu-Saba, Nicolas Youssef
9 Bu-Saba.

10 Q Can you spell the Nicolas portion for
11 us, please?

12 A N-I-C-O-L-A-S.

13 Q And you understand you're here in
14 connection with a deposition in relation to
15 three proceedings before the US Patent and
16 Trademark Office; is that right?

17 A Yes.

18 Q Okay. And have you been deposed before?

19 A Yes.

20 Q How many times have you been deposed?

21 A I can't recall the numbers of times, but
22 I've been deposed before.

1 Q More than five?

2 A I can't recall the number, so I don't
3 want to give you an inaccurate number.

4 Q I'm just trying to figure out how many
5 ground rules I need to give you since if
6 you've been deposed a lot, I'm going to do a
7 lot less ground rules; if you've been deposed
8 a little, I'm going to give you way more
9 ground rules.

10 A Again, I am guessing, but my guess is --
11 I shouldn't guess, but it is more than five.

12 Q More than five.

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

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

22 Do you understand that?

1 A Yes, I do.

2 Q Okay. So going back onto the three
3 proceedings before the US Patent and
4 Trademark Office, those three proceedings,
5 for the record, are known as IPR 2024-00279,
6 IPR 2024-00280 and IPR 2024-00669, okay?

7 A I see 0281. I don't see --

8 Q Do you want to talk about that for a
9 minute? So what happened is the 00281 IPR
10 appears to have been terminated in view of
11 the 00669.

12 Is that your understanding?

13 A I don't know the numbers exactly. All I
14 know is that the number in front of me says
15 00281.

16 Q So what I'm going to hand you right now
17 is your declaration, Nicolas Bu-Saba, it's
18 Exhibit 1083 in IPR 2024-0669.

19 Do you see that?

20 A Okay.

21 Q If you could just read through that,
22 please.

1 A Okay.

2 Q So if you could look at Paragraph 3 of
3 Exhibit 1083 from IPR 2024-0669 and just
4 confirm that you say, "I execute a
5 declaration that became Exhibit 1002 in
6 IPR 2024-00281."

7 Do you see that?

8 A I confirm that.

9 Q Okay. So the reason you're looking at
10 00281 is because that is the main declaration
11 that you submitted in that case and you're
12 resubmitting it in this case.

13 Is that your understanding?

14 A It is my understanding, yes.

15 (Whereupon, U.S. Patent No.
16 10,894,011 was marked as Exhibit
17 1001 for identification as of
18 this date.)

19 Q Okay. So the reason we're talking about
20 IPR 2024-00669 instead of IPR-00281 is
21 because the 00281 was canceled, but your
22 declaration was reused in the 00669.

1 Do you understand that?

2 A I do.

3 Q Okay. So you say you've been deposed,
4 but you don't know how many times, correct?

5 A That's correct.

6 Q And you've been deposed in the last
7 five years?

8 A Yes.

9 Q In connection with what cases?

10 A It was one personal injury case, and the
11 other one was -- my understanding was about
12 also personal injury pertaining to someone's
13 exposure. It was, like, multiple plaintiffs
14 in multiple states.

15 Q So if I understand you correctly, that
16 testimony was in connection with personal
17 injury proceedings, correct?

18 A Correct.

19 Q So in the last five years, have you had
20 any testimony outside of personal injury
21 proceedings?

22 A The personal injury proceeding was

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

6 Q I understand.

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

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

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

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

19 Is that a fair characterization?

20 A Yes.

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

1 A I have not.

2 Q Okay. So this is your first patent
3 case?

4 A That's correct.

5 Q Okay. So I see -- how many documents do
6 you have in front of you there?

7 A I -- you gave me one document. Besides
8 that document, I had four.

9 Q So is the bottom one the same as the one
10 I gave you?

11 A Yes.

12 Q Okay. So we can put that one aside.
13 We're not going to use that one anymore.

14 A Which one? This one?

15 Q Both of them 'cause they're identical.
16 That's just to confirm that your testimony in
17 the 00281 is being reused in the 00669, okay?

18 A Okay.

19 Q So then you have three other bound
20 documents in front of you, for the record,
21 What are those?

22 A These are the declarations, the three

1 declarations that I made pertaining to this
2 case.

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

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

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

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

12 Q Great.

13 A The second one is IPR 2024-00280.

14 Q Great.

15 A And the third one is IPR 2024-00281.

16 Q Okay. Thank you.

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

21 A Yes.

22 Q Okay. Are those clean copies of those

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

5 A That's correct.

6 Q Okay. So completely clean copies, okay.

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

11 A Yes.

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

14 A That's correct.

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

17 A That's correct.

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

20 A That's correct.

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

1 correct?

2 A That's correct.

3 Q So did you authorize counsel to
4 electronically sign this for you?

5 A Yes, I did.

6 Q Okay. So you understand this to be --
7 the document that's in front of you to be the
8 true and correct copy of your declaration in
9 IPR 2024-00279, correct?

10 A I do.

11 Q Okay. Let's do that same thing with
12 your other two. Can you please go to the
13 signature page?

14 A It looks like Page 158, so we're talking
15 about 00280.

16 Q Okay.

17 A Page 158.

18 Q So, again, we see the electronic
19 signature with the date of January 17, 2024,
20 correct?

21 A That's correct.

22 Q And so, again, you believe this to be

1 the true and correct copy of your declaration
2 from the IPR 2024-00280, correct?

3 A That's correct.

4 Q Okay. One more time. IPR 2024-00281,
5 please go to the signature page, Page 167.

6 A I am on that page.

7 Q Okay. So, again, I see in my copy a
8 date of January 17, 2024, electronic
9 signature of Nicolas Bu-Saba.

10 Do you see the same thing?

11 A I do.

12 Q Okay. So you, again, believe this to be
13 the true and correct copy of the declaration
14 you submitted in IPR 2024-00281, correct?

15 A That's correct.

16 Q Great.

17 So since you've been deposed before, you
18 know how this works. One thing I failed to
19 mention is that I typically take a break
20 about every 60 minutes.

21 Is that okay with you?

22 A That's okay with me.

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

5 Does that work for you?

6 A Yes.

7 Q Okay. Great.

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

11 Do you understand that?

12 A I do.

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

16 A Okay.

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

20 A That's correct.

21 Q Is there any reason you cannot testify
22 truthfully today?

1 A Not that I can think of.

2 Q You're not on any medications or
3 anything that would impair your testimony
4 today?

5 A That's correct. I'm not on medications
6 that would impair my testimony today.

7 Q Okay. Great.

8 Did you prepare for today's deposition?

9 A I did.

10 Q Okay. How so?

11 MR. STERN: You can answer the
12 question, but please just don't reveal
13 the content of any communications with
14 attorneys.

15 A I reviewed my three declarations. I
16 reviewed some of the prior art. I met with
17 counsel yesterday.

18 Q When you say "some of the prior art,"
19 what do you mean by that?

20 A The prior art which I cited in my
21 declaration.

22 Q But some, not all?

1 A I can't recall whether I looked at every
2 single one because this has been one year,
3 but I looked at things that are most relevant
4 or very relevant to my declarations.

5 Q Can you give me an example of one that
6 you thought was particularly relevant?

7 A I looked at Makower's. I looked at
8 Saadat. I looked at Fang. These are as far
9 as the prior art.

10 Q Okay. So if -- so you said "Makower."
11 So if I say "Makower" today, you'll know that
12 I'm referring to Exhibit 1005 across all
13 three IPR proceedings, correct?

14 A I don't recall the exact exhibit number,
15 but if this is where Makower is, then yes.

16 Q Let's just work off IPR 2024-00279 for
17 now, okay?

18 A Okay.

19 Q And let's go to the list of exhibits,
20 and that is on Page 181 of that declaration.
21 And do you see 1005?

22 A 1005, I see that.

1 Q And do you see the last name Makower?

2 A I see that.

3 Q So Makower, according to your appendix,
4 is Exhibit 1005, okay?

5 A Okay.

6 Q So then we go down one below because
7 we're going to be talking about Fang as well.
8 So we see 1006, and then there's a big, long
9 citation but then at the end of it, it says
10 "(Fang) ."

11 Do you see that?

12 A I see that.

13 Q So if we talk about "Fang" today, we're
14 going to be talking about 1006, correct?

15 A Correct.

16 Q And these same exhibits are the same
17 numbers across all three IPRs, I will
18 represent to you, okay?

19 A Okay.

20 Q And you also "Saadat," so Saadat is
21 Exhibit 1003. Do you see that?

22 A I see that.

1 Q Okay. So if at any time today you need
2 to refer to your appendix to understand what
3 documents we're talking about, please feel
4 free to do so, okay?

5 A Okay.

6 Q So you prepared yesterday with counsel.
7 Was anybody else present at that meeting
8 besides counsel?

9 A It was only counsel.

10 Q Counsel and you?

11 A Yes.

12 Q No outside parties?

13 A No outside party.

14 Q Did you prepare for your deposition
15 today with anybody else besides counsel?

16 A I did not.

17 Q Did you talk to anybody else about your
18 deposition today besides counsel?

19 A I did not.

20 Q Okay. Since you submitted the three
21 declarations in these IPR proceedings, have
22 your opinions changed related to any of those

1 declarations?

2 A They have not.

3 Q Okay. Is there any typographical errors
4 that you found that you would like to
5 correct?

6 A There were a few typographical errors,
7 but I don't remember them now. They're not
8 material. They wouldn't change the opinions
9 listed in these declarations, but I cannot
10 sit here and recite them. There were few
11 typographical errors.

12 Q Okay. How about this, as we're going
13 through today, if you see one, can you please
14 note it for the record, so we can make sure
15 we have a clean understanding of what your
16 opinions are?

17 A I would.

18 Q Thank you.

19 So I looked through your three
20 declaration. It seems to me that you have
21 many similar sections across the three.

22 Would you agree?

1 A I agree.

2 Q So for instance, I think the
3 introduction section, generally, matches
4 across all three IPR declarations.

5 Would you agree?

6 A I have to pull up the introduction
7 section just to be sure.

8 Q Sure. Take your time.

9 A I will give you a complete and accurate
10 answer.

11 Yes. It looks like it.

12 Q Great. Can you do that same exercise
13 for Qualifications and Experience, under
14 Section 2, and confirm for me that those
15 section are generally the same?

16 A They look the same.

17 Q And then in the Materials Considered
18 section, Section 3, can you do that same
19 exercise and confirm that those sections
20 across all three IPRs are basically the same.

21 A Page 11.

22 I looks like there is some more stuff

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

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

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

11 A It looks like, also, in Declarations
12 00281, I -- there is one more sentence
13 saying, "I have also relied on a conversation
14 with Dr. Gregory Martin and have reviewed his
15 declaration for this IPR." And then I list
16 Exhibit 1007.

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

19 Q Sure. Take your time?

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

1 considered that is not listed in the other
2 two.

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

6 A Correct.

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

11 Correct?

12 A That's correct.

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

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

17 Q And that's because you relied on a
18 conversation with Dr. Gregory Martin in the
19 0281, but not in 00279 or 00280, correct?

20 A That's correct.

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

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

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

11 MR. STERN: Objection to form.

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

15 Q So you felt the need talk to him in
16 00281 but you did not feel the need to talk
17 to him in 0279 and 0280?

18 MR. STERN: Objection to form.

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

1 0279 and 00280.

2 Q Oh, I understand that. But the question
3 is why?

4 MR. STERN: Objection to form.

5 A As I said, it was not there. I did not
6 feel the need to include it in my
7 declaration. When I formulated my
8 declaration and opinions and I reviewed the
9 prior art and reviewed the patents, I did not
10 feel the need to include his testimony when I
11 formulated my opinions and I wrote my
12 declaration.

13 Q Okay. We'll probably come back to this
14 later when we dug more into the references
15 and understand more what the claims are
16 saying, okay?

17 A Okay.

18 Q Okay. So just to continue on with
19 making sure that I understand that there's
20 really not many material differences, if any,
21 across several sections of your three
22 declarations.

1 Can you please look at Section 4 of your
2 declarations.

3 I'm sorry.

4 A Section 4 is material.

5 Q Yeah, sorry. I have the wrong thing.

6 So Section 5, my bad.

7 A Okay.

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

10 A That's correct.

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

16 A The last paragraph of this is different
17 in each of one of them. Each one references
18 different patent. So I -- if you look at
19 Paragraph 30, for instance, in Declaration
20 00280, the last paragraph, it is -- it
21 references the '011 Patent. While
22 Paragraph 30 in 00281 references the '077

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

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

7 Outside of that, is the text generally
8 the same?

9 A Yes.

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

13 A I do.

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

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

18 Q It's on the front page.

19 A US Patent 10,610,675.

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

22 If I say the '011 Patent, you will know

1 I mean US Patent No. 10,894,011?

2 A 10,894,011.

3 Q Okay. And then one more.

4 If I say the '077 Patent today, you will
5 understand I mean US Patent No. 11,679,077?

6 A That's correct.

7 Q Okay. Great.

8 Two more sections. If you could,
9 please, look at the overview of technology
10 section across the three.

11 This is a little bit longer, so take
12 your time and just confirm for me that they
13 are generally the same?

14 A Without the benefit of being able to
15 read them word for word, they look the same.

16 Q Okay. I'll represent to you that we've
17 done an analysis, a computerized analysis and
18 they appear to be generally the same to us as
19 well, so thank you.

20 Last one. There's a section in your
21 declaration called Claim Construction.

22 Can you just read through and confirm

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

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

7 Q Great thank you.

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

10 A That's correct.

11 Q How did you prepare these declarations?

12 A I reviewed the claims in question, or of
13 concern. I reviewed the patents. I reviewed
14 the prior art. I relied on my experience as
15 a person with ordinary skill in the art. I
16 formulated my opinion. I discussed my
17 findings with counsel. And I formulated the
18 declarations.

19 Q Did you create the first draft of the
20 declarations?

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

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

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

11 A I did not.

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

16 A That's correct.

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

20 A I got it.

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

1 Medical Inc." and "Neurent Medical Limited."

2 Do you see that?

3 A I see that.

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

8 A I do.

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

11 MR. STERN: Objection to form.

12 Q Do you know those companies?

13 A I know of the companies.

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

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

19 Q Fair enough.

20 How do you know of Neurent Medical?

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

1 Q So what do you know about them?

2 A I know they're in the field of
3 otolaryngology.

4 Q That's it?

5 A Yes.

6 Q You never worked with a Neurent device?

7 A I have not.

8 Q Do you know any people who work for
9 Neurent?

10 A I don't.

11 Q Okay. So you've never spoken with
12 anybody at Neurent?

13 A I have not.

14 Q And if we go down underneath that we see
15 patent owner is "The Foundry LLC."

16 Do you see that?

17 A I see that.

18 Q Do you know of that company?

19 A I only came to know about it when I was
20 involved in this case.

21 Q So you learned about The Foundry through
22 working on this case?

1 A That's correct.

2 Q So you did not know about The Foundry
3 before you were engaged to work on this case?

4 A I did not.

5 Q Do you know the company Aerin Medical,
6 A-E-R-I-N?

7 A I know of the company.

8 Q How do you know them?

9 A Also because they're in the field of
10 otolaryngology.

11 Q Do you know anybody who works at Aerin
12 Medical?

13 A I do not.

14 Q Okay. Have you worked with any Aerin
15 Medical devices?

16 A I have not.

17 Q Okay. If you can please go to
18 Paragraph 3 of the 0279 Declaration.

19 If you could just read that and let me
20 know when you're finished.

21 A You said Paragraph 3?

22 Q Yes.

1 A Yeah.

2 Q So you're finished?

3 A Yes.

4 Q Thank you.

5 So it says here:

6 "My curriculum vitae, which
7 describes my education experience,
8 professional activities, and lists,
9 among other things, my publications and
10 patents is attached as Appendix A."

11 Do you see that?

12 A I see that.

13 Q Can you go to Appendix A please. So
14 that's on Page 145, I believe; is that
15 correct?

16 A 146 -- I mean, it starts -- my CV starts
17 at 146.

18 Q That's right.

19 Can you point me to the patents in your
20 curriculum vitae?

21 A There are no patents in my curriculum.

22 Q Okay. So is there a typo, then, in

1 Paragraph 3 of you declaration?

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

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

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

11 MR. STERN: Objection to form.

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

15 Q So do you consider this a mistake or
16 not?

17 MR. STERN: Objection to form.

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

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

3 MR. STERN: Objection.

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

9 MR. STERN: Is there a question?

10 MR. BRIGGS: No.

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

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

16 MR. STERN: Objection to form.

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

20 Q Okay. So on Page 146 of your CV.

21 Do you see that, first page?

22 A Yes.

1 Q It says, "Date prepared, October
2 22, 2023"?

3 A Yes.

4 Q Are there any updates that you would
5 like to make to your CV at this time?

6 A There were -- I was an invited lecturer
7 for several meetings between then and now,
8 but I don't believe the talks I gave would
9 change my opinions. But I do have a more
10 updated CV because I keep updating my CV
11 regularly. And, as I said, it includes
12 invited lectures and national and
13 international meetings.

14 Q Is it fair to say there's nothing
15 material missing from your CV as it relates
16 to these three IPR proceedings?

17 A That's correct.

18 Q Okay. So below your name it says
19 "Office address."

20 Do you see that?

21 A Yes.

22 Q What company or university is that?

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

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

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

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

22 A Correct.

1 Q Okay. Sorry.

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

5 A That's correct.

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

8 A That's correct.

9 Q Those were both in Beirut?

10 A That's correct.

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

15 A Do I read the whole paragraph?

16 Q Yes. Please.

17 A Okay.

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

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

1 Do you see that?

2 A I see that.

3 Q Can you explain what that is, please.

4 A So this was a treatment for snoring and
5 sometimes people with mild sleep apnea.
6 Basically, it aims stiffening the soft palate
7 by ablating the submucosa tissue, which would
8 make the soft palate shrink and stiff, using
9 RF, radio frequency. This is done under
10 local anesthesia typically. Typically done
11 in the office.

12 Q What's the soft palate?

13 A The roof of the mouth, to be generic,
14 has a palate, and we divide it into the hard
15 and the soft. So the hard is the front part
16 which is the bony part, and the soft is the
17 back part of roof of the mouth. So we call
18 it the soft.

19 Q And does somnoplasty relate to just the
20 soft palate?

21 A Somnoplasty pertains -- somno means
22 sleep and snoring. So Somnoplasty was to the

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

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

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

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

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

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

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

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

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

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

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

22 "In the course of my clinical and

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

5 Do you see that?

6 A I see that.

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

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

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

18 A No. That's it.

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

1 devices for the treatment of the nose?

2 A I have not designed devices for the
3 treatment of the nose.

4 Q So have you designed devices for the
5 treatment of the ear?

6 A I have not designed devices for the
7 treatment of the ear.

8 Q Have you designed devices for the
9 treatment of throat conditions?

10 A I have not designed devices for the
11 treatment of throat conditions.

12 Q Okay. If we could -- and I'm sorry to
13 jump around on you, go to Page 181 of this
14 declaration, which, again, is your materials
15 considered section.

16 A Go to Page 181?

17 Q Correct.

18 A Okay.

19 Q So we're back in Appendix B, materials
20 considered section of your declaration,
21 correct?

22 A That's correct.

1 Q Outside of the materials listed here,
2 did you consider any materials in preparing
3 your declaration?

4 A I considered my experience and my
5 expertise.

6 Q Okay. But, is it fair to say that the
7 documents that you relied on, as it relates
8 to at least 00279 IPR are all listed in
9 Appendix B of your declaration?

10 A The documents that are cited in my
11 declaration are listed in this appendix.

12 Q And did you rely on these documents?

13 A I did.

14 Q Okay. So, again, looking at
15 Exhibit 1005 and Makower.

16 Do you know Mr. Makower?

17 A I don't.

18 Q Why don't I just give you copies of
19 Makower and Fang so we're just looking at the
20 same thing.

21 (Whereupon, U.S. Patent Pub. No.
22 2005/0240147 to Makower was

1 marked as Exhibit 1005 for
2 identification as of this date.)
3 (Whereupon, Fang Chao-xin and
4 Zhen Shao-Shao, Nasal endoscopy
5 was marked as Exhibit 1006 for
6 identification as of this date.)

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

9 A That's correct.

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

12 A I am ready.

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

15 Do you see those?

16 A I do.

17 Q The first one is Joshua Makower,
18 correct?

19 A That's correct.

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

22 A I do not.

1 Q Do you know Mr. John Y. Chang?

2 A I do not.

3 Q And then if we go to Fang, which is
4 Exhibit 1006, and we go a few pages in,
5 there's a couple of actually articles in
6 here, I don't know what actual page this is
7 of the exhibit because it's not labeled at
8 the bottom, but for the record, it's Page 876
9 at the top.

10 Do you see that?

11 A I see that.

12 Q Here we have the title, "Nasal endoscopy
13 combined with multiple radio frequency for
14 perennial allergic rhinitis."

15 Do you see that?

16 A I see that.

17 Q The first named author is Fang, correct?

18 A That's correct.

19 Q Do you know this person?

20 A I don't.

21 Q And the second named author is a person
22 with the last name Zhen.

1 Do you see that?

2 A I see that.

3 Q Do you know that person?

4 A I don't.

5 Q Do you know anybody at the Department of
6 Otorhinology -- I'm butchering it -- but
7 Otorhinology, I'm sorry, in that province of
8 China?

9 A I do not.

10 Q I'm going to hand you two more
11 references at this time.

12 For the record, I'm handing you
13 Exhibit 1008, which is Edwards, and 1009,
14 which is Stern. Here you go.

15 (Whereupon, U.S. Patent No.
16 6,517,535 to Edwards was marked
17 as Exhibit 1008 for
18 identification as of this date.)

19 (Whereupon, U.S. Provisional
20 Appl. No. 60/702,077 was marked
21 as Exhibit 1009 for
22 identification as of this date.)

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

7 A I see that.

8 Q The inventor is Stuart D. Edwards.
9 Do you see that?

10 A I see that.

11 Q Do you know Mr. Edwards?

12 A I don't know him?

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

18 MR. BRIGGS: Fair enough. I agree.

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

22 Do you see that?

1 A I see that.

2 Q And there's several inventors listed
3 here. Let's just go through them.

4 Roger A. Stern, do you know this person?

5 A I don't.

6 Q Next is Vincent N. Sullivan, do you know
7 this person?

8 A I don't.

9 Q Roxanne L. Richman, do you know this
10 person?

11 A I don't.

12 Q Lauren L. Roy, do you know this person?

13 A I do not.

14 Q Robert L. Marion, do you know this
15 person?

16 A I do not.

17 Q And, finally, Thomas D. Striegler, do
18 you know this person?

19 A I do not.

20 MR. STERN: Counsel, just the same
21 reservation, it looks like the bottom
22 might have been cut off. I'm not

1 seeing anything missing, but we'll
2 just reserve.

3 MR. BRIGGS: Fair enough.

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

11 A I'm fine if you're fine.

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

14 Do you see that?

15 A I see that.

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

18 A I am not an attorney.

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

1 relevant to your opinions.

2 Do you see that?

3 A Yes. I do.

4 Q And this is your first patent case,
5 correct?

6 A That's correct.

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

10 A I do.

11 Q It says:

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

17 Do you see that?

18 A I see that.

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

22 MR. STERN: Objection to form.

1 A This is -- if you read my declaration
2 and you see how I used my arguments to
3 formate my opinion based on anticipation,
4 you'll see how I understood or applied this
5 concept.

6 Q So can you point me to where you made an
7 anticipation argument in your declaration?

8 A I have to look over the declaration now
9 and to see where I made anticipation.

10 Q Sure.

11 A So for instance, on Page 59 in Heading A
12 right above Paragraph 82. And so I say
13 "Challenged Claims." I list the claims, and
14 I say they are anticipated by et cetera. And
15 the following paragraphs would show how I
16 applied what I understood about anticipation
17 when I came up -- when I formulated my
18 opinions on this declaration.

19 Q So in the context of Ground 1 of your
20 declaration and "is presence," what do you
21 mean by "is present" as it relates to Saadat?

22 MR. STERN: Objection to form.

1 A As you can see in Paragraph 83, I say,
2 "Saadat discloses a method of treating a
3 nasal condition of a patient." And then in
4 Paragraph 84 I say, "Saadat discloses methods
5 for treating conditions such as rhinitis."

6 Q Okay. And then if you could please go
7 back to Page 6 of your declaration. It says
8 "Obviousness."

9 Do you see that?

10 A I do.

11 Q What's your understanding of the
12 difference between "anticipation" and
13 "obviousness"?

14 MR. STERN: Objection to form.

15 A As I write in my declaration, "I
16 understand that a claim is" -- I'm talking
17 about obviousness now. "I understand that a
18 claim of unpatentable if it would have been
19 obvious to a person of ordinary skill in the
20 art at the time the alleged invention was
21 made. I understand that a claim could have
22 been obvious based on the teachings or

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

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

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

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

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

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

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

9 Q Can I interrupt you for --

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

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

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

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

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

18 So this is what I understood about
19 obviousness.

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

22 My question though was what is your

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

6 MR. STERN: Objection to form.

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

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

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

14 MR. BRIGGS: Sure. Ten minutes.

15 Okay. Off the record.

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

18 MR. BRIGGS: Back on the record.

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

22 A I did not.

1 Q Okay. Great.

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

4 A This is the 00279, you said, right?

5 Q That's right.

6 A Yes.

7 Q Are you at Page 39?

8 A Yes.

9 Q Okay. Great.

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

13 A "For the purpose of this declaration" --

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

15 A I'm sorry.

16 Q I apologize.

17 A Okay.

18 Okay.

19 Q So the first sentence says:

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

1 meaning."

2 Do you see that?

3 A I see that.

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

7 MR. STERN: Objection to form.

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

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

19 MR. STERN: Objection to form.

20 Foundation.

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

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

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

6 MR. STERN: Objection to form.

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

13 Q That's not what I asked.

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

16 MR. STERN: Objection to form.

17 Q That's my question.

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

20 Objection to form. Foundation.

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

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

3 Q Okay. Fair enough.

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

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

9 A Okay.

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

12 On Page 14 there's a picture.

13 Do you see that?

14 A I see that.

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

17 Do you see that?

18 A I see that.

19 Q Do you agree with this picture?

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

1 So what do you mean if I agree with this
2 picture?

3 Q Is there anything incorrect about this
4 picture?

5 A I don't see anything incorrect just
6 looking at it, no.

7 Q Okay. What is -- and I'm going to
8 butcher the name -- choana, it's on the
9 right-hand side of the picture. Can you tell
10 me how to pronounce that please?

11 A Choana.

12 Q What is the choana?

13 A The choana is the opening -- the choana
14 is the opening at the back end of the nasal
15 cavity where the nasal cavity meets the nasal
16 pharynx, so it's the back opening of the
17 nasal cavity.

18 Q Why did you add an arrow to this picture
19 with the word "choana"?

20 A This is to explain the nasal anatomy.
21 That was the only picture I added. Again,
22 it's a sagittal view and not a

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

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

11 A That's correct.

12 Q Why did you do that?

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

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

21 A You did.

22 Q So do you see that?

1 A Yes, I do.

2 Q And in my reading, I think I understand
3 "concha" to be equivalent to the term
4 "turbinate."

5 Do you have the same understanding?

6 A I do.

7 Q Is there a difference between a
8 turbinate and a concha?

9 A No. It depends on how you refer to
10 them.

11 Q Why do people skilled in the art use
12 turbinate sometimes and concha in other
13 times?

14 MR. STERN: Objection to form.
15 Foundation.

16 A It's more like -- depending which term
17 you like to use and which term become easier
18 to pronounce easier to vocalize. So now we
19 find word turbinate is easier, so we say
20 turbinate. Many of the old anatomic
21 textbooks they say concha, but you understand
22 that, you know, when we say inferior concha

1 or inferior turbinate, we understand these
2 are the equivalent.

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

6 A That's correct.

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

9 A That's correct.

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

12 A That's correct.

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

15 A That's correct.

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

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

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

22 Are their synonyms for superior concha,

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

3 MR. STERN: Objection to form.

4 A These are different dimensions; superior
5 versus inferior refers to different
6 dimensions than anterior versus posterior.

7 So when we say an anterior, it means the
8 front of the nose. When we say posterior we
9 mean the back of the nose.

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

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

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

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

1 part of everyone of these turbinate.

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

5 Q Understood.

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

10 MR. STERN: Objection to form.

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

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

17 A Correct.

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

1 A The posterior part of the superior
2 concha.

3 Q All right. Below the choana, there's
4 the torus tubarius.

5 Do you see that?

6 A Yes, I do.

7 Q What is that?

8 A Torus tubarius is the structure around
9 the opening of the eustachian tube. Again,
10 this is the sagittal view, so this is a two
11 dimensional view. And you see the opening,
12 the area that says "opening of the eustachian
13 tube," around it there is this inverted U
14 shaped structure, which is the torus
15 tubarius, right, the inverted U shaped
16 structure.

17 So this is not a circle. This is more
18 of an inverted U, inverted J. And it is a
19 round eustachian tube.

20 Q Okay. On the left-hand side of this
21 figure it says, "nasal bone."

22 Do you see that?

1 A I do.

2 Q And below that it says, "upper lateral
3 cartilage."

4 Do you see that?

5 A I do.

6 Q It says, "alar cartilage."

7 Do you see that?

8 A I do.

9 Q What is the alar cartilage?

10 A Alar cartilage is another term for it is
11 lower lateral cartilage. So as there is
12 upper lateral cartilage and lower lateral
13 cartilage.

14 And we're talking about the sidewall of
15 the nose. It's hard for me to show it
16 without pointing with my finger, but that
17 would not appear on the transcript.

18 But it is the sidewall, so the lower
19 part of the sidewall of the nose, where the
20 nasal ala is, the outer part of your nostril,
21 that's the lower lateral cartilage. And then
22 there's a crease above that, and that crease

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

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

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

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

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

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

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

4 A That's correct.

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

7 MR. STERN: Objection to form.

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

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

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

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

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

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

12 That's it.

13 Q Are you done?

14 A Yes.

15 Q I didn't want to interrupt you.

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

21 A That's correct.

22 Q What is shown in this figure here about

1 the nose on that section? I thought it was
2 cartilage, but you told me it was not.

3 A No, so this is different here. So this
4 is talking about the roof of the mouth here,
5 also.

6 Q Okay.

7 A So this is the floor of the nose, which
8 is the roof of the mouth. We discussed
9 before hard palate verses soft palate; this
10 is the hard palate part. So one of the
11 branches of the SPG goes down through a
12 foramen and then runs along the hard palate,
13 and then it goes back up to the nose, in the
14 front of the nose.

15 Q Would you go back to Page 14, please,
16 right before -- or right above the picture,
17 there's a sentence that says "the left and
18 right nasal cavities."

19 Do you see that?

20 A Yes.

21 Q It says, "The left and right nasal
22 cavities terminate at the posterior choana."

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

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

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

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

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

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

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

1 MR. STERN: So it's the seventh page
2 of the exhibit.

3 MR. BRIGGS: That's what I believe it
4 to be.

5 A Where is this again?

6 Q So this page right there.

7 And at the top, do you see published
8 in 2006 by Taylor and Francis Group?

9 A I see.

10 Q Okay. So this is a book that I
11 understand to be from 2006, okay?

12 A Okay.

13 Q Do you recognize this book?

14 A I don't.

15 Q You don't recognize this book?

16 A I don't.

17 Q Can you please go a few more pages to
18 Chapter 12?

19 A Okay. I see that.

20 Q So do you recognize this chapter?

21 A Now that I see it, I recognize it.

22 Q So how do you recognize it?

1 A I see my name listed there.

2 Q Do you want to take a few minutes to
3 read through this?

4 A I mean, I have to go over the chapter,
5 all of the chapters, this is -- I haven't
6 read this chapter --

7 Q So I'm particularly interested in some
8 discussion around Pages 233 to 240, to start.
9 If you wouldn't mind, take as much as time as
10 you want, to read Page 233 to 240.

11 A 233 -- so page?

12 Q 233 through 240.

13 A 240.

14 I would need to read it all so that I
15 can refresh my mind about it.

16 Q I would like you to, yes, please.

17 MR. STERN: And, Counsel, while he's
18 reviewing it, given we're just
19 receiving this, we'll reserve our
20 objections for this exhibit for
21 completeness or otherwise.

22 MR. BRIGGS: Understood.

1 A You said until Page 240?

2 Q Yes, please.

3 Okay.

4 A So I'm done reading through 240.

5 Anything more you'd like me to read?

6 Q No, I'd like to ask you some questions.

7 A Sure.

8 Q On Page 233, please.

9 At the top it says, "Surgical
10 management."

11 Do you see that?

12 A I do.

13 Q And below that is the name David Louis,
14 correct?

15 A Yes.

16 Q And then below that is Nicholas Y.
17 Bu-Saba, correct?

18 A Yes.

19 Q So are you a coauthor of this chapter,
20 then?

21 A Yes.

22 Q With David Louis?

1 A Yes.

2 Q How do you know David Louis?

3 A David Louis was one of our presidents at
4 the time, based on my recollection.

5 Q So there's an introductory paragraph on
6 Page 233.

7 Do you see that?

8 A I do.

9 Q Like, halfway through it says:

10 "There's also been a conceptual
11 shift away from attempting to
12 surgically exonerate the disease within
13 the paranasal sinuses to simply opening
14 specific areas in order to improve
15 sinus function and allow better
16 aeration and drainage."

17 Do you see that?

18 A I do.

19 Q And I'm assuming you agreed with that
20 in 2006?

21 A Yes.

22 Q And do you still agree with that?

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

10 Q Fair enough.

11 The next sentence says:

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

19 Do you see that?

20 A I see that.

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

1 A Also, it is in the correct clinical
2 context that we're talking about. It all
3 depends on what the indication is, why we are
4 operating. So the kind of surgery, the
5 extent of surgery we do, how much tissue we
6 remove, is dictated by what we are treating.

7 Q I agree. I'm just -- was this sentence
8 accurate when you wrote it with Dr. Louis
9 in 2006?

10 MR. STERN: Objection to form.

11 A It was accurate for the kind of
12 indication that this sentence applies to.

13 Q Okay. Since 2006, has there been any
14 efforts to increase the amount of tissue
15 removed during sinus surgery?

16 MR. STERN: Objection to form.

17 A It all depends on the clinical
18 indication. So it depends why we are
19 operating and what we are operating on. So
20 the diagnosis, the extent of the disease, and
21 the condition of the whole, i.e. the patient.
22 Multiple factors come into play when we

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

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

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

9 MR. STERN: Objection to form.
10 Foundation.

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

18 Q Can you give me examples?

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

1 and what are the key functional areas.

2 Q Well, it says key functional areas, it
3 doesn't say functional areas. So I'm
4 assuming there's like a finite number of
5 functional areas.

6 MR. STERN: Objection to form.
7 Foundation.

8 Q Is that correct?

9 A When we say key functional areas, we are
10 referring to specific disease, specific
11 disorder, in a specific patient, that's
12 causing symptoms. For that particular case,
13 there would be key functional areas.

14 Q How many key functional areas are there
15 in the nasal cavity?

16 MR. STERN: Objection to form.
17 Foundation.

18 A Well, the nose is a complex anatomic
19 structure.

20 Q I said nasal cavity.

21 A Nasal cavity. The nasal cavity is a
22 complex anatomic structure, depending on what

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

5 Q That doesn't answer my question.

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

8 MR. STERN: Objection to form.

9 Foundation.

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

13 Q How many surgeries have you performed?

14 A Thousands.

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

19 MR. STERN: Objection to form.

20 Foundation.

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

1 condition you're asking me about.

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

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

13 Is that an improper assumption?

14 MR. STERN: Objection to form.

15 Foundation.

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

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

1 look at the picture again.

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

4 MR. STERN: Objection to form.
5 Foundation.

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

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

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

14 MR. STERN: Objection to form.

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

1 history.

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

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

10 MR. STERN: Objection to form.

11 Foundation.

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

14 Q Okay.

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

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

21 A 233. Yeah.

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

1 there's a sentence above it that says:

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

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

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

19 MR. STERN: Objection to form.
20 Foundation.

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

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

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

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

22 Q I still don't think that answers my

1 question.

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

4 MR. STERN: Objection to form.

5 Foundation.

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

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

20 Q You've done thousands of surgeries,
21 right?

22 A Yes.

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

4 MR. STERN: Objection to form.
5 Foundation.

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

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

1 "Medical history."

2 Do you see that?

3 A I do.

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

8 A That's correct.

9 Q Is that still common practice today?

10 A Yes.

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

14 A That's correct.

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

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

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

1 A That's correct.

2 Q What is a nasal blockage?

3 MR. STERN: Objection to form.

4 A It means the nose is blocked.

5 Q What are some things that would block
6 the nose?

7 MR. STERN: Objection to form.

8 A Many things. Many things can block the
9 nose. Many things, external structures,
10 internal structures.

11 Q Can you give me an example of a few
12 internal structures that may block the nose?

13 A Large turbinates, deviated septum, nasal
14 polyps, tumor, foreign body, internal nasal
15 valve.

16 Q And then staying in Table 1. It says
17 rhinorrhea, correct?

18 A That's correct.

19 Q What is rhinorrhea?

20 A Mucus production by the nose. So mucus
21 dripping. So we mention rhinorrhea and post
22 nasal drip. Both refer to mucus production.

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

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

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

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

18 MR. STERN: Objection to form.

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

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

4 Q Just below that is hyposmia.

5 A Yes.

6 Q What's hyposmia?

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

9 Q And then hypogeusia?

10 A Reduced sense of taste.

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

13 Is that your understanding?

14 MR. STERN: Objection to form.

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

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

19 Do you see that?

20 A I see that.

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

1 Do you see that?

2 A I do.

3 Q What's anterior rhinoscopy?

4 A It is looking through the front part of
5 the nose. Typically, I mean, there are
6 different ways of doing it, but typically we
7 use what's called nasal speculum. But if I
8 put my finger on the tip of your nose, this
9 is the anterior, meaning, looking with my
10 eyes.

11 But, typically, to be able to see
12 through the head of the front of the nose,
13 through the section of nose, many times we
14 put what's called nasal speculum. Because
15 it's a cavity in there, we have to shine a
16 light to be able to see.

17 So, usually, in the past few years we
18 have the head mirror, which is still the
19 category of the otolaryngologist showing that
20 head mirror. But now there are different
21 ways of shining light. You can use a
22 headlight, any light source basically to

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

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

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

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

12 Q You mentioned nasal polyps a little bit
13 earlier.

14 What are nasal polyps?

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

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

22 A The polyp, if I want to explain to a

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

5 Q What's a nasal septum deviation?

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

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

17 MR. STERN: Objection to form.

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

22 Q And what is the problem with nasal

1 blockage?

2 A When people cannot breathe through their
3 nose, it can impact their day-to-day function
4 in many ways.

5 Q So if you could please turn to Page 236.
6 And then there's imaging.

7 Do you see that?

8 A Yes, I do.

9 Q So it appears that you do a medical
10 history, then a physical examination. And
11 then is imaging consistently done after those
12 two steps?

13 MR. STERN: Objection to form.

14 Foundation.

15 A No. It's not. Depending on the
16 indication and depending on the clinical
17 course.

18 Q So then down below that it says,
19 "Indications for paranasal sinus surgery."

20 Do you see that?

21 A I do.

22 Q That heading?

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

4 Do you see that?

5 A I do.

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

9 A That's okay.

10 Q Okay. Can you tell me what CRS is?

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

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

19 Do you see that?

20 A I do.

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

1 Do you see that?

2 A I do.

3 Q What's the difference between
4 inflammatory and infectious rhino-sinusitis?

5 MR. STERN: Objection to form.

6 A Any kind of inflammation would be
7 inflammatory. So inflammation may be induced
8 or caused by infection, or it can happen in
9 the absence of infections. So people can
10 have inflammation without infection. But
11 when they have infection, typically they have
12 inflammation associated with it. So
13 infectious inflammation is a category of the
14 broader term "inflammation."

15 Q So right below that it says, "Chronic
16 rhino-sinusitis that failed medical therapy."

17 Do you see that?

18 A Yes, I do.

19 Q What does it mean by "failed medical
20 therapy," I guess, in this context?

21 MR. STERN: Objection to form.

22 A Because it is inflammation, the primary

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

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

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

1 right?

2 A Yes.

3 Q Can you tell me what part of the nose
4 we're looking at here?

5 A So as you see, there's what's marked
6 "middle turbinate." There is what's marked
7 "uncinate process." There is what's marked
8 "deviated septum" and what's marked the
9 "polyps."

10 So we are looking in the space next to
11 the middle turbinate, so this would be the
12 middle meatus. So we're looking at the
13 middle meatus of the left side of the nasal
14 cavity. And this is the polyp, which is
15 rising and filling the middle meatus in that
16 left side.

17 Q I think you said "deviated septum," but
18 the words on the page are just "septum." Do
19 you see a deviation, or is it just a regular
20 septum?

21 A This one here, we're just indicating a
22 septum. So whoever is looking at that figure

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

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

7 A Did I say "deviated septum"?

8 Q Yes. You did.

9 A No. I'm sorry.

10 Q Just a regular septum.

11 A Yes. This is just a septum.

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

14 MR. STERN: Objection to form.

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

22 Q And then I think you -- on the

1 right-hand side it says "uncinate process."

2 I'm sorry if I said it wrong.

3 A Uncinate.

4 Q Uncinate process. What is that?

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

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

11 MR. STERN: Objection to form.

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

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

18 A That's correct.

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

21 A Um-hmm. Okay.

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

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

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

10 That seems to be a problem in 2006,
11 correct?

12 MR. STERN: Objection to form.
13 Foundation.

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

16 Q Agreed.

17 And then above that text there is a
18 Figure 3.

19 Do you see that?

20 A I see that.

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

1 A That's correct.

2 Q And it's got a middle turbinate pointed
3 to, correct?

4 A That's correct.

5 Q With an arrow?

6 A That's correct.

7 Q And then below that, I'm assuming, is
8 the inferior turbinate at that point in time?

9 MR. STERN: Objection to form.

10 A That's correct. So, yes, the structure
11 below the middle turbinate, the gray
12 structure -- it's hard for me to point out
13 for the reporter to know what I'm talking
14 about, but the lower structures in that
15 figure, this structure and that structure,
16 are the inferior turbinate.

17 MR. BRIGGS: So what the witness is
18 pointing to are two curved portions,
19 one of which has middle text directly
20 above it -- on top of it.

21 Q And then there's what appears to be, I
22 guess, the septum. And the right-hand side

1 would be the other inferior turbinate; is
2 that correct?

3 A That's correct.

4 Q Okay. And if we look at the middle
5 turbinates, the one on the right-hand side is
6 not, in my view -- and I'm not a doctor --
7 but is not nearly as large as the one on the
8 left-hand side.

9 Does the one on the left-hand side have
10 a condition? Is that why it's being pointed
11 to?

12 MR. STERN: Objection to form.
13 Foundation.

14 A The size of the turbinate varies from
15 side to side without necessarily meaning that
16 one size is better.

17 Q Okay?

18 A But they can vary from side to side.

19 In this paragraph, I mean, I don't know
20 where this CAT scan -- the patient's symptoms
21 for which we got this CAT scan, but it's my
22 understanding when I look at the chapter and

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

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

10 Q Okay. That makes sense.

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

13 MR. STERN: Objection to form.

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

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

1 correlates with your symptoms.

2 Q Okay. So going to the bottom of 239,
3 there's a sentence that says:

4 "There are two primary goals of
5 FESS. First is to open up the narrow
6 areas described above. The second is
7 to perform the surgery in as atraumatic
8 a manner as possible."

9 Do you see that?

10 A I do.

11 Q Is that accurate in 2006?

12 MR. STERN: Objection to form.

13 A Again, for the appropriate indication,
14 yes, it's accurate. So it is always in
15 context of what the indication is.

16 Q Yeah. I understand.

17 If you could please now go to Page 265?

18 A Of this chapter?

19 Q That's correct.

20 A Okay.

21 Q And there's a section called Lasers and
22 Sinus Surgery.

1 Do you see that?

2 A I do.

3 Q Would you mind just reading that to
4 yourself and let me know when you're
5 finished.

6 A Okay.

7 Q So this section is Lasers and Sinus
8 Surgery, correct?

9 A That's correct.

10 Q We briefly talked about earlier that you
11 have experience with, I guess, radio
12 frequency use of medical instruments?

13 A That's correct.

14 Q What is the difference between laser and
15 radio frequency surgery?

16 MR. STERN: Objection to form.

17 A Well, lasers are a form of light. So a
18 laser is applying light, a form of light.
19 Radio frequency is a different form of an
20 energy, so it's different forms of energy.

21 Q And you've used both, though; is that
22 right?

1 A Correct. Lasers, not lately because
2 they're expensive and I don't find them to be
3 useful for what I do, but I've used them
4 before.

5 Q Is there any reason you did not mention
6 radio frequency treatment in this chapter?

7 MR. STERN: Objection to form.
8 Foundation.

9 A Every chapter we write, I cannot be
10 exhaustive, so we chose to mention lasers
11 here. It doesn't mean -- it's not intended
12 to be a comprehensive chapter about every
13 kind of modality treatment or surgical
14 treatment, so we chose some topics. And it
15 looks like here we chose to mention lasers.

16 Q Okay. I'm done with this exhibit.

17 MR. STERN: I think we've gone a
18 little bit over an hour if you want to
19 take a break.

20 MR. BRIGGS: Can we take 15 minutes?

21 MR. STERN: Off the record.

22 (Whereupon, a recess was taken

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

2 MR. BRIGGS: Back on the record.

3 Q Welcome back, Dr. Bu-Saba?

4 A Thank you.

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

7 And can you please Paragraph 26 through
8 30 to yourself and let me know when you're
9 ready.

10 A Great.

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

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

17 Do you understand that?

18 A Yes.

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

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

6 MR. STERN: Objection to form.

7 A Correct.

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

10 A I don't.

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

14 A Yes.

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

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

21 A Yes.

22 Q Is there a reason that you didn't

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

3 MR. STERN: Objection to form.
4 Foundation.

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

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

11 MR. STERN: Objection to form.
12 Foundation.

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

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

1 MR. STERN: Objection to form.

2 Foundation.

3 A It all depends what the someone -- you
4 said electrical engineering degree?

5 Q Yeah.

6 A Yeah, so it depends what the person with
7 an electrical engineering degree was asked to
8 opine about. If they're experience applies
9 to what they're opining about, then they are
10 a POSITA for that opinion.

11 Q Wouldn't it be better to have somebody
12 with nose experience as opposed to somebody
13 who has no nose experience?

14 MR. STERN: Objection to form.

15 Foundation.

16 A Again, here -- what I'm stating in this
17 declaration, the definition of a POSITA, in
18 general, like this is what I define a POSITA
19 in this -- as relevant to my declaration, as
20 is my relevant to my opinions. This is how I
21 defined it.

22 Q That's not my question.

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

5 MR. STERN: Objection to form.

6 Foundation.

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

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

13 MR. STERN: Objection to form.

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

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

19 MR. STERN: Objection to form.

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

22 Q Would you like to look at every claim?

1 A Sure.

2 Q So heres the '675 Patent, which is
3 Exhibit 0771 and IPR 00279.

4 (Whereupon, U.S. Patent No.
5 10,610,675 was marked as Exhibit
6 0771 for identification as of
7 this date.)

8 Q And the claims are at the back, which
9 I'm sure you're aware of now.

10 If you could just look at Claim 1,
11 please, which is in Column 27, starting at
12 Line 37.

13 A The page -- you said, which page, sorry?

14 Q It's Column 27.

15 A Yes. I see that.

16 Q Line 37.

17 A Line 37. I don't see the lines here.

18 Q They're in the middle of the page.

19 A Yes, yes. Okay. Sorry.

20 Q So if you could just read Claim 1 to
21 yourself, please.

22 A Okay.

1 Q So in the middle of the claim, it says:

2 "So as to disrupt neuro activity
3 such that mucus secretion is reduced in
4 the nasopharyngeal passage," correct?

5 A That's correct.

6 Q So Claim 1 relates, at least in part, to
7 the nasopharyngeal passage, correct?

8 A That's correct.

9 Q Do you understand the concept of the
10 Neurent claims?

11 A As I've already stated in my
12 declaration, yes.

13 Q So Claim 2 says, "The method of
14 Claim 1."

15 Do you see that?

16 A I do.

17 Q Which means Claim 2 includes all the
18 text of Claim 1 plus the additional text
19 that's recited in Claim 2, correct?

20 A That's correct.

21 Q So Claim 2 also requires the
22 nasopharyngeal passage, correct?

1 A That's correct.

2 Q And if we just go down, we can see that
3 all of the claims, 3 through 16, are
4 dependent claims, either directly or
5 indirectly off of Claim 1, correct?

6 A That's correct.

7 Q So every single one of those claims
8 relates to the nasopharyngeal passage, at
9 least in part, correct?

10 A That's correct.

11 Q Okay. And then Claim 17, which is a
12 new, what's called, independent claim.

13 Again, we have administering therapy to
14 the target tissue with the treatment device
15 to alter nasopharyngeal cells, such that
16 congestion in the nasopharyngeal passage is
17 reduced?

18 Do you see that?

19 A Sorry. Do you mind telling me which
20 claim was that?

21 Q That was 17. It's right around Line 30.

22 A Okay. 30, okay.

1 I see that.

2 Q And then after Claim 17, we have
3 dependent Claims 18 through 30, and each of
4 those refer either directly or indirectly to
5 Claim 17, correct?

6 A That's correct.

7 Q So every claim, 17 through 30, requires
8 a relation to the nasopharyngeal passage,
9 correct?

10 A That's correct.

11 Q So all claims of the '675 Patent recite
12 a requirement that relates to the
13 nasopharyngeal passage, correct?

14 A That's correct.

15 Q So my question is, since the claims of
16 the '675 Patent all relate, at least in part,
17 to the nasopharyngeal passage, wouldn't it be
18 better if somebody with experience with the
19 nasopharyngeal passage or the nasal cavity,
20 in general?

21 MR. STERN: Objection to form.

22 Foundation.

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

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

10 MR. STERN: Objection to form.

11 Foundation.

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

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

22 Q So as it relates to the nasopharyngeal

1 passage, should that person have nasal/nose
2 experience?

3 MR. STERN: Objection to form.
4 Foundation.

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

7 Q That's right.

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

11 Q Okay. That's what I was asking.

12 Now, let's go to page -- I'm sorry.
13 Paragraph 37 of your declaration, in the
14 00279 IPR, please.

15 A Mm-hmm.

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

18 A Yes.

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

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

3 Correct?

4 A That is what I stated in my declaration.

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

7 A Yes.

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

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

13 Do you see that?

14 I'm sorry, on the next page.

15 A Next page. Yes, I see that.

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

18 A Yes.

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

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

3 Do you see that?

4 A I see that.

5 Q Is this definition consistent with the
6 definition of Rubinsky?

7 MR. STERN: Objection to form.

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

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

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

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

1 The patent law term of lexicography?

2 MR. STERN: Objection to form.

3 A I am not.

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

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

15 MR. STERN: Objection to form.

16 Foundation.

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

1 them to certain electric pulses.

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

9 So it talks about various ways of
10 achieving that goal, but ultimately, the goal
11 is the same, which is poration, making the
12 cell porous.

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

15 And go to Line 27.

16 A And you said which line, sorry?

17 Q 27.

18 A 27, I see that, yes.

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

21 A It looks like it, yes.

22 Q It says, "For purposes of those

1 specifications, the term 'poration'
2 includes," and it goes on to list, correct?

3 A Yeah.

4 Q So that means the patent has defined the
5 term "poration."

6 Is that your understanding?

7 MR. STERN: Objection to form.

8 Foundation.

9 A They defined the term poration as it
10 applies to this -- to that application.

11 Q Right.

12 A Yeah.

13 Q Did you apply this definition in your
14 analysis of the '675 Patent?

15 A I have to see where I referred to it in
16 my declaration to see how I referenced this.

17 So if you can point me to where in my
18 declaration I mention this, and then I can
19 see and I can tell you how I applied it and
20 how I understood it.

21 Q Okay. We can do that later.

22 I was just concerned that you cite

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

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

7 And go to Paragraph 60.

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

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

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

14 Q 60, 61, and 62 please.

15 A Okay.

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

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

21 A Yes.

22 Q And so that refers to Provisional

1 Application No. 60/702,077, right?

2 A Okay.

3 Q And the reason that's important is we're
4 going to be talking about it a little. Okay.
5 So we're all on the same page about what 077
6 provisional means, right?

7 A Right.

8 Q Okay. So then we go down to the next
9 paragraph, 61.

10 And you say, "Following the 077
11 provisional."

12 Do you see that?

13 A Yes, I do.

14 Q And then you have a bunch of
15 applications listed in the bullet point form
16 under that paragraph, right?

17 A That's correct.

18 Q And there's eight of them, right?

19 A Yes.

20 Q And they all have different definitions,
21 so if we need to go back and look at the
22 definitions, we can.

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

3 Do you see that?

4 A I do.

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

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

10 Do you see that?

11 A I do.

12 Q Which issues as the '675 Patent.

13 Do you see that?

14 A I do.

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

17 And there you say:

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

1 the alleged invention in the challenged
2 claims."

3 Do you see that?

4 A I do.

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

9 Do you see that?

10 A Yes.

11 Q That sentence says:

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

15 A That's what I read.

16 Q That's what you read.

17 Now, if you could please go back to the
18 '675 Patent and turn to Column 3.

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

21 A Okay.

22 Q So starting at line 56, the '675 Patent

1 says:

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

10 A Yes.

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

14 MR. STERN: Objection to form.

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

18 Q Okay. Great.

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

21 "To define target areas within
22 the nasal cavities, including

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

4 Do you see that?

5 A Yes. I see that.

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

9 MR. STERN: Objection to form.

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

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

15 A Yes. I meant the nasal cavity.

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

19 A This is different one now?

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

1 A Okay.

2 Q So if you could please go to
3 Paragraph 61 of your declaration in 00281,
4 which relates to the '077 Patent that's on
5 Page 43.

6 A Yeah.

7 Q Kind of towards the bottom of the page,
8 it says:

9 "Each challenged claim requires" and it
10 lists a whole bunch of things, including an
11 apparatus for treating rhinitis and elongate
12 body comprising a proximal portion and a
13 distal portion configured for positioning,
14 and so on and so forth.

15 And then if we go down below, it says:

16 "The '077 provisional of following
17 applications do not describe each limitation
18 of the challenged claims," right?

19 A That's correct.

20 Q And it says:

21 "Instead, these applications only
22 disclose applying neurotoxins to the

1 bronchial tubes."

2 Do you see that?

3 A That's correct.

4 Q So the first thing, and, again, let's go
5 to -- I'm going to give you Exhibit 1001 from
6 the 0281 IPR which also relates to the IPR
7 00669. If you could again then go to
8 Column 3, I'll get you the right line number
9 in a minute.

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

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

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

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

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

3 MR. STERN: Sounds good.

4 MR. BRIGGS: Okay.

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

8 A Column 4, line four. Okay.

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

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

19 Correct?

20 A That's correct.

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

1 and the nasal cavity, correct?

2 MR. STERN: Objection to form.

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

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

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

20 A Lines which one, sorry?

21 Q 11 through 28.

22 A Okay.

1 Q So this time it says, "According to the
2 present invention," at the beginning of that
3 paragraph, correct?

4 A I see that.

5 Q But we have a very similar disclosure.
6 If we go down to line 18, for instance, it
7 says:

8 "The region where the toxin is
9 introduced may comprise any portion of the
10 nasal cavity such as a single paranasal sinus
11 or a portion thereof, in nasopharyngeal
12 passage, two or more paranasal sinuses, or
13 some cases may comprise substantially the
14 entire nasal cavity of the patient,
15 particular target region for the toxin may
16 comprise a nasopharynx, which is the back of
17 the nasal passage."

18 Do you see that?

19 A I see that.

20 Q So, again, now the '077 Patent is
21 specifically tied its invention to delivery
22 of toxins to those areas, correct?

1 MR. STERN: Objection to form.

2 A In this paragraph they are talking about
3 delivering toxins to these areas.

4 Q So you agree that the '077 Patent talks
5 about delivering as part of its invention,
6 the toxins to the nasal cavity and the nasal
7 pharynx?

8 MR. STERN: Objection to form.

9 A In this paragraph that you just read, so
10 you cited, yes, they are talking about
11 delivering toxins to the areas that you just
12 cited.

13 Q Okay. If you could please go to
14 Column 7, which is just on the other side,
15 and read lines 41 to 50.

16 A Okay.

17 Q And then starting at line 41 of
18 Column 7, it says:

19 "In other aspects, embodiment of the
20 present invention by treatments for any
21 disease or condition for which rhinorrhea is
22 a result or a symptom."

1 Do you see that?

2 A I see that.

3 Q And then down below that, it says,
4 "Rhinorrhea," and it goes on, "can be a
5 symptom of a number of diseases such as a
6 common cold, sinusitis or rhinitis," correct?

7 A I see that.

8 Q So, again, the '077 Patent specifically
9 ties embodiments of the invention to
10 treatment of rhinitis, correct?

11 MR. STERN: Objection to form.

12 A Again, in this paragraph, they talk
13 about any disease or condition for which
14 rhinorrhea is a result or symptom. And then
15 they say rhinorrhea is the term describing
16 the influence of mucus from the lining of the
17 nasal passage, like we discussed before.
18 Nasal passage or nasal pharynx.

19 Q Including rhinitis, correct?

20 A Including rhinitis, correct.

21 Q So if you go back to your declaration.
22 Sorry to make you jump around. Page 43, at

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

4 MR. STERN: Objection to form.
5 Foundation.

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

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

13 MR. STERN: Sorry, which one?

14 MR. BRIGGS: Of the '077 Patent.

15 Thank you, Counsel.

16 Q And there's a section called catheter
17 device.

18 Do you see that?

19 A Section called catheter devices.

20 Q Line 20.

21 A I see that.

22 Q It says:

1 "To achieve the goals of the present
2 invention, it may be desirable to employ
3 methods and apparatus for achieving cell
4 membrane permeabilization via the application
5 of the energy source", correct?

6 A Correct.

7 Q So now we've got apparatus that are
8 permeabilizing the cells, correct?

9 MR. STERN: Objection to form.

10 A It mentions the word apparatus here. So
11 the word apparatus is mentioned in this
12 sentence.

13 Q For achieving cell membrane
14 permeabilization, correct?

15 A Correct.

16 Q The neuro toxins are delivered to those
17 permeable cells, correct?

18 MR. STERN: Objection to form.

19 A In the context of poration, so no
20 poration, then the medication or toxin is
21 applied to the areas that are being porated.

22 Q Okay. If you could stay in the

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

3 Do you see that?

4 A I do.

5 Q It says:

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

9 Do you see that?

10 A I do.

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

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

16 A Elongate body. I see elongate body.

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

20 MR. STERN: Objection to form.

21 Foundation.

22 A The '077 mentions -- where was the

1 paragraph, the catheter devices.

2 Q The catheter devices are defined at
3 line 26?

4 A So it says, may be used to refer to an
5 elongate element. It says elongate element.
6 Whole or solid, flexible or rigid.

7 Q All of those encompass an elongate body,
8 correct?

9 MR. STERN: Objection to form.
10 Foundation.

11 A It is talking about a catheter and it is
12 talking about elongate element. So it is
13 talking about the catheter. It is talking
14 about the elongate element.

15 Q Do you believe the '077 Patent discloses
16 an elongate body?

17 MR. STERN: Objection to form.
18 Foundation.

19 A Whatever body we're talking about. Here
20 it says element. Whatever the word element
21 means in a legal definition. I mean, it says
22 element, so I go by what's listed here, which

1 is referred to an elongate element.

2 Q My question is, do you believe the '077
3 Patent discloses an elongate body as you
4 quote in Paragraph 61?

5 MR. STERN: Objection to form.
6 Foundation.

7 A All I can go is by what this paragraph
8 is stating, elongate element. This is what
9 the patent owner wrote. This is what I can
10 state back to you, which is a catheter can be
11 used to refer to a elongate element.

12 Q What's your understanding of the term
13 body as it relates to the claim?

14 MR. STERN: Objection to form.
15 Foundation.

16 Q To remind you, we went over claim
17 construction earlier and that requires the
18 application of the plain and ordinary meaning
19 of the word body.

20 So I'm asking you, in the context of
21 Claim 1 of the '077 Patent, what is your
22 understanding of body?

1 MR. STERN: Objection to form.

2 Foundation.

3 A Body is a part of that device, whatever
4 that part of the device is. So depending how
5 you apply the term body. If we're talking
6 about the word device, the body of the device
7 is the body of the device.

8 Q If you can go to sheet five in the
9 drawings of the '077 Patent.

10 A Sheet five. So which figure are you
11 now?

12 Q At the top it says sheet number, so I'm
13 trying to get you to the right sheet first.

14 Sheet 5 has a Figure 5.

15 Do you see that?

16 A I see that.

17 Q And Figure 5 has -- in the text of this
18 is where we just were, so if you want to go
19 back and forth between Column 16 and
20 Figure 5, that's fine. I'll read it out
21 loud.

22 Starting at Column 16, Line 35, it says,

1 "Figures 5 and 5A-5B depict a system
2 utilizing electroporation catheter 22," okay?

3 A Which page?

4 Q That was Column 16, Line 35.

5 A Column 35.

6 MR. STERN: Sorry, did you mean

7 "column" or "line"?

8 Q I'll correct myself. Column 16,
9 Line 35. I apologize if I said it
10 incorrectly.

11 A Okay. "5A and 5B depict the system
12 utilizing electroporation catheter for
13 selective electroporation of the target cell.
14 In certain configurations of the present
15 invention voltages may be applied to the
16 electroporation in order to introduce
17 reversible electroporation at the same time
18 as the catheter delivers the fragmented
19 neurotoxin to the target region."

20 This what you want me to read?

21 Q Well, mainly to point out to you that
22 Number 22 is defined as the electroporation

1 catheter in Figure 5, okay?

2 MR. STERN: Objection to form.

3 A Okay.

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

7 MR. STERN: Objection to form.

8 Foundation.

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

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

12 MR. STERN: Objection to form.

13 Foundation.

14 A It looks elongated, as I said.

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

18 MR. STERN: Objection to form.

19 Foundation.

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

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

3 MR. STERN: Objection to form.

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

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

10 MR. STERN: Objection to form.

11 Foundation.

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

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

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

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

1 MR. STERN: Objection to form.

2 Foundation.

3 Q I'm in your declaration at Page 43.

4 A Page 43, sorry.

5 Q So there's two requirements "A proximal
6 portion; and a distal portion configured for
7 positioning in the nasal cavity."

8 Do you see that?

9 A Yes.

10 Q So the distal portion is positioned in
11 the nasal cavity, correct?

12 MR. STERN: Objection to form.

13 A In this, what I'm referencing here, the
14 distal portion configured for position in the
15 nasal cavity.

16 Q Right. 'Cause that's part of the claim,
17 right?

18 A Yes.

19 Q Okay. And so going back to Figure 5,
20 does it depict a proximal portion and a
21 distal portion?

22 MR. STERN: Objection to form.

1 Foundation.

2 A Just looking at the figure itself
3 without context, without explanation,
4 difficult to say what's proximal, what's
5 distal, how's this being used, which cavity
6 this is being used. So just looking at the
7 figure without how it is applied in a certain
8 particular case, I cannot look at the figure
9 and say what's proximal, what's distal.

10 Q Let me help you out. Column 16, Line 49
11 of '077 Patent says, "The catheter further
12 comprises an electroporation element 26 at a
13 distal 28 end thereof."

14 A Okay.

15 Q So 28 is called distal.

16 With that context, does Figure 5
17 disclose a proximal portion and a distal
18 portion?

19 MR. STERN: Objection to form.

20 Foundation.

21 A I mean, they're saying 26 is distal
22 without explaining what "distal" means and

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

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

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

15 A I do.

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

18 MR. STERN: Objection to form.

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

1 distal to something.

2 Q So this is why patent law is important.

3 We've already said plain and ordinary

4 meaning, correct? And in the plain and

5 ordinary meaning of people who use devices

6 that go in the nose, what is the distal end?

7 MR. STERN: Objection to form.

8 Foundation.

9 A You said in devices that are used in the

10 nose?

11 Q Correct.

12 A So if a device is inserted into the

13 nose, the distal end of that device -- if I'm

14 holding a device, and I'm inserting it in the

15 nose, the part close to me is proximal, the

16 part which is far from me is distal. If that

17 part which is far from me is inside the nose,

18 then that part is inside the nose. If that

19 part is in a different part, then that part

20 is in a different part.

21 But distal -- so if I'm holding the

22 instrument, and I'm the reference, distal is

1 reference to me and proximal is reference to
2 me.

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

5 MR. STERN: Objection to form.

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

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

17 MR. STERN: Objection to form.

18 Is there a question?

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

22 MR. STERN: Objection to form.

1 Foundation.

2 A I answered this question before, and I
3 don't know how can I answer differently.

4 MR. BRIGGS: I'm going to object to
5 his answer as being nonresponsive.

6 A I don't know how I can answer it in a
7 different way while being truthful and
8 accurate. I gave you my best answer, and you
9 can refer to my answer.

10 I believe I defined what distal and
11 proximal is, and I gave the answer in the
12 best way I can give it to you. You can refer
13 to my answer.

14 Q So sitting here today, you've gone over
15 these various claim elements in Paragraph 61
16 of your declaration, correct? You've cited
17 those claim elements, correct?

18 A You're talking about Page 61?

19 Q That's correct.

20 A Yes.

21 Q Paragraph 61, I apologize.

22 A Paragraph 61. Yes.

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

5 MR. STERN: Objection to form.
6 Foundation.

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

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

20 A That's correct.

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

1 end or proximal end?

2 MR. STERN: Objection to form.

3 Foundation.

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

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

13 MR. STERN: Objection to form.

14 Foundation.

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

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

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

3 A I see that.

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

7 MR. STERN: Objection to form.
8 Foundation.

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

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

17 MR. STERN: Objection to form.
18 Foundation.

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

1 operator, "a distal portion positioned in the
2 nasal cavity," so here I define "distal
3 portion" is the portion that goes into the
4 nasal cavity, "that it has multiple radio
5 frequency electrodes coupled with the distal
6 portion of the elongate body," which is the
7 body that is in the nasal cavity. "And a
8 radio frequency generator coupled with the
9 proximal portion of the elongate body," which
10 is -- the proximal portion, which is the one
11 being held by the operator of that device,
12 "for supplying radio frequency energy to
13 multiple radio frequency electrodes to treat
14 target tissue in the nasal cavity and thus
15 treat rhinitis."

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

19 Q Is that your answer?

20 A Excuse me, sorry?

21 Q Is that your answer?

22 A What was the question that you -- can

1 you please ask me it?

2 Q Sure. So at Paragraph 61 in the
3 beginning, it says:

4 "In my opinion, none of these
5 applications, including the written
6 description and figures of the '077
7 Patent convey to a person of ordinary
8 skill in the art that the inventors
9 were in possession of the alleged
10 invention in the challenged claims."

11 So I'm going off that sentence, and I'm
12 going to the next sentence that says, "Each
13 challenged claim requires," lists a few
14 things, "a proximal portion of an elongate
15 body."

16 My question is do you believe the '077
17 Patent provides written description support
18 for a proximal portion of an elongate body.

19 MR. STERN: Objection to form.

20 Foundation.

21 A We just -- I mean, we just looked at
22 Figure 5 together, and we looked at the -- at

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

4 Q Sure. Take your time.

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

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

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

17 A Yes, I do.

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

20 A My declaration?

21 Q Correct.

22 A Page 11.

1 Q And we're in the '077 Patent
2 declaration, just to make sure we're on same
3 page since --

4 A It is.

5 Q Okay. Is Page 11, Paragraph 23.
6 That paragraph's labeled "Written
7 Description," correct?

8 A That's correct.

9 Q It says:

10 "I've been informed and
11 understand that to satisfy the written
12 description requirement, the patent
13 specification must describe the claim
14 invention in sufficient detail that a
15 person of ordinary skill in the art
16 could reasonably conclude that the
17 inventor had possession of the claimed
18 invention at the time of the filing."
19 Correct?

20 A That's correct.

21 Q And you applied this standard in
22 Paragraph 61 of you declaration, which

1 relates to the written description; is that
2 correct?

3 A Page 61?

4 Q Paragraph 61, I apologize.

5 A Paragraph 61.

6 So I reference the written description
7 and the figures of the '077 Patent, the
8 parent, '011 Patent, and the grandparent '675
9 Patent, and so I mention including the
10 written description.

11 Q Right. So the test is -- it says, "to
12 satisfy," I'm back in Paragraph 23, "the
13 written description requirement, the patent
14 specification must describe the claimed
15 invention in sufficient detail that a person
16 of ordinary skill in the art could reasonably
17 include that inventor had possession of the
18 claim invention at the time of filing."

19 Do you see that?

20 A The -- which page, sorry?

21 Q Paragraph 23.

22 A Paragraph 23.

1 Q Written description.

2 A Yes.

3 Q Just reminding you of the standard.

4 A Yes. Okay.

5 Q Does the specification of the '077
6 Patent reasonably convey the claim limitation
7 of an elongate body with a proximal portion?

8 MR. STERN: Objection to form.

9 Foundation.

10 A I have to refer back to the written
11 description pertaining to this device.

12 Q Did -- the portions that I gave you are
13 not enough for you to make that conclusion?

14 MR. STERN: Objection to form.

15 Q We've went over Figure 5, we've gone
16 over Column 16.

17 Those are insufficient for you to make a
18 conclusion?

19 MR. STERN: Objection to form.

20 Foundation.

21 A I might have skipped it here. I don't
22 see anywhere nasal cavity. Do you see nasal

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

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

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

9 MR. STERN: Objection to form.
10 Foundation.

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

17 Q Sure.

18 A If I remember correctly. Now -- so, if
19 I can look back. In the paragraphs that you
20 gave me to read in the -- I'm reading the
21 '675 Patent, did you give me?

22 Q No, the '077.

1 A Oh, sorry.

2 Q The specification is the same, so that's
3 okay. They're just slightly different in
4 where the column and line numbers are.

5 But I will happily refer you to
6 Column 8.

7 A Column 8.

8 Q Line 33, it appears to 36, which reads:

9 "It will be appreciated that the
10 energy may be applied to the regions of
11 the nasal membrane, which are the same
12 or different from the regions as to
13 which the toxin has been introduced."

14 Do you see that?

15 A Yes, I see that.

16 Q We can see we've got a catheter device
17 that we've talked about, that catheter device
18 is going to apply energy, that energy is
19 going to be the same or different from the
20 region in which the toxin has been
21 introduced. And then above that, in
22 Column 8, Line 18 through 25, we talked about

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

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

10 MR. STERN: Objection to form.

11 Foundation.

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

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

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

22 MR. STERN: Objection to form.

1 Foundation.

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

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

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

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

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

1 Q There's an opposing proximal, correct?

2 A Correct.

3 Q Okay.

4 MR. STERN: So we've been going over
5 an hour, up to you, is this a good
6 place to stop?

7 MR. BRIGGS: I mean, I've got like
8 five minutes left on this.

9 MR. STERN: Yeah, that's fine.

10 MR. BRIGGS: Then definitely.

11 Q So the next part of your Paragraph 61
12 that I would like to talk about, is -- it
13 says, "multiple radio frequency electrodes
14 coupled with the distal portion of the
15 elongate body," at the top of Page 44.

16 Do you see that?

17 A I see that, yes.

18 Q And if we could, then, go to the '077
19 Patent, Column 16, again, please.

20 And if you could read Column 16, Line 59
21 through Column 17, Line 8.

22 A Which line you said, sorry?

1 Q Line 8.

2 A Okay.

3 Q You're ready?

4 A Yes.

5 Q Okay. So starting at Column 16, Line
6 59, it says, "Figure 5A depicts an
7 arrangement of electrodes, 30 and 32, that
8 produce an electric field."

9 Do you see that?

10 A Yes.

11 Q Does that disclose multiple
12 radiofrequency electrodes?

13 MR. STERN: Objection to form.

14 A What was the question? I'm sorry.

15 Q No problem.

16 So starting on Column 15, Line 59, it
17 says, "Figure 5A depicts an arrangement of
18 electrodes, 30 and 32, that produces an
19 electric field."

20 Do you see that?

21 A I see that.

22 Q Are those multiple radiofrequency

1 electrodes?

2 MR. STERN: Objection to form.

3 Foundation.

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

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

9 A More than one. Yeah, two.

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

13 A Column 13, Line 31.

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

16 A I did.

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

19 MR. STERN: Objection to form.

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

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

1 to 58, it looks like -- why don't you read
2 that, then.

3 A Okay.

4 Q Thank you.

5 Column 16, Line 42, says:

6 "Referring to Figure 5,
7 electroporation catheter system 20
8 further comprises a pulse generator
9 24".

10 Do you see that?

11 A I see that.

12 Q Is that a radiofrequency generator?

13 MR. STERN: Objection to form.

14 A They don't specify. They say a "pulse
15 generator."

16 Q Could it be a radiofrequency generator
17 given that we just saw that the electrodes
18 could be radiofrequency electrodes?

19 MR. STERN: Objection to form.

20 A If you are applying radiofrequency
21 energy, it has to be radiofrequency
22 generator.

1 Q Correct.

2 Last question before break.

3 There's a generator called Cyto Pulse
4 Science.

5 Do you see that, on Line 3?

6 A I see that.

7 Q Do you know that generator?

8 A I don't.

9 MR. BRIGGS: Okay. We can go off the
10 record.

11 (Whereupon, a recess was taken
12 from 12:51 PM until 1:23 PM.)

13 MR. BRIGGS: Let's go back on the
14 record.

15 Q Dr. Bu-Saba, welcome back from lunch.

16 A Thank you.

17 Q During lunch, did you talk with counsel,
18 at all, about your testimony?

19 A No.

20 Q Okay. Why don't we go to -- let's go
21 back to the 279 -- 00279 declaration, and
22 let's go to Paragraph 81.

1 A 81 for Fang, the one that starts Fang?

2 Q That's correct. Why don't you just read
3 that paragraph to yourself and let me know
4 when you're ready.

5 A I'm okay. Yes.

6 Q So about half down you say:

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

12 Do you see that?

13 A I do.

14 Q Why did you add nasal wall after the
15 sphenopalatine foramen?

16 MR. STERN: Objection to form.

17 A This is the only -- whoever is reading
18 is not familiar with the anatomy, so they
19 understand what you're talking about.

20 Q I guess, I don't understand. How does
21 the sphenopalatine foramen relate to the
22 nasal wall.

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

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

14 Do you see that?

15 A I do.

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

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

1 Q Had you heard of an SHP-15 organ
2 radiofrequency therapy instrument before
3 reading this article?

4 A I have not.

5 Q Okay. And you say it comes with many
6 factory preset settings.

7 How do you know that?

8 A I have to go to the paper again and see
9 whether Fang mentioned this.

10 Q Be my guest. I gave you Fang earlier.
11 It's exhibit 1006.

12 A He does mention a certain level. Once
13 he mentions certain levels, it means there
14 are different levels.

15 Q Why don't you take your time. I think
16 that section -- excuse me -- that sentence
17 we're talking about is in Section 1.2,
18 treatment methods.

19 Why don't you go ahead and read 1.2,
20 because we're going to talk about it anyway.

21 A So he mentions with the Level 3
22 intensity selected. So when I read Level 3,

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

4 Q Okay. So it says "factory preset
5 settings," though. Does Level 3 connote to
6 you preset settings?

7 MR. STERN: Objection to form.

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

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

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

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

1 Do you see that?

2 A Yes, I do.

3 Q How do you know it's an off-the-shelf
4 device?

5 A I mean, it is available on the market.

6 I don't see, when I read Fang, that it
7 was purely solely designed for this
8 indication. So off-the-shelf, I mean, it is
9 available in the market, at least where Fang
10 practices.

11 Q Okay. And, then, you say, in your
12 declaration, in that same sentence, and I am
13 quoting:

14 "That those of ordinary skill in the art
15 would routinely use and know how to operate."

16 Do you see that?

17 A I do.

18 Q How do you know that based just off this
19 one disclosure in Fang?

20 MR. STERN: Objection to form.

21 A Then I listed, there are many available,
22 many others available in the two thousands.

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

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

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

11 MR. STERN: Objection to form.

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

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

21 A This particular machine, I have not.

22 Q Okay. Let's start going through Fang in

1 detail, please.

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

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

12 A They have both abstracts of Fang?

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

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

18 So what's the question?

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

22 A Sixty-three patients with...

1 Okay, yeah.

2 Q Both abstracts appeared identical, at
3 least as to the methods part.

4 It says, "63 patients" -- and I'm
5 reading from the second abstract -- "with
6 perennial allergic rhinitis whose symptoms
7 failed to be controlled by medication
8 received nasal endoscopic surgery for sub
9 mucosus resection of the nasal septum
10 combined with radio frequency ablation of the
11 bilateral Sphenopalatine foramen, anterior
12 ethmoidal nerve, and inferior nasal concha",
13 correct?

14 A Correct.

15 Q What does it mean by bilateral
16 sphenopalatine foramen?

17 MR. STERN: Objection to form.

18 A The sphenopalatine foramen in the left
19 side and sphenopalatine foramen in the right
20 side of the nasal cavity.

21 Q Of both sides of the nasal cavity, is
22 what it means?

1 A Correct.

2 Q Okay. Can you read the first paragraph
3 below the abstract. It starts, there are
4 many, to yourself, and let me know when
5 you're ready.

6 A I did.

7 Q So it says:

8 "There are many surgical treatments for
9 perennial allergic rhinitis but a single
10 treatment method has a higher rate of
11 long-term reoccurrence."

12 Do you see that?

13 A I see that.

14 Q So single treatment method has a higher
15 rate of long-term occurrence, what does he
16 mean by single treatment method?

17 MR. STERN: Objection to form.

18 A Fang believes that there is one single
19 method which has a higher grade of long-term
20 recurrence, among the many surgical
21 treatments. So it looks like Fang is
22 referring to one of these treatments that he

1 refers to.

2 So he says, many surgical treatments.

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

7 Q Okay. So then moving down, he says:

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

18 A Correct.

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

1 by applying many treatments at once?

2 MR. STERN: Objection to form.

3 Foundation.

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

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

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

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

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

1 resection of the nasal septum, correct?

2 A I have to look whether all had submucous
3 resection of the septum.

4 Q Why don't you read the Section 1.1 down
5 below, I think that might clarify it for you.

6 A So it looks like the 63 patients that
7 they selected for this study had a deviated
8 septum.

9 Q Right. And we see down towards the
10 bottom, it says:

11 "The 63 patients were randomly
12 selected as the treatment group
13 according to the admission period,
14 another 20 patients with the same
15 disease who underwent nasal septum
16 surgery alone were selected as the
17 control group."

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

1 A That is my understanding, yes.

2 Q Okay. So going back to the top
3 paragraph, which says, "There are many
4 surgical treatments for perennial allergic
5 rhinitis."

6 Do you see that?

7 A I see that.

8 Q There's several documents I've seen that
9 say sinusitis, and there's several documents
10 I've seen that say rhinitis. What does a
11 person of ordinary skill consider the
12 difference between sinusitis and rhinitis?

13 MR. STERN: Objection to form.

14 Foundation.

15 A As it pertains to Fang or in general?

16 Q To a medical doctor working in your
17 field, what's the difference between
18 sinusitis and rhinitis?

19 MR. STERN: Objection to form.

20 Foundation.

21 A As we discussed earlier, itis means
22 inflammation. And the first part of the word

1 refer to the anatomic site. So sinusitis,
2 inflammation of the sinuses. Rhinitis,
3 inflammation of the nose. Rhino is nose,
4 rhinitis is inflammation of the nose,
5 sinusitis, inflammatory of the sinuses.

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

9 MR. STERN: Objection to form.
10 Foundation.

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

19 Q Okay. Thank you.

20 What are common symptoms of perennial
21 allergic rhinitis?

22 MR. STERN: Objection to form.

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

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

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

1 nasal itching, among others.

2 Q Okay. In the clinical data paragraph
3 that we reviewed, there's a sentence that
4 says:

5 "All the patients complied with the
6 diagnostic criteria for perennial rhinitis."

7 Then there's a citation to one.

8 Do you see that?

9 A I see that.

10 Q And then if we go to the next page,
11 there's a reference one.

12 Did you review the reference one on
13 Page 877 to determine what the criteria were?

14 A I did not review the reference one, no.

15 Q Okay. If you could please read the
16 treatment methods paragraph and let me know
17 when you're finished.

18 A Okay.

19 Q Great. So the first sentence says:

20 "The patients in the treatment group
21 were put in a supine position and treated
22 with 2 percent dicaine and 1/1000th

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

3 Do you see that?

4 A I see that.

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

7 A I don't know what diacane means. I use
8 lidocaine in my practice. So I usually use
9 1 percent or 2 percent lidocaine. I use a
10 lower concentration of adrenaline. I use
11 one -- I dilute it more. So I use one to
12 100,000. But basically it is anesthesia and
13 decongestants. And there are different ways
14 of achieving that, there are different
15 solutions.

16 Q So the next sentence says:

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

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

5 Do you see that?

6 A I see that.

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

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

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

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

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

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

20 Do you see that?

21 A I see that.

22 Q I thought the lateral wall was the same

1 as sphenopalatine foramen?

2 MR. STERN: Objection to form.

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

7 Q Because he says anterior?

8 A Correct.

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

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

15 Do you see that?

16 A I see that.

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

19 MR. STERN: Objection to form.

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

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

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

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

14 Do you see that?

15 A I see that.

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

19 MR. STERN: Objection to form.

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

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

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

8 MR. STERN: Objection to form.

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

17 Q Would he have used radio frequency to do
18 that?

19 MR. STERN: Objection to form.

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

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

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

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

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

17 A That's correct.

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

20 A That's correct.

21 Q And at the nasal ridge?

22 A Did he say nasal ridge? Which line?

1 Q So I don't know which line, but it's
2 right after the parentheses. And I'll just
3 read it. It says, "And at the anterior upper
4 part of the lateral wall of the nasal
5 cavity" --

6 A The nasal ridge.

7 Q It says "the nasal ridge." So is he
8 also treating the nasal ridge with RF energy?

9 A I don't know what he means with the
10 nasal ridge in this -- in this paper, I don't
11 know what he means by the nasal ridge.

12 So I read it based on what he mentions
13 in the abstract. If you look at the
14 introduction part, he mentions the anterior
15 ethmoidal nerve. So it looks like he's
16 targeting the areas where the anterior
17 ethmoidal nerve supply. And that would be
18 the lateral wall of the nose anteriorly, the
19 upper part of the septum.

20 Q And then right after the nasal ridge, it
21 says, "And the anterior part of the inferior
22 nasal turbinate."

1 A I see that.

2 Q So he also did RF energy to anterior
3 part of the inferior nasal turbinate?

4 A That's correct.

5 Q And then on top of that for those with
6 severe hypertrophy, he also did a partial
7 resection of the inferior turbinate, correct?

8 A That's correct.

9 Q The next sentence says, "It was
10 advisable to have a white ring around the
11 radio frequency head."

12 Do you see that?

13 A I see that.

14 Q Why do you think it was advisable to
15 have a white ring around the radio frequency
16 head?

17 MR. STERN: Objection to form.

18 A Again, I don't know the device. I have
19 not used the device. I don't know how they
20 had it configured. So I don't know -- I
21 cannot sit here and answer you why he's
22 saying what he says here.

1 Q Okay. So the next sentence says:

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

9 Do you see that?

10 A I see that.

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

14 MR. STERN: Objection to form.

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

20 Q The next sentence says:

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

1 uncinate process resection, sinus
2 opening, lateral part resection of the
3 middle turbinate or nasal polypectomy
4 were performed for those who had
5 hypertrophy of the uncinate process,
6 sinusitis, hypertrophy or polypoid
7 lesion of the middle turbinate, or
8 nasal polyps."

9 Do you see that?

10 A I see that.

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

14 A Yes.

15 Q So after the surgery -- next sentence:

16 "After the surgery, both nasal
17 cavities were filled with expanded
18 sponges, and the fillers were removed
19 48 hours later."

20 Do you see that?

21 A I see that.

22 Q Is that common practice after a surgery?

1 A Not in my practice, but sometimes if
2 we're worried about bleeding, we pack the
3 nose. The duration of packing varies,
4 depending on how much bleeding we expect.

5 Q And in the last sentence in treatment
6 method, as we've already confirmed:

7 "For patients in the control
8 group, only submucosal resection of the
9 nasal septum was performed."

10 Correct?

11 A That's correct.

12 Q So we know we've got 20 patients in the
13 control, only submucosal resection, and 63 in
14 the --

15 A Experimental group.

16 Q Experimental group.

17 A For lack of a better term, yeah.

18 Q And those 63 received RF treatments that
19 we've talked about, but they could have also
20 received a variety of other treatments on top
21 of that, correct?

22 MR. STERN: Objection to form.

1 A That's correct.

2 Q So Section 1.3, Evaluation criteria for
3 efficacy.

4 Do you see that?

5 A I see that.

6 Q "The efficacy was evaluated according to
7 the evaluation criteria for allergic
8 rhinitis." Again, we have the same document
9 cited there.

10 Do you see that, Document 1?

11 A That was evaluated, yes.

12 Q And we don't have a copy of that
13 document, and you've not evaluated it,
14 correct?

15 A I have not. I don't have a copy of it.

16 Q Okay. So let's look at the results. If
17 you could just read the results section to
18 yourself and let me know when you're ready.

19 A Okay.

20 Q So I'm going to look at the one month
21 after surgery paragraph, okay?

22 A Yeah.

1 Q It says:

2 "The rate of excellent recovery
3 was 92.1 percent, the efficacy rate was
4 7.9 percent, and the total efficacy
5 rate was 100 percent."

6 Do you see that?

7 A I see that.

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

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

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

22 Q Have you commonly seen papers that

1 report both efficacy rate and total efficacy
2 rate?

3 MR. STERN: Objection to form.

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

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

14 MR. STERN: Objection to form.

15 A Because I love math, I see 92.1 plus
16 7.9; this is 100 percent. So when I look at
17 the math, it looks like he added 92.1 to the
18 7.9.

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

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

1 paragraphs and let me know when you're ready.

2 A Okay. Yeah.

3 Q Thank you.

4 So the first sentence is very long. It
5 starts "Numerous studies."

6 Do you see that?

7 A I do.

8 Q And then at the end of it, it's got a
9 citation to Articles 2 through 4. Do you see
10 that?

11 A I see that.

12 Q So my understanding of that sentence is
13 that Fang is referring to other folks to
14 support the -- either analysis or conclusions
15 he has in that first sentence.

16 Is that your understanding as well?

17 MR. STERN: Objection to form.

18 A Yes. That's correct.

19 Q So next sentence does not have any
20 citation. He says:

21 "The treatment of perennial
22 allergic rhinitis mainly relies on

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

4 Do you see that?

5 A I see that.

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

8 A That's correct.

9 Q Okay. So then the next one:

10 "Reasonable surgical
11 interventions should be carried out
12 based on the specific structural
13 characteristics."

14 Do you see that?

15 A I do.

16 Q No citations to any external articles,
17 right?

18 A That's correct.

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

21 MR. STERN: Objection to form.

22 A We discussed this before when we're

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

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

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

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

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

22 "Due to the complex innervation

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

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

7 "In two cases, the radiofrequency
8 ablation of sphenopalatine foramen was
9 used to block the posterior
10 parasympathetic fibers of the
11 sphenopalatine nerve, and the medial
12 and lateral branches of the anterior
13 ethmoidal nerve were damaged by
14 radiofrequency ablation of the anterior
15 upper part of the nasal septum of the
16 lateral wall of the nasal cavity."

17 Do you see that?

18 A I see that.

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

21 Do you see that?

22 A I do.

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

5 MR. STERN: Objection to form.
6 Foundation?

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

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

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

21 MR. STERN: Objection to form.

22 A I do.

1 Q Okay. So then he goes:

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

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

8 A This is my understanding that he's
9 talking about his technique here when he says
10 "3-5 points." But that's only my
11 understanding of the manuscript without the
12 benefit of reading all the references that
13 are cited in this manuscript and to see what
14 these references mention or cite. So I'm
15 going by what this manuscript is.

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

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

1 achieves the therapeutic purposes."

2 Do you see that?

3 A I see that.

4 Q And he cites Reference 7?

5 A I see that.

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

9 Is that your understanding?

10 MR. BRIGGS: Objection to form.

11 A Yes.

12 Q Okay. So then it says "pterygoid."

13 How do you pronounce that word?

14 A Pterygoid.

15 Q Pterygoid. Thank you.

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

22 Do you see that?

1 A I see that.

2 Q Why is he saying pterygoid canal
3 neurotomy alone and/or anterior ethmoidal
4 neurotomy or inferior terminate preserves?

5 MR. STERN: Objection to form.

6 Foundation.

7 A As I read this, this paper, he's listing
8 all the potential cites of the nasal cavity,
9 nasal passage. And he's saying if you just
10 treat one of these sources it might not
11 achieve the goal, because you missed other
12 sources of the innervation.

13 Q Okay. The next sentences says,
14 "However, due to the presentation of the
15 allergic reaction arcs, the postoperative
16 effect is poor and the recurrence rate is
17 high." And then there's two citations to
18 eight and nine.

19 Do you see that?

20 A I see that.

21 Q What does he mean by "allergic reaction
22 arcs"?

1 MR. STERN: Objection to form.

2 A I don't use this term in my practice. I
3 cannot sit here and tell you what he means by
4 what he stated here.

5 Q The next sentence says, "For the
6 patients in this group, all the nasal mucosa
7 parasympathetic pathways, including the
8 posterior ganglionic fibers of the
9 sphenopalatine nerve, the parasympathetic
10 fibers of the anterior ethmoidal nerve, and
11 cholinergic ganglia within the inferior
12 turbinate mucosa were blocked."

13 Do you see that?

14 A I see that.

15 Q So my question is: he says the patients
16 in this group, does he mean the patients that
17 he cited earlier or does he mean the patients
18 that he treated in the experimental study?

19 MR. STERN: Objection to form.

20 A I haven't had a chance to look at the
21 references, but when I read the manuscript, I
22 understand he's talking about the -- his

1 experimental group of 63 patients.

2 Q Is there something in this sentence that
3 indicates that to be the case to you?

4 A Because he says "for the patients in the
5 group," so "this group" refers to this group.

6 Q Okay. I think we -- if we could go to
7 the last paragraph, please.

8 And he says:

9 "The case study of the
10 experimental group has demonstrated the
11 following advantages; one, acute
12 localization of the surgical area,
13 especially the precise effect of nerve
14 blockade while avoiding accidental
15 injury to adjacent important tissues."

16 What does he mean "a precise
17 effect of nerve blockade while avoiding
18 accidental injury to the adjacent
19 tissues"?

20 MR. STERN: Objection to form.

21 A I have to take him at what he says,
22 "precise effect of the nasal blockage," which

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

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

12 A Yes.

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

17 MR. STERN: Objection to form.

18 Foundation.

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

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

6 MR. STERN: Objection to form.
7 Foundation.

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

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

20 Avoid injury in vein, avoid damaging
21 nasal tissue.

22 Q Okay. Then he also treats, I think the

1 anterior upper part of the nasal septum.

2 Do you remember that from Section 1.2?

3 A Yes.

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

6 MR. STERN: Objection to form.

7 Foundation.

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

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

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

19 Do you remember that one from
20 Section 1.2?

21 A Yes, I do.

22 Q What are the adjacent important tissues

1 to avoid when doing that radiofrequency
2 treatment?

3 MR. STERN: Objection to form.
4 Foundation.

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

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

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

22 Do you see that?

1 A I see that.

2 Q Do you agree with his characterization
3 of radiofrequency there?

4 MR. STERN: Objection to form.

5 A There are different ways radiofrequency
6 achieves its goal. One of them is that it
7 can coagulate and denature protein, it can
8 evaporate tissue, it can -- it has different
9 ways -- different modalities of impacting the
10 tissue. One of them is this, but it can also
11 have other ways of effecting tissue.

12 Q Okay. The next sentence says, "The
13 temperature at the radiofrequency ablation
14 site is low, 60 to 80 degrees centigrade."

15 Do you see that?

16 A I see that.

17 Q Do you agree that is a low temperature
18 for his purposes?

19 MR. STERN: Objection to form. I
20 apologize. I didn't mean to
21 interrupt.

22 Objection to form and foundation.

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

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

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

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

18 Q Welcome back, Dr. Bu-Saba.

19 A Thank you.

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

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

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

6 A Okay.

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

13 A Okay.

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

17 A Okay.

18 Q So Paragraph 2 of Makower appears to
19 provide --

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

22 Q Oh, go ahead and read Paragraph 2,

1 that's fine.

2 A Okay.

3 Okay.

4 Q So Paragraph 2 appears to be a somewhat
5 anatomical overview of the nose by Makower.

6 Is there anything you disagree with in
7 Paragraph 2?

8 MR. STERN: Objection to form.

9 A Not that I could see while reading this
10 paragraph.

11 Q Okay. And if you could now -- I think
12 you already read Paragraph 3; is that right?

13 A Yes.

14 Q So halfway down, about, it says,
15 "Disorders that interfere with drainage of
16 mucus, e.g. eclosion of the sinus ostia can
17 result if a reduced ability of the peroneal
18 sinuses to function normally."

19 Do you agree with that.

20 MR. STERN: Objection to form.

21 A It is one mechanism how you -- how you
22 define the sinus cannot function normally.

1 Q Okay. If you could read the first
2 sentence of Paragraph 4, please.

3 A Okay.

4 Q In Paragraph 4 he says, "The nasal
5 turbinates are three (or sometimes four bony
6 proses)."

7 Do you see that?

8 A I see that.

9 Q Why does he say "or sometimes four"?

10 MR. STERN: Objection to form.

11 A In some patients, there is what's called
12 the supreme turbinate, this is in a small
13 subset of people, individuals. We talked
14 about the inferior, middle, superior, a small
15 subset of patients, of individuals, of
16 individuals there is a fourth structure above
17 the superior turbinate, we call it the
18 supreme turbinate.

19 Q Oh, okay. Would you just read the rest
20 of Paragraph 4, then, please.

21 A Okay.

22 Q Makower is talking about turbinate,

1 mucosal tissues, meatus, et cetera, in

2 Paragraph 4.

3 Is there anything you disagree with in

4 Paragraph 4 of Makower?

5 MR. STERN: Objection to form.

6 A The first sentence I think it is a bit,

7 sort of not as accurate as precise as I would

8 like it to. The nasal turbinates are bone

9 processes. The turbinates have a bony

10 process, but they also have tissue covering

11 that bony process.

12 So the turbinate, when we talk about the

13 nasal turbinate, we're talking about the

14 entire structure and not only the bone; in

15 this first sentence. So it is not as precise

16 as I would have used, but otherwise, the

17 stuff which I read there is generally,

18 generally, acceptable.

19 Q You don't think he's dividing turbinates

20 and mucosal tissue because he says, a few

21 sentences down, the mucosal tissue that

22 covers the turbinates, it's capable of, and

1 he goes on.

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

4 MR. STERN: Objection to form.

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

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

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

19 A Okay.

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

22 A Five mentions nasal polyps and 6 does

1 also talking about the nasal polyps.

2 Q Fair enough.

3 Is there anything in Paragraph 6 that
4 you disagree with?

5 MR. STERN: Objection to form.

6 A I would have used more precise terms.
7 So he says nasal polyps often result from
8 chronic allergic rhinitis or other chronic
9 inflammation of the nasal mucosa, but nasal
10 polyps can also start in the sinuses and
11 extend into the nose. So nasal polyps can
12 be -- they can start in the sinus, extend
13 into the nose, and they can start in the
14 nose. Typically, they are secondary to
15 inflammation.

16 Q Okay. And Paragraph 7 through 14 relate
17 to his definition of sinusitis, correct?

18 A Correct.

19 Q Anything in Paragraph 7 through 14 that
20 you disagree with?

21 MR. STERN: Objection to form.

22 A It says -- the term sinusitis refers

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

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

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

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

1 A 17, 18, you said?

2 Q All of 17 through 19, please.

3 A Okay.

4 Q So Paragraph 17 through 19 are
5 discussing deviated septum, correct?

6 A Correct.

7 Q And we've talked about deviated septum
8 in relation to Fang, correct?

9 A That's correct.

10 Q Is the same deviated septum that's
11 discussed here in Makower, these paragraphs,
12 generally applicable to what Fang was meaning
13 by deviated septum?

14 MR. STERN: Objection to form.
15 Foundation.

16 A Deviated septum is deviated septum. So
17 I understand it as a septum which is
18 deviated.

19 Q And then could you read Paragraphs 20 to
20 21, please.

21 A Okay.

22 Q So in Paragraphs 20 to 21, Makower is

1 discussing reduction/removal of nasal
2 turbinates, right?

3 A That's correct.

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

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

10 Do you see that?

11 A I see that.

12 Q Do you agree with that?

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

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

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

8 A That's correct.

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

12 A Okay.

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

16 A That's correct.

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

19 MR. STERN: Objection to form.

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

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

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

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

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

22 Q Okay. In Paragraph 40, there's an

1 instrument called the Somnoplasty.

2 Do you see that?

3 A Yes, I do.

4 Q Are you familiar with that Somnoplasty
5 system?

6 A I am.

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

10 A That's correct.

11 Q Were you using the Somnoplasty system
12 in 2005?

13 A Yes, I was.

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

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

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

22 "The Somnoplasty system includes

1 a radiofrequency generator attached to
2 a probe."

3 Do you agree with that?

4 A Yes, I do.

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

9 Do you see that?

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

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

15 A Okay.

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

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

1 prescribed medications, nor be
2 considered candidates for surgery."

3 Do you see that?

4 A I do.

5 Q Do you agree with that, as of 2005?

6 MR. STERN: Objection to form.

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

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

22 So I wouldn't have worded it this way,

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

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

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

15 Do you agree with that?

16 MR. STERN: Objection to form.

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

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

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

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

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

14 A Okay.

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

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

22 Do you see that?

1 A Yes.

2 Q Do you agree?

3 MR. STERN: Objection to form.

4 Q As of 2005?

5 A I don't agree with this sentence, no.

6 Q Which part or the whole thing?

7 A He says so bloody, I don't understand
8 what he means by so bloody. In most patients
9 blood loss is minimal. And he says so
10 painful, I don't understand what he means by
11 so painful. Many patients only require
12 Tylenol.

13 And then he says that straight
14 instrumentation are used. No, we use curved
15 instrumentation as well. We have been using
16 curved instrumentation in '05 and before '05.
17 So we have used curved instrumentation when
18 we do nose or sinus surgery.

19 So this, sometimes many things I don't
20 agree with.

21 Q Okay. I'm going to go to the last
22 sentence in the paragraph. It says:

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

8 Do you see that?

9 A I see that.

10 Q So the next paragraph says:

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

16 Do you see that?

17 A I see that.

18 Q And the next sentence further describes
19 here:

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

1 possible."

2 Do you see that?

3 A I see that.

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

6 "Many of the above described
7 procedures and techniques may be
8 adaptable to minimally invasive
9 approaches and/or the use of flexible
10 instrumentation. There exists a need
11 in the art for the development of such
12 minimally invasive procedures and
13 techniques, as well as instrumentation,
14 e.g. Flexible instruments or catheters
15 usable to perform such procedures and
16 techniques."

17 Do you see that?

18 A I see that.

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

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

1 conditions of the ear, nose and throat."

2 Do you see that?

3 A I do.

4 Q Paragraph 43, the top sentence:

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

13 Do you see that?

14 A I see that.

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

17 A Okay.

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

21 A You said 132, right?

22 Q 132, please.

1 A 132. Okay.

2 Q Great. So Paragraph 132 starts:

3 "The present invention provides the
4 comprehensive system of devices and
5 associated methods for diagnosing and
6 treating disorders of the ears, nose and
7 throat in a less invasive fashion of current
8 day approaches."

9 Do you see that?

10 A I see.

11 Q "So, specifically, examples of which are
12 described below, the invention provides
13 devices that are wholly or partially effect a
14 fluid type seal of the operative field."

15 Do you see that?

16 A I see that.

17 Q So, I'm going to represent to you that
18 the rest of it talks about fluid tight seal.
19 If you go down about seven or eight lines, it
20 says:

21 "Another aspect of the invention is a
22 set of methods and devices usable to assess

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

7 Do you see that?

8 A I do.

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

16 Do you see that?

17 A I see that.

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

22 MR. STERN: Objection to form.

1 Foundation.

2 A This is what's listed in this paragraph.

3 Q So we have fluid tight seal at the start
4 of the paragraph, correct?

5 A He mentions a fluid tight seal.

6 Q And then he says:

7 "Another aspect is a set of
8 methods and devices usable to assess
9 the static and dynamic nature of the
10 paranasal sinuses."

11 Correct?

12 A That's correct.

13 Q And then another aspect is "the use of
14 device's methods, which are designed for
15 minimally invasive entry into the sinus
16 passageways or regional ducts under image,"
17 and we talked about the language, correct?

18 A That's correct.

19 Q Okay. And then down below that
20 sentence, it says:

21 "In a number of embodiments, the
22 present invention utilizes flexible

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

7 Do you see that?

8 A I do.

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

13 Do you see 133?

14 A The one line?

15 Q Correct.

16 A Yes.

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

19 Do you see that?

20 A I do.

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

1 Do you see that?

2 A I do.

3 Q It says, "B. Variations in occluder
4 design and suction apparatus." So that's the
5 second section, correct?

6 A That's correct.

7 Q Okay. So then if we go to
8 Paragraph 160. If you could look at that,
9 please. It's on Page 13.

10 A Paragraph 160. Okay. Sorry, yes.

11 Q It says:

12 "C. Working devices for
13 delivering substances or for cutting,
14 ablating, remodeling or expanding bone
15 or soft tissue."

16 Do you see that?

17 A I do.

18 Q So that's a third section, correct?

19 A That's correct.

20 Q So then if we go to -- it's several
21 pages forward on Page 22.

22 A Page 22. Okay.

1 Q Paragraph 205 says, "D. Preshaped guide
2 catheters," correct?

3 A Yes.

4 Q So that's a fourth section, correct?

5 A Yes.

6 Q So on that same page, Paragraph 213, we
7 have another section says, "Devices and
8 methods for treatment within paranasal
9 sinuses."

10 Do you see that?

11 A Yes.

12 Q So that's a fifth section, correct?

13 A Yes.

14 Q And then if we go to Page 23,
15 Paragraph 222.

16 A Okay.

17 Q It says:

18 "General examples of
19 interventions using the occluder and
20 access devices and/or working devices."
21 Right?

22 A Yes.

1 Q So that's a sixth section, right?

2 A Yes.

3 Q And then Paragraph 239 is the final
4 section. It's on Page 25.

5 A Yes.

6 Q It says, "Cochlear implant procedure,"
7 correct?

8 A Correct.

9 Q And then after that we get to the claims
10 at the right-hand side of Page 25, correct?

11 A That's correct.

12 Q So we have seven sections of Makower in
13 the specification, correct?

14 A A through G. And these are --

15 Q My first name begins with H, and I'm
16 pretty confident that H is the eighth letter
17 in the alphabet, so I'll represent to you
18 that that's correct.

19 Okay. So if you could please go all the
20 way back to the first section, Page 7,
21 Paragraph 134.

22 A Okay.

1 Q If you wouldn't mind just reading that
2 and let me know when you're finished.

3 A Okay. You said 134 only?

4 Q Yeah.

5 A Yes.

6 Q So the first sentence of Paragraph 134
7 reads:

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

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

16 Do you see that?

17 A I do.

18 Q So we have -- they tie again flexible
19 catheters or other flexible elongate working
20 devices to Figures 5A through 5Y.

21 Do you see that?

22 MR. STERN: Objection to form.

1 Foundation.

2 A I see that.

3 Q Okay. So if we then go to -- I guess
4 let me just ask you a question: Do you know
5 what an occluder is in the context of the
6 Makower patent?

7 MR. STERN: Objection to form.

8 A Occluder is something which occludes.
9 And based on his drawings, it occludes a
10 certain part of the airway.

11 Q Okay. And why does he need occluders?

12 MR. STERN: Objection to form.

13 Q Why does he disclose occluders?

14 MR. STERN: Objection to form.

15 A Because if you are treating a certain
16 part, for instance, the nasal passage, and
17 you don't want blood or whatever to spill
18 down to your throat, you need to occlude the
19 back edge of the nasal passage so that stuff
20 wouldn't go to where they are not supposed
21 to.

22 Q Okay. If you could now turn to Page 13

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

4 A Okay.

5 Q So Paragraph 161 reads:

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

15 Do you see that?

16 A I see that.

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

22 Do you see that?

1 A I do.

2 Q The sentence below that says:

3 "It is within the scope of this
4 approach that these devices may be
5 partially flexible or have rigid and
6 flexible portions to facilitate their
7 control and guidance."

8 Do you see that?

9 A I do.

10 Q Paragraph 164, could you look at that
11 please.

12 A Okay.

13 Q So Paragraph 164 says, "Also, some of
14 the working device is shown in Figures 5A
15 through 5Y," I guess with the triple quotes.

16 Do you see that?

17 A I do.

18 Q So is it your understanding that Makower
19 uses the word "working devices" when he's
20 talking about Figures 5A through 5Y?

21 A He's talking about working devices.

22 This is what he states, working devices.

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

6 MR. STERN: Objection to form.
7 Foundation.

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

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

15 Do you see that?

16 A I see that.

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

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

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

8 Q Fair enough. We can skip that.

9 Paragraph 165 says:

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

20 A Okay.

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

1 types of devices.

2 Do you agree?

3 MR. STERN: Objection to form.

4 Foundation.

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

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

14 A 5H is between 5A. So when he says 5A to
15 5Y, he's including 5H.

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

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

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

4 Do you see that?

5 A I do.

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

9 Do you see that?

10 A I do.

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

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

18 Do you see that?

19 A I do.

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

1 Do you see that?

2 A I do.

3 Q Paragraph 184, "Figure 5F shows a
4 balloon/cutter catheter device comprising a
5 flexible catheter 106."

6 Do you see that?

7 A I do.

8 MR. STERN: Objection to form.

9 Q Paragraph 186:

10 "Figures '5G' through "'5G'" show
11 a device 160 and method for delivery of
12 a pressure-expandable stent. This
13 device 160 comprises a flexible
14 catheter 162."

15 Do you see that?

16 A I do.

17 Q Paragraph 187, "Figure 5H shows an
18 electrosurgical device comprising a flexible
19 shaft 210."

20 Do you see that?

21 A I do.

22 Q Paragraph 188, in the middle of the

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

3 Do you see that?

4 A I'm sorry, which one?

5 Q Paragraph 188.

6 A Okay.

7 Q In the middle of the page, it says,
8 "This device comprises a flexible catheter
9 220."

10 Do you see that?

11 A Yes, I do.

12 Q Okay. Paragraph 190:

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

19 Do you see that?

20 A I do.

21 Q Paragraph 191:

22 "Figures 5M and 5N show a side

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

4 Do you see that?

5 A I do.

6 Q Paragraph 196 on Page 19:

7 "Figure 50 shows a flexible
8 catheter 733 having a working lumen
9 that extends through the catheter."

10 Do you see that?

11 A I do.

12 Q Paragraph 197:

13 "Figure 5P shows a balloon
14 catheter and pressure-expandable stent
15 system 744, which includes all of the
16 elements of the ballooned expandable
17 stent system shown in Figures 5G
18 through "'5G"'.

19 Do you see that?

20 A I do.

21 Q And do you understand that what means is
22 that 5P also includes the flexible catheter

1 described in Figures 5G through '5G', I'm
2 sorry, "'5G"'?

3 MR. STERN: Objection to form.

4 A Well, it says it includes all of the
5 elements of the balloon-expanded stint system
6 shown in Figures 5G -- '5G' prime.

7 Q Great.

8 Page 20 of Makower, Paragraph 198:

9 "Figures 5Q and '5Q' show a
10 self-expanding stint and delivery
11 system comprising a flexible outer
12 sheathe 762, a flexible inner tube
13 764."

14 Do you see that?

15 A I do.

16 Q Below, Paragraph 199, "Figure 5S shows a
17 snare apparatus comprising a flexible
18 catheter 782."

19 Do you see that?

20 A I do.

21 Q Paragraph 200, "Figure 5T," T as in Tom
22 "shows a forceps 790, which comprises a

1 flexible shaft 792."

2 Do you see that?

3 A I do.

4 Q Paragraph 201 on Page 21 of Makower,
5 "Figures 5U and '5U' show a telescoping
6 system 800 comprising a flexible catheter
7 802."

8 Do you see that?

9 A I do.

10 Q Paragraph 202:

11 "Figure 5V shows a side port
12 suction cut slice cutting device 820,
13 which comprises a flexible outer tube
14 822, a flexible inner tube 830, is
15 disposed coaxially and rotatably
16 mounted within the outer tube 822."

17 Do you see that?

18 A I do.

19 Q Paragraph 203, same page, second
20 sentence, "For example, Figures 5W through
21 "5W" show a device 840 that comprises a
22 flexible catheter 842."

1 Do you see that?

2 A I do.

3 Q If you could, please, go to Page 22.

4 Could you just, please, read
5 Paragraph 214 for me and let me know when
6 you're finished.

7 A Okay.

8 Q In the middle of the paragraph -- I
9 guess, scratch that.

10 Now, we're talking about paranasal
11 sinuses, correct?

12 A Yeah, in this paragraph, yes.

13 Q In this section, the section starts at
14 one paragraph above, we're in the Section E
15 now, right?

16 A Yes.

17 Q Okay. So Paragraph 214 says, second
18 sentence, "In the methods of the prior art,
19 rigid or flexible scopes are sometimes used
20 to visualize the ostia of sinuses, but
21 typically such scopes have not actually been
22 advanced into the interior of the sinuses."

1 Do you see that?

2 A I do.

3 Q Do you agree, as of 2005, that was the
4 case?

5 MR. STERN: Objection to form.

6 A I don't agree. Sometimes we advance
7 these scopes into the sinus cavity and we can
8 see inside the sinus cavity.

9 Q Okay. Paragraph 215, the second
10 sentence says, "This device, 168, comprise a
11 flexible catheter, 168," correct?

12 A I'm sorry. So this is Paragraph 215,
13 you said, right?

14 Q That's right.

15 A And which lines of -- so you're reading
16 the line which -- the sentence, which starts,
17 "by this device."

18 Q That's right.

19 A Okay.

20 Q So this device -- 168 comprises a
21 flexible catheter 168.

22 Do you see that?

1 A Yes, I do.

2 Q Paragraph 216, second sentence, about
3 four lines down, "This device, 174, comprises
4 a flexible catheter, 176".

5 Do you see that?

6 A I do.

7 Q Paragraph 217, Figure 7C shows a balloon
8 catheter device 180 which comprises a
9 flexible catheter 182.

10 Do you see that?

11 A I do.

12 Q Paragraph 218 on Page 23, Figure 7D
13 shows a sensor equipped catheter device 190
14 that comprises a flexible catheter 192.

15 Do you see that?

16 A I do.

17 Q Paragraph 219, Figure 7E shows an
18 implant delivery device, 196, which comprises
19 a flexible catheter 198.

20 Do you see that?

21 A I do.

22 Q Paragraph 220, Figure 7F -- actually

1 second sentence, my bad. "A flexible
2 catheter 242 is positioned in or near the
3 sphenoid sinus ostium, SSO."

4 Do you see that?

5 A I do.

6 Q Paragraph 221, same page, second
7 sentence, "A flexible catheter, 242, is
8 positioned in or near the sphenoid sinus."

9 Do you see that?

10 A I do.

11 Q Now, if we could just go back to
12 Paragraph 41.

13 Okay.

14 I'm sorry, 43. My bad. I had my note
15 wrong.

16 Having gone through numerous sections of
17 Makower, the majority of which talk about a
18 device with flexible catheters; isn't it
19 fair, as it states in Paragraph 143, that the
20 focus of Makower is to provide "one or more
21 flexible catheters or other flexible elongate
22 devices, as describe herein that may be

1 inserted into the nose, nasal pharynx,
2 paranasal sinuses, middle ear, or associated
3 anatomical passageways to perform
4 intervention or surgical procedure"?

5 MR. STERN: Objection to form.

6 Objection to foundation.

7 A Here he says provides methods for one or
8 more flexible catheters, or other flexible
9 elongate devices. So this is what he states
10 in this paragraph.

11 Q My question is: Isn't it fair that the
12 focus of Makower is such flexible devices?

13 MR. STERN: Same objection.

14 A In this paragraph it is flexible. One
15 of the other paragraphs that you read for me,
16 it says the catheter could be rigid or
17 flexible.

18 Q So let's look at that.

19 A So there was one of the paragraphs that
20 you read for me where he says it could be
21 rigid or flexible.

22 Q Let me find that.

1 So, Dr. Bu-Saba, yeah, please, you were
2 on Page 13, Paragraph 161.

3 A Okay.

4 Q If we look at the bottom of
5 Paragraph 161, as it reads on to the next
6 column, it says, "Is within the scope of this
7 approach that these devices may be partially
8 flexible or have rigid portions and flexible
9 portions to facilitate their guidance and
10 control."

11 Do you see that?

12 A I see that.

13 Q So to me that sentence says, may be
14 partially flexible, or it can have rigid and
15 flexible portions.

16 Do you disagree with that understanding?

17 MR. STERN: Objection to form.

18 Foundation.

19 A So this sentence itself mentions this,
20 but when I look at other paragraphs, for
21 instance, 187, when it talks about Figure 5,
22 it says, "Comprising a flexible shaft," but

1 then he says "example catheter or solid
2 shaft."

3 So at least in this paragraph, he
4 mentions a solid shaft. So this is what I
5 said, in his description he mentions
6 flexible, but at least in this paragraph, he
7 says it could be solid.

8 Q I don't disagree.

9 My question was: Given everything we've
10 gone through in Makower, is it fair to say
11 that the focus of Makower is the development
12 of flexible catheters or devices that allow
13 better insertion of working devices into
14 various cavities of the body?

15 MR. STERN: Objection to form.

16 Foundation.

17 A In the paragraphs that you cited and the
18 paragraphs that you read and made me read,
19 the "flexible" is mentioned repeatedly.

20 Q Okay. Besides Figure 5H of Makower, are
21 you aware of any illustration in Makower
22 showing RF electrodes on a device?

1 MR. STERN: Objection to form.

2 A I have only considered Makower as it
3 applies to my declaration and to the claims
4 that you are discussing, that's why I chose
5 Figure 5H. I haven't considered other
6 aspects of Makower in the declaration, so I
7 cannot sit here and give you a complete and
8 accurate answer, when I have not considered
9 all the other factors or all the other issues
10 that are out there.

11 Q Sitting here today, can you recall any
12 figure in Makower besides Figure 5H that has
13 electrodes that -- for a device that is
14 inserted into a body cavity?

15 MR. STERN: Objection to form.

16 A Well, I have to go back and look at
17 every figure now. Because I cannot recall
18 every figure listed in the Makower.

19 Q Sure. If you want to go through the
20 working devices figures, which are the
21 Figures 5A through 5Y, we can do that.

22 A I mean, just looking at the figure

1 quickly and without the benefit of reading
2 Makower word for word and see what he says of
3 every figure, the only one that I see that
4 has radiofrequency is this 5H.

5 Q Okay. Why don't we talk about 5H,
6 Figure 5H for a little bit.

7 Do you have Figure 5H in front you,
8 Dr. Bu-Saba?

9 A I have it.

10 MR. STERN: And I don't want to
11 interrupt your flow --

12 MR. BRIGGS: It's a good stopping
13 point. So we can go off the record.

14 (Whereupon, a recess was taken
15 from 3:27 PM until 3:40 PM.)

16 Q So, Dr. Bu-Saba, welcome back.

17 A Thank you very much.

18 Q You now have in front of you two
19 Exhibit 1005 Makower's, correct, so you can
20 look at the figure in one and the text in the
21 other, correct?

22 A That's correct.

1 Q Okay. If you could, please, in one of
2 those, turn to the page that has Figure 5H,
3 and in the other, please, turn to the page
4 that has Paragraph 92.

5 Go ahead and read Paragraph 92 and let
6 me know when you're ready.

7 A Okay.

8 Q Paragraph 92 says, "Figure H is a
9 partial perspective view of a tissue
10 shrinking electrode device being used in
11 accordance with the present invention,"
12 correct?

13 A That's correct.

14 Q Do you know what a partial perspective
15 view is?

16 A No.

17 Q Do you know what a perspective view is?

18 A Yes.

19 Q So when we're looking at Figure 5H and
20 he says "partial perspective view," how do
21 you interpret that?

22 A Not full perspective.

1 Q Okay. But we can agree a perspective
2 view of Figure 5H, correct?

3 A That's correct.

4 Q Okay. So if you could, then, please,
5 turn to Paragraph 187 of Makower,
6 Exhibit 1005, please.

7 A Okay.

8 Q Paragraph 187, Figure 5H of Makower,
9 correct?

10 A That's correct.

11 Q And there are no other paragraphs that
12 describe Figure 5H of Makower besides
13 Paragraph 92 that we just read, correct?

14 MR. STERN: Objection to form.
15 Foundation.

16 A There was the paragraph that you just
17 referred to before that talks about 5H.

18 Q I agree. So let me ask you a better
19 question.

20 Other than Paragraph 92, which we just
21 read and Paragraph 187, that you're now
22 looking at, are you aware of any other

1 discussions of Figure 5H in Makower?

2 MR. STERN: Objection to form.

3 Foundation.

4 A All I can say is that these two
5 paragraphs do mention and refer to the Figure
6 5H. I cannot sit here and give you a full
7 answer whether there's any reference anywhere
8 in Makower about 5H. I don't know the
9 answer.

10 Q Fair enough.

11 The first sentence of Paragraph 5H
12 says -- or excuse me.

13 The first sentence of Paragraph 187
14 says, "Figure 5H shows an electrical surgical
15 device, 208, comprising a flexible shaft
16 (e.g. a catheter or solid shaft) having
17 arched strut members 214 attached thereto."

18 Do you see that?

19 A I see that.

20 Q What's your interpretation of a strut
21 member?

22 MR. STERN: Objection to form.

1 A A member of struts. So strut member is
2 a member with strut.

3 Q So the plain and ordinary meaning of
4 strut?

5 MR. STERN: Objection to form.

6 A With my English, I understand strut as a
7 structure, a framework, strut, yeah.

8 Q Okay. Do you generally interpret strut
9 to be a rigid structure?

10 MR. STERN: Objection to form.

11 Foundation.

12 A It can be rigid; it can be flexible.

13 Q Do you believe the strut members of
14 Makower are flexible?

15 MR. STERN: Objection to form.

16 A I have to -- what he says collapsable
17 and expandable, so I think it can be
18 flexible, if they are collapsible and
19 expandable.

20 Q In Figure 5H of Makower, how many strut
21 members does he illustrate?

22 A Here he points to two; when he says --

1 when he use reference 214 as indicating the
2 struts, he points towards two.

3 Q Okay. In Figure 5H just below the
4 number 214, there appears to be a point
5 extending from the end of the struts.

6 Do you see what I'm referring to?

7 A You're talking about the figure or the
8 paragraph now?

9 Q The figure.

10 A Okay. So the figure you're saying -- do
11 you mind repeating?

12 Q No. No problem.

13 So we've identified the strut members,
14 correct?

15 A Correct.

16 Q And extending from those strut members,
17 in what I would call a generally
18 northeasterly direction is a point or a tip.

19 Do you see that?

20 A Yes, I do.

21 Q And what is the purpose of that object?

22 MR. STERN: Objection to form.

1 A I don't know what Makower intends with
2 that object. I see it as part of the shaft,
3 but I don't know what he intends. What does
4 he extend beyond the struts, I don't know.

5 Q Okay. The next sentence of Figure 5H
6 says:

7 "Electrodes 216 are located on
8 the strut members 214".

9 Do you see that?

10 A I do.

11 Q How many electrodes are illustrated in
12 Figure 5H?

13 MR. STERN: Objection to form.

14 A In his figure when he says 216, Makower
15 points to two. When I look at the whole
16 figure, there are other structures not shown
17 on this figure that resemble them. But
18 Makower did not specify whether these are --
19 I mean, when he say 217 he pointed to two
20 such structures.

21 But I see four such structures in there,
22 but he points to two of them.

1 Q Okay. Makower says that those
2 electrodes are located on the strut members
3 214.

4 Do you see that?

5 A I do.

6 Q How are they located on those strut
7 members as illustrated in Figure 5H?

8 A How? I don't know. But he points to
9 them on the struts. So 214 is the strut, 216
10 is electrode; 216 in on -- what he refers to
11 as the strut. So these electrodes are
12 located on the strut, but how, I don't know
13 how.

14 Q Okay. Next sentence says, in
15 Paragraph 187, says:

16 "In some cases the strut members may be
17 a fixed configuration. In other cases the
18 strut members may be collapsible and
19 expandable."

20 Do you see that?

21 A I do.

22 Q Which one do you think is illustrated in

1 Figure 5H?

2 MR. STERN: Objection to form.

3 Foundation.

4 A Just seeing one figure at one point in
5 time, I cannot sit here and tell you which
6 one of these he's referring to in this
7 partial perspective that we talked about when
8 he says partial perspective of Figure 5H.

9 So just looking at one Figure, one point
10 of time and one -- in one page, I cannot say
11 whether this, he means these are fixed or
12 whether he means these are collapsible, or
13 whether he means they are expandable. I
14 can't make that determination just looking at
15 this figure.

16 Q How would you need to design Figure 5H
17 to make it both collapsible and expandable?

18 A If I'm designing it, and if I intend to
19 say collapsible and expandable, I would have
20 '5H', "5H", "'5H'", showing it in different
21 modalities. Within how the medical artist
22 can show it, to show it in collapsed form, to

1 show it in an expanded form.

2 I cannot show it in a flexible or rigid
3 form because this is not dynamic. It's a
4 video. So as far as rigid or flexible, this
5 will not show here unless I describe.

6 But collapse or expanded, then I have to
7 show you collapsed, and I have to show you
8 expanded. And that way I can tell you, this
9 is collapsed, this is expanded.

10 Q Okay. Thank you.

11 My question was slightly different.
12 Which was, how would you configure the device
13 of 5H so that that device could be both
14 collapsible and expandable?

15 A How would I configure it, even though I
16 am not the patent owner?

17 Q How do you interpret being able to do
18 that, is my question, given Makower says that
19 that's an option?

20 A That could be many mechanisms. I mean,
21 I am not the patent owner, but there are many
22 mechanisms. Maybe you can expand strut in

1 many ways. It can be mechanical, it can be
2 pneumatic, it can be any form, by injecting
3 fluid into it. I mean, there are many ways
4 that you can make someone go from being
5 collapsed into being expanded.

6 Q Okay. The next sentence of
7 Paragraph 187 says:

8 "In operation, the device 208 is
9 advanced into a passageway such as a nostril,
10 a nasal cavity hiatus, ostium, interior of a
11 sinus, et cetera".

12 Do you see that?

13 A I do.

14 Q Do you know which one of those Makower
15 is illustrating in Figure 5H?

16 MR. STERN: Objection to form.

17 A No. I do not.

18 Q Can you look at Figure 5A for me,
19 please.

20 A 5A.

21 Q Would be the other way. There you go.

22 A 5A.

1 Q So can you compare the tissue, alleged
2 tissue of Figure 5A, versus the tissue of
3 Figure 5H and how that's illustrated, please,
4 and then let me know when you're finished.

5 A Just looking at the figures without
6 reading the description?

7 Q You can read the description if you want
8 to, but I will tell you, it's not stated, but
9 you can go ahead and confirm that, if you
10 want.

11 A Just looking at the figures, I cannot
12 say what's the difference in tissue. So just
13 looking at the figures alone, I cannot
14 differentiate what kind of tissue is being
15 represented here.

16 So without the benefit of reading what
17 Makower described about 5A and 5H, there is
18 no way for me to know, just looking at the
19 figures.

20 Q Well, for Figure 5H, we just read the
21 locations, right, but it's easily not
22 discernible which location he's talking

1 about, or illustrating, excuse me, from

2 Figure 5H alone. Is that fair?

3 MR. STERN: Objection to form.

4 A From 5H alone and this figure, I cannot
5 know -- I cannot sit here and tell you where
6 it is.

7 Q Okay. So if you look at Figure 5A,
8 please.

9 A Yes.

10 Q And we see that the tissue is
11 represented with lines that are generally
12 angled, but parallel.

13 Do you see that?

14 A I do.

15 Q Is that a common way to illustrate
16 tissue in the medical field?

17 MR. STERN: Objection to form.

18 Foundation.

19 A There are many ways of drawing tissue.

20 Q Let me ask you a better question.

21 Is that the way that tissue is labeled,
22 would that readily indicate to a person of

1 ordinary skill in the art which tissue that
2 would be?

3 For instance, what I have in my head is
4 some kind of legend, so certain times use
5 certain labeling characteristics in maps or
6 other things to indicate geographical
7 features.

8 Is there something similar to that which
9 going on in Figure 5A, where these diagonal
10 lines are indicating a certain type of
11 tissue?

12 MR. STERN: Objection to form.
13 Foundation.

14 A Not that I'm aware of, not that I've
15 used.

16 Q Does that same answer also apply to
17 Figure 5H, 5I, 5J, for instance, where we
18 have tissue labeled with a series of dots
19 instead of the diagonal lines?

20 A Any of these figures, I cannot just look
21 at that figure say, uh-huh, this is Makower
22 is referring to tissue A or tissue B or

1 location A or location B, I cannot tell this
2 just looking at figures.

3 Q Okay. Is the device of Figure 5H
4 suitable for use in the sinus?

5 Specifically, he says, interior of a
6 sinus. Do you consider that device to be
7 suitable for use interior of a sinus?

8 A I don't know what he means by interior
9 of the sinus, and which sinus he's talking
10 about. There are four sinuses. Which have
11 different shapes, different sizes.

12 So I can't sit here and answer you if
13 this is appropriate for the inside of the
14 sinus, because I don't know which sinus and
15 what does he mean by inside of the sinus.

16 I mean, inside, I know that, but I don't
17 know whether he's treating a structure inside
18 the sinus, or what is he treating in the
19 sinus. The lesion in that sinus, is it tumor
20 in that sinus. I don't know what he says
21 inside the sinus, what he means. So I cannot
22 answer you whether this device, I cannot

1 answer your question.

2 You asked me whether this device is
3 suitable for inside the sinus, correct?

4 Q That's what I said, yeah.

5 A So I cannot sit here and answer because
6 I don't know what he means and which sinus
7 he's talking about and for which indication.

8 Q Okay. The next sentence of
9 Paragraph 187 of Makower reads:

10 "Thereafter, current is applied to the
11 electrodes 216 causing tissue adjacent to the
12 struts 214 to be cauterized or heated."

13 Do you see that?

14 A I do.

15 Q Is there a difference between
16 cauterizing and heating?

17 MR. STERN: Objection to form.

18 A It depends how much -- for me, as a
19 surgeon, cauterize means burn. So you do
20 cauterization, means you are burning tissue.
21 Heated means heating tissue.

22 So this is the difference, in my mind,

1 when I say cauterized or heated.

2 Q Okay. How does Makower supply the
3 electrical current necessary to energize the
4 electrodes of Figure 5H?

5 A I have to go back and look entire
6 Makower. But my understanding is that he did
7 not go into specifics about that, and he said
8 people who of ordinary skill in the art would
9 know what to use, what generally to use,
10 depending on what they're doing.

11 Q And you're a person of ordinary skill in
12 the art, right?

13 A I am a person of ordinary skill in the
14 art.

15 Q So, with that understanding, he's saying
16 people would know is there a manner in which
17 you understand Figure 5H to be able to
18 electrically connect electrodes to an
19 external generator?

20 A If these are electrodes, they can be
21 connected to an external generator. And what
22 generator, what their generator generates is

1 the kind of energy you are applying.

2 Q Would the wires be on the outside of the
3 struts to connect to an electrical generator?

4 MR. STERN: Objection to form.

5 A I'm not an electrical engineer, but I
6 can -- the electric engineer would make
7 determination what's the most optimal way,
8 what's the optimal way of connecting these
9 two, which is efficient and safe.

10 Q Okay. The next sentence of
11 Paragraph 187 of Makower reads:

12 "The electrode 216 may be bipolar,
13 monopolar or facilitated by any other
14 suitable form of energy such as gas or plasma
15 arc."

16 Do you see that?

17 A I do.

18 Q What is a monopolar electrode?

19 A So an electrode is an electrode, and
20 monopolar indicates the way you are
21 delivering energy through that electrode.

22 So monopolar means there is one pole.

1 So that electrode is delivering energy. So
2 there is one delivering energy, this is
3 monopolar. There is a point in the body
4 where that energy exits. And, usually, when
5 we use monopolar, there is a pad somewhere in
6 your body where the current will exit. So
7 basically there is an electrode that is being
8 used in the monopolar mode.

9 Q And how does the bipolar electrode work?

10 A Again, bipolar refers to the modality of
11 delivering energy to these electrodes. So
12 bipolar indicates two poles. Bipolar. So
13 there are two poles, therefore, two
14 electrodes. One that is active, one where
15 the energy enters, and one where the energy
16 exits. So, hence, becomes bipolar from pole
17 to pole, bipolar.

18 Q Do you know if the device of Figure 5H
19 is illustrated in a bipolar or monopolar
20 configuration?

21 MR. STERN: Objection to form.

22 A It shows multiple electrodes. Again, at

1 least two electrodes. So these two
2 electrodes, they can be configured to be each
3 one of them monopolar. They can be
4 configured that they match together and they
5 function in bipolar modality.

6 So you can activate one of them in the
7 monopolar mode. You can activate two of them
8 in monopolar modes, or you can pair them
9 together in the bipolar mode.

10 Q Okay. When you're using a device such
11 as Figure 5H in Makower, is it better to use
12 a monopolar or bipolar configuration?

13 MR. STERN: Objection to form.

14 Foundation.

15 A It depends on the indication. And there
16 are many indications. So it depends on the
17 indication. So sometimes monopolar is
18 better, sometimes bipolar is better.

19 Q When you say indication, I don't know
20 that I understand that term.

21 What do you mean by indication?

22 A The reason you are using this device for

1 what condition you are treating.

2 Q Okay.

3 A So the reason you are using this device
4 will also -- this is the indication, the
5 clinical reason, that's the indication. And
6 then there are some medical conditions that
7 are better treated with the monopolar
8 modality. Some are better treated through a
9 bipolar modality.

10 Q Is bipolar or monopolar better for
11 controlling bleeding?

12 MR. STERN: Objection to form.
13 Foundation.

14 A Each one has its place. So I've used
15 both monopolar and bipolar for controlling
16 bleeding.

17 Q In what situations have you used
18 monopolar for controlling bleeding?

19 A Many times. If you come to me with a
20 laceration and there is bleeding, sometimes I
21 use monopolar, and then I stopped the
22 bleeding site. So many times when there is

1 bleeding during the case, we use monopolar.
2 And this is very frequently used, many times.
3 But at times we feel that bipolar is the
4 better way of utilizing it.

5 So, for instance, when you use
6 cauterizing, you always have both modes
7 available, and many times switch between
8 monopolar and bipolar, depending on what
9 we're doing, the indication and so on.

10 Q Can you ablate tissue with both bipolar
11 and monopolar configurations?

12 MR. STERN: Objection to form. Lacks
13 foundation.

14 A Yes.

15 Q Does ablation destroy tissue or modify
16 tissue?

17 MR. STERN: Objection to form.

18 Objection to foundation.

19 A It can be both. So when you ablate, you
20 can destroy tissue and/or you can modify
21 tissue.

22 Q What's the difference between modifying

1 and destroying tissue?

2 MR. STERN: Objection to form.

3 A Destroying means destroying. While
4 modifying, it means the tissue is still
5 there, but modified.

6 Q When you destroy the tissue, what
7 happens to that tissue typically?

8 MR. STERN: Objection to form.

9 Foundation.

10 A It depends where that tissue is located.
11 If it's externally, it's lost. If I ablate
12 your skin, it's lost, it falls off, and it is
13 on the ground. If it is under the surface,
14 there are mechanisms for the body to take
15 care of that. To take care of that ablated
16 tissue.

17 Q Would you want to destroy tissue when
18 you're using RF energy on an inferior
19 turbinate?

20 MR. STERN: Objection to form.

21 Foundation.

22 A It depends what is the indication, why I

1 am doing it. So what I intend to
2 achieve depends why I'm doing the indication,
3 the symptoms, the structure, the disease.

4 So sometimes destroying tissue is
5 reasonable. Sometimes preserving tissue, but
6 altering it is more reasonable. So this --
7 so I, as a surgeon, would have to make that
8 decision. For this indication, this is
9 better, for that indication, that is more
10 reasonable.

11 Q Okay. That sentence that we have been
12 speaking about concludes with, "or
13 facilitated by any other suitable form of
14 energy such as gas or plasma arc."

15 Do you see that?

16 A I do.

17 Q How would you use electrodes of Figure
18 5H with gas?

19 A I am not a gas expert, so I cannot
20 answer that question.

21 Q How would you use the electrodes of
22 Figure 5H with plasma arc?

1 A I have to know more about what he means
2 with plasma arc.

3 Q So as a person of skill in the art, how
4 do you interpret plasma arc?

5 MR. STERN: Objection to form.

6 A I have to understand the context of this
7 plasma arc, what does Makower mean with
8 plasma arc.

9 Q Is the term plasma arc used routinely in
10 this field?

11 MR. STERN: Objection to form.

12 A Not by me and not by my colleagues.

13 Q Okay. So Figure 5H discloses those
14 arched struts, correct?

15 A That's correct.

16 Q And if you position those arched struts
17 in the nose, is it possible that some of the
18 electrodes may be in touch with tissue where
19 others would not be in touch with tissue?

20 MR. STERN: Objection to form.

21 Foundation.

22 A I can envision that, yes.

1 Q So what happens when the device is
2 working but not touching tissue of Figure 5H?

3 MR. STERN: Objection to form.
4 Foundation.

5 A So for instance, if -- let's say these
6 are four electrodes, and two are touching
7 tissue and two are just floating in the air,
8 the two floating in the air would be
9 inactive, while the two touching the tissue
10 would be used to either ablate or alter
11 tissue.

12 Q The last sentence of Paragraph 187 says:

13 "Additionally, sensing elements
14 may also be attached to the catheter,
15 and/or strut member to monitor various
16 parameters of the catheter and/or
17 surrounding tissue (e.g., temperature,
18 et cetera)."

19 Do you see that?

20 A I do.

21 Q Besides temperature, which is mentioned,
22 what else would be monitored with the

1 Figure 5H device of Makower?

2 MR. STERN: Objection to form.

3 A I've used devices where impedance is
4 being measured. I've used devices where the
5 total amount of juice -- amount of energy is
6 being measured. So there are different
7 things that you can measure.

8 Q Okay. If you could now go to your
9 declaration in the 0279 IPR, Paragraph 171,
10 which is on Page 114 of your declaration.

11 A Okay.

12 Q If you could just read that to yourself
13 and let me know when you're ready.

14 A Which paragraph you want me to read?

15 Q One hundred seventy-one?

16 A Okay.

17 Q The last sentence of Paragraph 171 says:

18 "Fang provides additional details
19 about the well-known design
20 construction and operation of the
21 Makower electrosurgical device that
22 delivers RF energy."

1 Do you see that?

2 A I do.

3 Q I see no citation to Fang there. Do
4 you?

5 A I don't.

6 Q Can you point me to the portions of Fang
7 that provide the additional details about the
8 well-known design, construction and operation
9 of the Makower device?

10 MR. STERN: Objection to form.

11 A Setting at a -- setting of three would
12 be one way of operation.

13 Q Level three?

14 A Level three.

15 Seeing where he would place it that
16 would also be operation. He mentions the
17 machine that he mentions, the device that he
18 mentions. And that would be about design and
19 construction. So he specifically mentions a
20 device that he used; therefore, that talks
21 about the design and construction.

22 And he also describes how he used it,

1 how did he apply it, where he applied it and
2 which setting. And that would be operation.

3 Q We talked earlier about Figure 5H of
4 Makower and that it appears to be the only
5 figure in the Makower having RF electrodes
6 illustrated on the device, correct?

7 MR. STERN: Objection to form.

8 A As we -- as I answered this question
9 before, without going through and read it,
10 every word in Makower, 5H shows a device with
11 electrodes.

12 Q And we've also gone through the numerous
13 disclosures in Makower about the importance
14 of flexible catheters, correct?

15 MR. STERN: Objection to form.

16 Foundation.

17 A We talked about flexible, and we talked
18 about rigid. So we cited many paragraphs
19 where the word "flexible" came up, and we
20 talked about paragraphs where "rigid" also
21 came up.

22 Q Do you agree that Makower's focus is the

1 use of flexible catheters with various
2 working devices, occluders, et cetera?

3 MR. STERN: Objection to form.

4 Objection to foundation.

5 A I haven't considered all what
6 Makowers (sic) writes or what Makowers claim.
7 I just chose parts that are relevant to my
8 declaration and that are relevant to Fang's
9 teachings. So I found Figure 5H with the
10 descriptions about it rather than to Fang's
11 teaching, so that's why I included this -- I
12 included Figure 5H with Fang.

13 Q Prior to reading Makower, had you ever
14 seen a device like Figure 5H in practice?

15 MR. STERN: Objection to the form.

16 A Exactly like Figure 5H?

17 Q Yeah.

18 A Not that I recall.

19 Q If you could please go to your 00281
20 declaration.

21 A Okay.

22 Q Exhibit 1007 from that proceeding.

1 (Whereupon, Declaration of Dr.
2 Gregory T. Martin was marked as
3 Exhibit 1007 for identification
4 as of this date.)

5 Q We'll look at Exhibit 1007 in a second,
6 but why don't we first go to Paragraph 26 of
7 your declaration.

8 A Paragraph 26, you said?

9 Q Okay. That's not right. Let me get you
10 to the right place, I'm sorry.

11 Twenty-five, you already told me about
12 it. Paragraph 25 of your declaration for
13 00281.

14 A Twenty-five; yes.

15 Q The last sentence reads:

16 "I have also relied on a
17 conversation with Dr. Gregory Martin
18 and have reviewed his declaration for
19 this IPR."

20 Correct?

21 A That's correct.

22 Q And what I handed you, Exhibit 1007, is

1 the declaration of Dr. Gregory T. Martin,
2 correct?

3 A I don't recall how his declaration
4 looks.

5 Q If you look at the front page, it has
6 his name.

7 A Okay. Okay.

8 Q And if you want to leaf through it real
9 quick and make sure that it appears to be the
10 declaration you're referring to here, that
11 would be great.

12 A I'll take your word for it.

13 Q Don't take my word for it. I mean, it
14 says Exhibit 1007 --

15 A Okay.

16 Q -- right, in your declaration, and that
17 appears to me to be Exhibit 1007, so.

18 A Okay.

19 Q Let's assume that is the declaration
20 then.

21 A Okay.

22 Q So when did this conversation with

1 Dr. Martin occur?

2 A I don't recall the date.

3 Q Okay. Obviously prior to January 7,
4 2024, correct?

5 A Prior to me writing my declaration.

6 Q Okay. And what did you guys discuss?

7 A I had some questions for him. He had
8 some questions for me. We went over his
9 findings.

10 Q What kind of questions?

11 A I don't recall the exact questions.
12 This happened almost a year ago.

13 Q Was there particular topics that you
14 wanted to talk to Dr. Martin about?

15 A He has engineering background, so it was
16 issues pertaining to the engineering part.

17 Q Okay. Do you know Dr. Martin -- did you
18 know Dr. Martin before you had this
19 conversation with him?

20 A I did not.

21 Q You've never previously met Dr. Martin
22 before this proceeding?

1 A I have not.

2 Q Okay. Did you know Dr. Martin was
3 deposed in conjunction with these
4 proceedings?

5 A I do.

6 Q You do know that?

7 A Yeah.

8 Q Did you happen to review his deposition
9 testimony?

10 A No.

11 Q So when Dr. Martin provided this
12 declaration to you, did you provide any
13 comments to him on it?

14 A Comments on his declaration?

15 Q Right.

16 A Like things to edit?

17 Q Right.

18 A No.

19 Q You simply reviewed it?

20 A That's correct.

21 Q Did he review your declaration?

22 A That I don't know, but when I spoke with

1 him, I hadn't written my declaration yet. So
2 I don't know whether counsel gave him my
3 declaration later on and whether he reviewed
4 my declarations later on. I don't know.

5 Q But you didn't receive any edits from
6 Dr. Martin on your declaration?

7 A No. I did not.

8 Q Okay. So in 00281, your declaration, if
9 we could go to Paragraph 214, which is --
10 starts on Page 161.

11 A Okay.

12 Q So Paragraph 214 says:

13 "As detailed below, the
14 combination of Makower, Fang,
15 Edwards-535 and Stern renders Claim 4
16 obvious."

17 Do you see that?

18 A Yes, I do.

19 Q And this is the claim that you had a
20 discussion about with Mr. -- or excuse me,
21 Dr. Martin, correct?

22 A I forgot what I asked him about this

1 particular claim. If I cite Dr. Martin in
2 this paragraph of my declaration, it means I
3 referenced my discussion with him. If I
4 don't cite it here, I don't recall.

5 Q I'm sorry, let me help you. Please go
6 to Paragraph 222.

7 A Okay.

8 Q Why don't you go ahead and read that.

9 A Okay.

10 Q So it's correct that you talked to
11 Dr. Martin, or at least relied on his
12 declaration, as it relates to Claim 4 of the
13 '077 Patent, correct?

14 MR. STERN: Objection to form.

15 A I discussed it with Dr. Martin, but the
16 opinions are mine. And his opinions --
17 looking for the word -- sort of coincided or
18 reinforced or affirmed my opinions.

19 Q And Claim 4 requires, if we look at
20 Page 161, the apparatus at Claim 2 when at
21 least two bipolar radiofrequency electrodes
22 comprise multiple pairs of bipolar

1 radiofrequency electrodes, correct?

2 A That's correct.

3 Q Why did you feel it was necessary to
4 reach out -- or not reach out. Strike
5 that -- to rely on Dr. Martin's declaration
6 to confirm your understanding for this claim?

7 MR. STERN: Objection to form.

8 Foundation.

9 A We discussed the electric circuitry and
10 how you can configure various electrodes to
11 perform in a bipolar mode and which
12 electrodes to be paired together and how do
13 you do that.

14 Q Did you have knowledge of how to do that
15 before you spoke with Dr. Martin?

16 A I am not an electrical engineer, so
17 whatever my general knowledge about the
18 field, no, but I'm not an electrical
19 engineer.

20 Q So since you're not an electrical
21 engineer, you wanted to talk to Dr. Martin
22 about Claim 4?

1 MR. STERN: Objection to form.

2 Foundation.

3 A To -- so that I can spoke -- so I spoke
4 with Dr. Martin to get his take, his
5 understanding, based on his experience being
6 an engineer about these electrodes.

7 Q Would you have felt comfortable
8 submitting this declaration without
9 Dr. Martin's analysis?

10 MR. STERN: Objection to form.

11 Foundation.

12 A Just -- I mean, knowing about what I
13 know from physics in medical school about
14 electrodes and electricity and switches, I
15 have knowledge how switches work and how you
16 can pair two electrodes and how -- but I've
17 been -- I don't know the technical how on how
18 to make it, but I know that it can be made.

19 Q Is there anything you disagreed with in
20 Dr. Martin's declaration?

21 A I mean, I am not here to say whatever
22 Dr. Martin -- agree or disagree, because my

1 opinions are my opinions. And my opinions
2 are based on my review of the case. So I'm
3 not here in the position to say if Dr. Martin
4 is -- agree or disagree -- or I mean, I'm not
5 in a position to discuss Dr. Martin's
6 declaration.

7 Q You know that conflicts with the
8 reliance on Dr. Martin's declaration,
9 correct?

10 MR. STERN: Objection to form.
11 Foundation.

12 A I relied on it on how he explained these
13 things, but I'm not here to say whether every
14 sentence in there -- I'm not an electrical
15 engineer. So I'm not here to say -- I am not
16 the person to say whether Dr. Martin's
17 declaration is right or wrong, or accurate or
18 not accurate. I'm not the expert. I mean,
19 I'm not in a position to make that
20 determination.

21 Q Okay. If you could, please, go to
22 Exhibit 1007, which is Dr. Martin's

1 declaration.

2 A Okay.

3 Q And if you could, please, go to Page 49
4 and Paragraph 89 says, "As I explained in
5 section Roman numeral 9A2" it cites the
6 grounds "Stern teaches two bipolar
7 radiofrequency electrodes that comprise
8 multiple pairs of bipolar radiofrequency
9 electrodes."

10 Do you see that?

11 A I do.

12 Q So Dr. Martin is referring us to Section
13 9A2, we should go there. So if we go to
14 Page 27 of Dr. Martin's declaration.

15 I'm sorry, it's not -- oh, it is
16 Page 27.

17 Why don't you read Paragraphs 55, 56 and
18 let me know when you're finished?

19 A 55 to 56, you said -- 55 and 56?

20 Q Yes, please.

21 So Paragraphs 55 through 56, Dr. Martin
22 is talking about the Stern reference,

1 correct?

2 A That's correct.

3 Q And at the end of Paragraph 56 he says:

4 "In other words, Stern teaches
5 two bipolar radiofrequency electrodes
6 that comprise multiple pairs of bipolar
7 radiofrequency electrodes."

8 Do you see that?

9 A I do.

10 Q Do you agree with that conclusion?

11 A Stern shows multiple electrodes. And
12 Stern says these can be used either monopolar
13 or bipolar, and that you can chose to pair
14 any of these two electrodes in a bipolar way.

15 Q So the answer is yes, you agree with
16 Dr. Martin here, that Stern teaches bipolar
17 radiofrequency electrodes that comprise
18 multiple pair of bipolar radiofrequency
19 electrodes?

20 MR. STERN: Objection to form.

21 A I mean, I agree with the concept, but I
22 might word it differently. If I'm writing

1 this, I would have worded it differently.

2 Q Do you know why he has the words in
3 italics?

4 A Because he's copying from Stern, I
5 assume. But I did not write his declaration,
6 so I don't know why he's using italics.

7 Q I see the issue. So why don't we go
8 back to your declaration, and why don't we go
9 back to Page 161.

10 A Yeah.

11 Q And at Page 161, the claim is in bold.

12 A Yeah.

13 Q Reading the claim it says, "Be at least
14 two bipolar radiofrequency electrodes
15 comprise multiple pairs of bipolar
16 radiofrequency electrodes."

17 Do you see that?

18 A I do.

19 Q And if we look at italicized language of
20 Dr. Martin, at the end of Paragraph 56, that
21 aligns with the language of Claim 4, correct?

22 A I'm sorry. Which paragraph now again,

1 in Martin's?

2 Q Paragraph 56, Page 30, the last
3 sentence.

4 A I see that.

5 Q So would you agree that Dr. Martin is
6 quoting the claim language in his last
7 sentence, by the use of italics for those
8 words?

9 A I see the words are similar. I don't
10 know why he's using it in italics, but the
11 words appear to be similar.

12 Q So my interpretation is he's using those
13 italics because they align with the claim
14 language.

15 So my question is: Do you agree with
16 his analysis because that analysis relates to
17 Claim 4?

18 A In his analysis that Stern teaches
19 bipolar radiofrequency electrodes that
20 comprises multiple pairs of electrodes?

21 So I agree that Stern teaches multiple
22 electrodes, which can be paired together and

1 depending on how many of them you pair, they
2 can become multiple pairs if you pair many of
3 them together. So each two can become a
4 pair. So if you decided to activate five of
5 them, then he's activating five pairs;
6 because for every bipolar you need two.

7 And so they're using -- yes, so you need
8 two electrodes to be able to be bipolar, so
9 to be able to deliver energy in a bipolar
10 form you need two electrodes as we discussed;
11 bipolar from pole to pole. And this can be
12 multiple pairs if there are multiple
13 electrodes.

14 Q So, yes, you agree that Dr. Martin's
15 analysis that Stern discloses the limitations
16 in Claim 4?

17 A Yeah.

18 Q Okay.

19 MR. BRIGGS: Let me check with my
20 external colleagues real quick, and I
21 will be right back.

22 MR. STERN: Sure. Should we go off

1 the record?

2 MR. BRIGGS: Off the record, please.

3 Thank you.

4 (Whereupon, a recess was taken
5 from 4:33 PM until 4:36 PM.)

6 MR. BRIGGS: Back on the record.

7 No further questions for Dr. Bu-Saba,
8 at this time.

9 MR. STERN: Petitioners don't have any
10 questions, either.

11 (Whereupon, this examination was
12 concluded at 4:36 PM.)

13

14

15

16 _____
NICOLAS BU-SABA

17

18

19 Subscribed and sworn to
20 before me on this ____ day
of _____, _____.

21

22

Notary Public

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I N D E X

WITNESS: DR. NICOLAS BU-SABA

EXAMINATION BY	PAGE
MR. BRIGGS	4

E X H I B I T S

EXHIBIT	DESCRIPTION	PAGE
Exhibit 1001	U.S. Patent No. 10,894,011	8
Exhibit 1005	U.S. Patent Pub. No. 2005/0240147 to Makower	47
Exhibit 1006	Fang Chao-xin and Zhen Shao-Shao, Nasal endoscopy	47
Exhibit 1008	U.S. Patent No. 6,517,535 to Edwards	49
Exhibit 1009	U.S. Provisional Appl. No. 60/702,077	50
Exhibit 2001	Sinusitis, from microbiology to management	79
Exhibit 0771	U.S. Patent No. 10,610,675	122
Exhibit 1007	Declaration of Dr. Gregory T. Martin	304

CERTIFICATE OF NOTARY PUBLIC

I, Raechel Meyerowich, Notary Public,
do hereby certify that the aforementioned witness
was sworn before me at the aforementioned location,
and that I am neither counsel for, related to, nor
employed by any of the parties to this case and
have no interest, financial or otherwise, in its
outcome.

IN WITNESS WHEREOF, I have hereunto set
my hand and affixed my notarial seal this 17th day,
of October, 2024.

My Commission Expires: June 7, 2030

Raechel Meyerowich

Raechel Meyerowich, Notary Public
for the State of Massachusetts

C E R T I F I C A T E

I, KIARA MILLER,, Certified Reporter,
do hereby certify:

That DR. NICOLAS BU-SABA, the witness whose
deposition is hereinbefore set forth, was duly
sworn by me before the commencement of such
deposition and that such deposition was taken before
me and is a true record of the testimony given by such
witness.

I further certify that the adverse party,
PETITIONERS, was represented by counsel at the
deposition.

I further certify that the deposition of
DR. NICOLAS BU-SABA occurred at the offices of
WILMER CUTLER PICKERING HALE & DORR, LLP, 60 State
Street, Boston, MA 02109, on Thursday, October 17,
2024, commencing at 9:03 AM to 4:36 PM.

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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