

FORTE BIOSCIENCES, INC.,)
)
 Petitioner,)
) Case No. PGR2023-00014
 vs.)
) Patent No. 11,278,505
UNIVERSITY OF MASSACHUSETTS,))
)
 Patent Owner.)
_____))

Location:
The Westin Dallas Southlake
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Southlake, Texas 76092

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PREVIOUSLY MARKED EXHIBITS

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(Exhibits were retained by counsel and are not
attached hereto.)

P R O C E E D I N G S

THE REPORTER: We are here for the deposition of Ronald Todd Plott. Today's date is September 22, 2023. The time is 9:03 a.m. We are here in the matter of Forte Biosciences, Petitioner, versus University of Massachusetts, Patent Owner, before the United States Patent and Trademark Office, Case No. PGR2023-00014.

Would counsel please state your appearances, beginning with the noticing attorney.

MS. ROBERTS: Hi, Dr. Plott. My name is Jessica Roberts on behalf of Patent Owner, and I'm here with Mark Feldstein, also on behalf of Patent Owner.

MR. MILLS: Jad Mills with Wilson Sonsini representing Forte Biosciences, Petitioner.

(The witness was sworn by the reporter.)

R. TODD PLOTT, M.D.,
having been first duly sworn, testified as follows:

E X A M I N A T I O N

BY MS. ROBERTS:

Q. Thank you. I see you have a folder there with you. Can you please tell me what's in your binder?

A. I have my declaration.

1 Q. Okay. Great. Do you need a separate
2 copy, or are you okay to use that and rely on that
3 copy?

4 A. I'm fine to use this copy.

5 Q. Do you have the documents that are also
6 cited in your declaration?

7 A. I do.

8 Q. Okay. Have you considered -- one other
9 question. The first document, you have a copy of
10 the patent, which is Exhibit 1001. It's labeled on
11 the bottom-hand corner if you see that there.

12 A. Yes, I see that.

13 Q. Okay.

14 A. Yes, I do.

15 Q. And then your declaration is labeled
16 Exhibit 1004.

17 A. Yes, I have that.

18 Q. And then besides what you have before you
19 and anything cited in your declaration, did you rely
20 on any other information to form your opinions in
21 this case?

22 A. No, I did not.

23 Q. No? You had previously noted that you
24 have received a first place in a national research
25 competition for your research into vitiligo. Can

1 you describe what type of research you did for
2 vitiligo?

3 A. We had normally pigmented and vitiliginous
4 skin on patients where we took their normally
5 pigmented skin and grew those cells in -- the
6 epidermal cells and the melanocytes in culture.

7 Q. Okay.

8 A. And then took those cells and dermabraded,
9 which means kind of removed that protective layer of
10 skin, and put those cells into the depigmented area
11 of the vitiliginous skin to see if we could get
12 repigmentation.

13 Q. Were they treated with anything?

14 A. No, just --

15 Q. No?

16 A. It was a cell culture transfer. So, you
17 know, trying to expand their normally pigmented skin
18 cells to cover a larger area.

19 Q. Okay. And this was done in human -- you
20 had a subset of human patients that you did this
21 study in?

22 A. They were all humans.

23 Q. They were all humans? And what year was
24 that research done in?

25 A. That was done in '88 and '89.

1 Q. In paragraph 10 you mention that you
2 considered various other documents. What are those
3 various other documents that you're referring to?

4 A. I'm not sure what -- paragraph 10 of --

5 Q. Paragraph 10 on page 2 of your
6 declaration.

7 A. Okay. Right. As I stated here, I've also
8 reviewed and considered the patent and various other
9 documents that are cited in this declaration. So
10 I've only relied on the documents that were cited in
11 this declaration.

12 Q. Okay. Did you investigate if there were
13 any other references to support your opinions that
14 you made in your declaration?

15 A. No. These were the documents that I
16 relied on.

17 Q. And then if you turn to paragraph 24 and
18 25, you state that -- in the first line of each, you
19 said that you reviewed the '505 patent in its
20 entirety. Can you just explain what you mean by
21 "entirety"?

22 A. Well, reading it from the first page to
23 the last page.

24 Q. Did you consider any of the references
25 that were cited in the patent?

1 A. I did consider some of those references.

2 Q. Do you recall which references
3 specifically that you --

4 A. In particular, the references that I have
5 listed in --

6 Q. In your --

7 A. -- in my document.

8 Q. Okay. If you can open up Exhibit 1001 of
9 the '505 patent and column 7. In column 7, about
10 halfway down on line 33, there's a section called,
11 "Inhibitors of IL-15 and the IL-15 receptor."

12 A. I see that.

13 Q. Did you consider any of those references
14 when you relied on and prepared your declaration?

15 A. So I'm sure that we're talking about the
16 same thing, are you referring to all the references
17 that might be listed in the rest of column 7?

18 Q. Right. The first reference is recited in
19 about line 39. It's a WO number, and that's a
20 patent publication ending in 822. So that
21 references a patent publication describing benzoic
22 acid derivatives that are small molecule inhibitors
23 of the IL-15 receptor alpha chain.

24 Are you familiar with any of those
25 references?

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1 MR. MILLS: Objection to form.

2 A. If -- if you're asking about what
3 documents I've referred to or used to form my
4 opinions, all of those are listed here.

5 Q. Okay. So this one, it would not -- is not
6 in your declaration, so you did not specifically
7 rely on that reference in considering --

8 A. I'm not familiar with that particular
9 number. But if it's not listed in my declaration,
10 then I didn't consider that.

11 Q. Okay. I'm going to hand you an Exhibit
12 1030. And this reference is -- so in the last line
13 of column 7, there's a reference here called
14 Hechinger 2015, and it describes antibodies that
15 specifically bind the IL-2 and the IL-15 receptor
16 gamma unit. Are you familiar with this document?

17 A. No. This was not one of the documents I
18 considered.

19 Q. Just summarizing in the abstract, it
20 relates to therapeutic activity of a CD132 inhibitor
21 that they use for the treatment of GVHD. And in the
22 fourth line, they had done some studies and reasoned
23 that inhibition of CD132 could have a profound
24 effect of GVHD.

25 And I can -- please feel free to take a

1 chance to review the abstract. Would you agree that
2 this type of document relates to inhibition of
3 CD132?

4 MR. MILLS: Objection to form, scope.

5 A. Well, I have not had an opportunity to
6 review this and I wouldn't have an opinion to give
7 to you today about this article since, you know,
8 I've not had an opportunity to look at it before.

9 Q. Okay. If it had an effect on GVHD, would
10 you expect that there was some studies done to test
11 the effect of this particular antibody in GVHD?

12 MR. MILLS: Objection to form and scope.

13 A. Yeah, I'll just repeat my former
14 statement, which is, I have not had an opportunity
15 to review this, so I don't have an opinion about
16 this.

17 Q. Okay. Can I hand you Exhibit 1011?

18 Are you familiar with this document?

19 A. Yes, I am.

20 Q. If you turn to column 4, line 25, about
21 halfway down it states, "The invention further
22 provides methods of suppressing an undesired immune
23 response in a patient, comprising administering to a
24 patient an effective regime of any of the
25 antibodies."

1 It goes on. It says, "In some methods,
2 the patient has an autoimmune disease, for example,
3 sclerosis, rheumatoid arthritis, lupus, diabetes,
4 psoriasis," and a few others as it goes on.

5 What sort of basis of concluding that an
6 antagonist of IL-15 signaling would treat those
7 diseases in humans?

8 MR. MILLS: Objection to form, scope.

9 Q. Let me take a step back. Do you know what
10 the -- the abstract, what does it describe,
11 generally, as what the invention relates to?

12 MR. MILLS: Objection to form and scope.

13 A. What you're looking at is a patent that is
14 concerning monoclonal antibodies which are a very
15 specific type of antibody and that are designed to
16 specifically bind a CD122 site. And there again,
17 this abstract states that these are monoclonal. So
18 these are very specific antibodies. And by telling
19 us that they're monoclonal, they're telling us about
20 specificity and that they bind both IL-2 and IL-15
21 such that they can impact the function of those
22 signals. Right?

23 Q. So back to column 4, what is your
24 understanding that these antibodies that inhibit
25 IL-2 or IL-15, what is your understanding that they

1 would have a basis for treatment of the diseases
2 that were cited in the paragraph starting at 25?

3 MR. MILLS: Objection to form, lacks
4 foundation, outside the scope.

5 A. I'm not sure what you're -- where you're
6 going with that, but I can tell you that this is a
7 very different kind of patent than the patent that
8 we are here to look at today. And what this patent
9 pertains to are some antibodies which are being used
10 to inhibit the IL-2 and IL-15. And they are, you
11 know, suggesting in the paragraph that you're
12 mentioning that this might be useful in a host of
13 different conditions that may or may -- where it may
14 or may not be helpful in those conditions. But
15 they're supposing that.

16 Q. And what is your understanding that
17 they -- would they be inferring from other pathways
18 that it would have potential in these recited
19 diseases?

20 MR. MILLS: Objection to form, lacks
21 foundation, calls for speculation, outside the
22 scope.

23 A. I wouldn't speculate about that.

24 Q. And you mentioned monoclonal antibodies.
25 How do they differ from mouse antibodies?

1 MR. MILLS: Objection to form, foundation.

2 Q. Or can you explain what makes a monoclonal
3 antibody specific?

4 A. Well, to make a monoclonal antibody is to
5 make an antibody that's very -- it's much like a key
6 that only fits one lock rather than a master key
7 that might fit many locks. So these are very
8 specific keys that just fit this one lock. And
9 that's what's really important about their
10 instruction here in the abstract is that this is a
11 very specific key.

12 That's not the -- not what we're told
13 about in the '505 patent. The '505 patent doesn't
14 give us any instruction like that. The antibody
15 that's discussed in the '505 patent, ChBMC7 (sic), I
16 believe, the description about that is almost near
17 nonexistent.

18 Q. Were the targets for IL-15 known? You
19 said that this had a lock and a key. So the fit was
20 known, the target site was known, is that correct,
21 as of --

22 A. To make the --

23 MR. MILLS: Hold on.

24 THE WITNESS: Sorry.

25 MR. MILLS: Doctor, she needs to finish

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1 her question before you start answering. Okay?

2 Had you finished, Counsel?

3 Q. As of 2017, was the target site for these
4 monoclonal antibodies against IL-15 signaling known?

5 MR. MILLS: Objection to form, lacks
6 foundation, outside the scope.

7 A. I'd prefer not to speculate on that.

8 Q. So do you not know the answer to that
9 specifically, or you choose not to speculate?

10 MR. MILLS: So I'm going to object to the
11 extent the question calls for speculation.

12 A. I don't have an opinion that I can give
13 you here today.

14 Q. And you mentioned the ChMB7 antibody in
15 the patent. That was a commercial antibody. Is
16 that correct?

17 MR. MILLS: Objection to form. Also
18 object on the basis of lack of foundation.

19 A. I don't recall seeing where the
20 investigator had gotten that antibody.

21 Q. Did you investigate whether the ChMB7
22 antibody was a commercial antibody?

23 MR. MILLS: Objection, foundation.

24 A. No. He just said that that was the
25 antibody that was used.

1 Q. Turning back to Exhibit 1011. There are
2 several examples in the patent. Example 2 on
3 page -- column 21, the bottom of the page, Example 2
4 is titled, "Inhibition of IL-15-Mediated
5 Proliferation."

6 Is it your understanding that these
7 antibodies were tested to determine whether they
8 were antagonist of the IL-15 signaling pathway?

9 MR. MILLS: Objection to form, scope.

10 A. I'm sorry. Tell me where you're at again.

11 Q. Column 21, the bottom of the page.

12 A. Can you repeat your question?

13 Q. Yes. As of 2017 would you have
14 understood -- is it your understanding that this
15 patent provided data that tests whether the
16 anti-CD122 monoclonal antibodies inhibit IL-15
17 signaling?

18 MR. MILLS: Objection to form, foundation,
19 scope.

20 A. I don't have an opinion to share with you
21 today.

22 Q. Did you investigate whether this patent
23 included any data that provided support for
24 inhibition of IL-15 signaling?

25 MR. MILLS: Objection, form, foundation,

1 scope.

2 A. The patent speaks for itself with regard
3 to that.

4 Q. What is your understanding of nucleic
5 acids that inhibit IL-15 signaling? Are you
6 familiar with any nucleic acids that inhibit IL-15
7 signaling?

8 MR. MILLS: Objection, form, foundation,
9 scope.

10 A. That's a really broad question.

11 Q. Have you ever worked with any inhibitors
12 of IL -- inhibitors of -- I'm sorry. Let me repeat
13 the question.

14 Have you ever worked as of 2017 with any
15 nucleic acids that inhibit a particular cytokine?

16 A. No, I've not had the opportunity to do
17 that.

18 Q. Are you familiar with any other nucleic
19 acid inhibitors that would inhibit cytokine
20 signaling?

21 MR. MILLS: Objection to form.

22 A. Off the top of my head, I cannot think of
23 any right now, but there may be that could be
24 provided later.

25 Q. Do you know if a person skilled in the art

1 as of 2017 would understand how to prepare a nucleic
2 acid sequence if the DNA sequence was known?

3 MR. MILLS: Objection, form, foundation,
4 scope.

5 A. I'm sure that a person skilled in the art
6 would know how to do that.

7 Q. Are you familiar with the types of nucleic
8 acids? For instance, the patent lists Si-RNA as an
9 example. Are there other types of nucleic acids
10 that inhibit gene sequence -- gene -- that inhibit
11 the particular gene?

12 MR. MILLS: Objection to form, foundation,
13 scope.

14 A. There may be other types of nucleic acids
15 that inhibit gene sequences. As a clinician, I'm
16 not familiar with those.

17 Q. Are there any that are approved for use in
18 the clinic, Si-RNAs, for instance?

19 MR. MILLS: Objection to form, foundation,
20 scope.

21 A. There are none approved in the clinic that
22 I'm aware of.

23 Q. And what are the types of Si-RNA that
24 you're familiar with?

25 MR. MILLS: Objection to form, foundation,

1 scope.

2 A. Well, again, as a clinician, there's none
3 approved for the -- for use in humans, so I would
4 not be familiar with those.

5 Q. Turning back to the '505 patent which is
6 Exhibit 1001, how many examples does the patent
7 include, working examples?

8 MR. MILLS: Objection to form.

9 A. The patent lists six examples.

10 Q. And did you consider all six examples for
11 forming your opinions in your declaration?

12 A. Yes, I did.

13 Q. What is your understanding of Example 1?

14 A. I think the best summary is what's given
15 at the top of that example, that they believe that
16 autoreactive T cells within lesions of vitiligo
17 patients express TRM phenotype, which is a type of
18 memory cell, and they express IL-15 receptors.

19 Q. To obtain those results, is it your
20 understanding that that example includes mechanistic
21 or maybe functional studies to make that conclusion?

22 MR. MILLS: Objection to form.

23 A. Well, that example was described in Figure
24 1, and so there was an investigation related to
25 that. It's diagrammed in Figure 1.

1 Q. And what is your understanding for the
2 basis of their conclusion that these TRM cells
3 express the IL-15 receptor and have this specific
4 phenotype?

5 MR. MILLS: Objection to form.

6 A. Well, their claim about that has to do
7 with their laboratory experiment that they did
8 looking at those markers on cells.

9 Q. Were those cells from humans or were they
10 from animals?

11 MR. MILLS: Objection, form.

12 A. Those cells were from human vitiligo
13 subjects.

14 Q. So is it your understanding that the
15 conclusion that they make about IL-15 receptor
16 expression applies to human vitiligo lesions?

17 MR. MILLS: Objection to form, foundation,
18 scope.

19 A. In this example, they simply make an
20 observation about the expression of IL-15 receptor
21 in affected skin cells in humans. It's just an
22 observation.

23 Q. As of 2017, can you explain what your
24 understanding of IL-15 inhibitors and their ability
25 to block the pathway for therapeutic activity was?

1 MR. MILLS: Objection to form, scope.

2 A. To answer your question about what was
3 known, I think I would take you back to the Xing
4 reference, which is Reference 1007 in my document.
5 And there's a great deal explained in this document
6 as what was known, as well as the Harris article
7 that's listed as 1006 provides information that we
8 would have known in 2017.

9 Q. Do you know when IL-15 inhibitors were
10 first identified?

11 A. I wasn't a historian.

12 Q. Beyond the Xing and Harris that you
13 mentioned, what was known as of 2017 regarding the
14 therapeutic use of IL-15 inhibitors?

15 MR. MILLS: Objection to form, scope.

16 A. Again, I'm not a historian on IL-15. In
17 the clinic in 2017, it was not a common thing to use
18 a molecule or an antibody to treat a skin disease.
19 So particularly with what we're talking about here
20 with vitiligo, it was a very uncertain time with
21 regard to what role IL-15 might have had in
22 vitiligo.

23 Q. So you're not aware of any references
24 prior to or did not consider any references prior to
25 two thousand fif- -- 2017 --

1 Let me start again.

2 As of 2017, are you aware of any
3 references that connected the therapeutic potential
4 of IL-15 and vitiligo specifically?

5 MR. MILLS: Objection to form.

6 A. I don't know of every instance, but I do
7 know of the references provided under 1006. There
8 may be others that are not coming to mind as
9 quickly. But since this is the case that we're
10 concerned about, I think it's particularly telling
11 to a person of ordinary skill.

12 Q. Is it your understanding that
13 Exhibit 2006 -- I'm sorry -- 1006 describes the
14 therapeutic potential of inhibiting IL-15 in
15 treating human vitiligo?

16 MR. MILLS: Objection to form.

17 A. 2006 (sic) hypothesizes that there could
18 be, and I quote, a therapeutic potential for this
19 approach, meaning a therapeutic potential for using
20 these types of antibodies to affect vitiligo. They
21 suggest that, but they don't provide any evidence
22 for -- that that had been done or could be done
23 successfully.

24 Q. So when you say "these antibodies," which
25 types of antibodies do you mean?

1 A. Well, the antibody that they used. What
2 was it, ChBMC7?

3 Q. Do you agree that the ChMB7 antibody is
4 not described in the Harris Exhibit 1006?

5 A. Well, for the moment, I don't see the
6 reference to that. It may be in here. I just off
7 the top of my head don't see that, but it is
8 described in the patent.

9 Q. On page 1874 of Harris Exhibit 1006, on
10 the right-hand column about two-thirds of the way
11 down, it concludes that, "The clinical significance
12 of the treatment response to IFN gamma
13 neutralization reported here lies in its potential
14 use as a new therapy for vitiligo."

15 So is it your understanding that the
16 authors in Harris concluded that targeting IFN-gamma
17 is a potential use for treating vitiligo?

18 MR. MILLS: Objection, form.

19 A. Well, clearly what the authors are saying,
20 that this new mechanism that they've identified
21 might be a therapeutic target to do further
22 investigation about. It certainly does not say that
23 it is a treatment. Right? It does say it has
24 potential use. It also warns that this mechanism is
25 important for, quote, clearance of a number of

1 pathogens. So it's clear that this is not something
2 that we would take to the clinic.

3 Q. Okay. But you agree that Harris shows the
4 potential use of anti-interferon-gamma for vitiligo?

5 MR. MILLS: Objection to form, foundation.

6 A. I would agree that he's found an
7 interesting mechanism that needs more study.

8 Q. Do you agree that the study's data in
9 Harris focused on interferon-gamma and they do not
10 disclose IL-15?

11 MR. MILLS: Objection, form.

12 A. While Harris talks about interferon-gamma,
13 also talks of CD8-positive T cells, and IL-15 and
14 IL-2 are all wrapped up in that. So a person, a
15 POSA, if you will, would understand what he's
16 talking about, that the discussion here would also
17 have implications with IL-15 and IL-2.

18 Q. Would you agree that there's no mention of
19 IL-15 in Harris, Exhibit 1006?

20 MR. MILLS: Objection, form.

21 Q. Explicit mention?

22 A. I don't know. I'd have to search the
23 document for that, but I doubt you want me to sit
24 here and do that.

25 Q. Please take your time. If you can point

1 me to any disclosure of IL-15, I would like to see
2 that section.

3 A. As I said, I think that a person, a POSA,
4 if you will, would understand the context of IL-15
5 and IL-2 when there's a discussion of CD8-positive T
6 cells and gamma interferon and would understand the
7 mechanisms and understand the obviousness of IL-15
8 and IL-2 with its -- with the relationship there.

9 Q. Do you agree that Exhibit 1006 does not
10 specifically mention IL-15?

11 A. Yeah, I have not searched it, so I do not
12 know whether it does or not.

13 Q. So you did not thoroughly investigate
14 Harris to determine whether it discloses IL-15 as a
15 therapeutic potential for treating vitiligo?

16 MR. MILLS: Objection, form, scope.

17 A. I think I read Harris as any other POSA
18 would and understood the relationship between all of
19 these things I've mentioned, IL-15, IL-2,
20 interferon-gamma, CD8-positive T cells.

21 Q. So as of 2017, someone skilled in the art
22 reading Harris would have an understanding of the
23 cytokine pathway underlying CD8 T cell-mediated
24 pathogenesis of vitiligo?

25 MR. MILLS: Objection to form.

1 A. No, I think that's a very big jump looking
2 at Harris. I think that what Harris provides is a
3 possible mechanism for vitiligo. It doesn't
4 discover the mechanism of that.

5 (Reporter Clarification)

6 A. Does not discover the mechanism of
7 vitiligo.

8 Q. Okay. Just to clarify, someone -- a
9 person skilled in the art reading 1006 would have a
10 general understanding of the cytokine pathway
11 involved in IFN-mediated signaling in vitiligo?

12 MR. MILLS: Objection, form and scope.

13 A. A person skilled in the art would have an
14 understanding of these documents that -- the
15 publications that we've listed here, provided here.

16 Q. Would that understanding include knowledge
17 of IL-15 receptors?

18 MR. MILLS: Objection to form, scope.

19 A. It would certainly have an understanding
20 of relationships between CD8-positive T cells,
21 IL-15, IL-2, interferon-gamma.

22 Q. So the signaling between these components
23 was generally understood as of April 2017?

24 MR. MILLS: Objection to form, scope.

25 A. My recollection of 2017, I would say yes,

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1 a POSA would understand the connection between
2 those.

3 Q. You explain what a person skilled in the
4 art is in your declaration, but you also explain
5 that you provide the perspective of a medical
6 practitioner.

7 What added insight do you offer from being
8 a medical practitioner?

9 A. I'd like to answer your question, but I'm
10 not sure what you're asking.

11 Q. What is the difference between a person
12 skilled in the art as of 2017 and the perspective of
13 a medical practitioner?

14 MR. MILLS: Objection, form.

15 A. I've provided a description of someone
16 skilled in the art in my declaration, paragraph 31
17 and 32.

18 Q. I see that paragraph. But then in
19 paragraph 35 and 36, you start off by saying,
20 "From the perspective of a medical practitioner
21 who diagnosed and treated vitiligo at the critical
22 date."

23 What difference is there between a person
24 skilled in the art as of 2017 and the perspective of
25 a medical practitioner?

1 MR. MILLS: Objection to form.

2 A. Well, a person skilled in the art would
3 also be a medical practitioner, so it would include
4 a medical practitioner as someone who's
5 knowledgeable. You seem to phrase that like they
6 would be two different things. I think that a
7 person skilled in the art also includes medical
8 practitioner.

9 Q. In the context of treating a human
10 patient, are there other considerations you have
11 before giving a particular drug to a human?

12 MR. MILLS: Objection to form, foundation,
13 incomplete hypothetical, outside the scope.

14 A. I'm sorry. I'm not sure what you're
15 asking about.

16 Q. For instance, are you looking for a
17 certain level of safety to administer a drug to a
18 patient?

19 MR. MILLS: Objection, form.

20 A. As a physician treating a patient, I need
21 to know what the risk-benefit of any treatment would
22 be. I need to know about efficacy and the
23 likelihood of success and then what side effects the
24 patient might experience, as a physician.

25 Q. If there's a potential for side effects,

1 does that influence your decision to administer a
2 particular drug to a patient?

3 MR. MILLS: Objection to form, foundation,
4 incomplete hypothetical, outside the scope.

5 A. It's a very broad question, and I'll
6 answer it in a very general kind of way, which is
7 that I think that any physician would be concerned
8 about side effects in prescribing a medication to a
9 patient.

10 Q. Without any information on side effects,
11 would a medical practitioner not administer a
12 potential drug?

13 MR. MILLS: Objection to form, foundation,
14 incomplete hypothetical.

15 A. I'm sorry. Maybe could you say that in a
16 different way?

17 Q. Without knowing any information about the
18 side effect of a drug, are there any other reasons
19 that you would not administer a potential drug?

20 MR. MILLS: Same objections.

21 A. Well, I think what you're saying is if I
22 didn't know anything about side effects and I had no
23 idea about side effects. As a physician, you would
24 err on the side of safety. And if you had no idea,
25 you would either find out or not administer that

1 drug.

2 Because, again, there's a risk-benefit to
3 administering -- administering a drug to a patient.
4 The patient should expect that it would be
5 beneficial, not harmful. Without that information,
6 a physician couldn't make that decision.

7 Q. Is it true that you can never actually
8 treat a patient prior to the FDA approval of a drug
9 itself?

10 MR. MILLS: Objection, form, foundation,
11 outside the scope.

12 A. No, that's -- it's not true that you would
13 not treat a patient with a drug before FDA approval.
14 And one of the reasons for that is that there is a
15 process in the United States for investigating drugs
16 that have not been approved by the FDA, and there's
17 a process for that.

18 I've had a long experience in drug
19 development and 16 years in drug development.
20 There's a process to investigate all aspects of a
21 particular drug before. And it would be admitted
22 to -- administered to a patient prior to that FDA
23 approval under those research situations.

24 Q. So what type of information would you need
25 to administer a drug without FDA approval?

1 MR. MILLS: Objection to form, outside the
2 scope, incomplete hypothetical.

3 A. Yeah, that -- the amount of information
4 would be volumes and fill up 18-wheeler trucks
5 headed to the FDA to go for approval. That's a
6 question that, you know, has a very long answer and
7 is really the subject of whole drug, you know, FDA
8 approval investigations and pharmaceutical companies
9 that spend millions and millions of dollars
10 developing that information.

11 Q. Are there general categories? For
12 instance, if a drug was known, would that be one
13 potential for getting FDA approval, for
14 administering a drug before FDA approval?

15 MR. MILLS: Objection, form, incomplete
16 hypothetical, outside the scope.

17 A. Well, if you're asking about the process
18 for drug approval, there's typically a pre-clinical
19 stage where safety studies are done on animals to
20 know about toxicities. Then there's early stages
21 about safety done in humans called Phase 1 studies.
22 Phase 2 studies in humans typically look at
23 different doses which might be different amounts of
24 drugs or different frequency of drugs. And then
25 finally, Phase 3 studies in humans that are related

1 to efficacy, so efficacy greater than placebo or
2 maybe efficacy greater than an existing product.

3 MR. MILLS: We've been going for over an
4 hour. Are we ready for a break?

5 MS. ROBERTS: Can I ask one more question
6 on this topic before we take a break?

7 MR. MILLS: Do you want to do one more, or
8 do you want the break now?

9 THE WITNESS: Sure, I'll answer one more.

10 Q. Understanding the different phases of
11 clinical development, what type of information is
12 needed to get from a preclinical model to a Phase 1
13 human study?

14 MR. MILLS: Objection to form, incomplete
15 hypothetical, lacks foundation, and outside the
16 scope.

17 A. The types of animal studies needed to get
18 to a human study would really depend on the drug
19 that we're dealing with. It might be different for
20 different drugs.

21 MR. MILLS: Thank you. We're off the
22 record.

23 (Recess from 10:08 to 10:19)

24 BY MS. ROBERTS:

25 Q. In paragraph 36 of your declaration, you

1 state that from the perspective of a medical
2 practitioner, you would not -- this patent
3 specification would not have enabled a person to
4 make and use any method of treating vitiligo other
5 than doing so using the ChMB7 antibody in the CD8
6 T cell-dependent mouse model.

7 What else would a practicing physician
8 need to know to treat vitiligo using the ChMB7
9 antibody?

10 MR. MILLS: Objection to form, foundation,
11 incomplete hypothetical, outside the scope.

12 A. Well, you were reading from my paragraph
13 36. I'd like to provide a little bit more color in
14 answering your question by reading some of the rest
15 of it, which is -- it states, "Treating vitiligo is
16 not a simple or predictable art," which was the case
17 and still is the case.

18 It goes on, "Instead, it is complex and
19 unpredictable. Treating it using cytokine
20 inhibition was only at its nascent stages in '17
21 or '18. The claims as issued are very broad,
22 encompassing treating many different kinds of
23 vitiligo in any species of subject. The claims
24 encompass a diverse collection of diseases sharing a
25 commonality of depigmentation lesions but arising

1 from a variety of known and unknown causes.

2 "From the perspective of a medical
3 practitioner, the '505 patent's data from the mouse
4 model would not enable treatment of natural or
5 spontaneous vitiligo, especially not in humans. The
6 only way for a POSA to know which compounds were
7 IL-15 or IL-15 receptor inhibitors and useful for
8 treating vitiligo in a given subject would be to
9 test the specific compounds through a repetitive
10 trial and error process.

11 "Though a POSA would likely have an
12 advanced degree and much expertise, the disclosures
13 of the '505 patent simply would not be ade- --
14 simply would" -- I'm sorry -- "the '505 patent
15 simply would be inadequate to enable a POSA to make
16 a full and useful scope of the genus of methods
17 claimed in the '505 patent."

18 The -- a POSA, in particular a clinician
19 like myself, recognizes that what's described in the
20 '505 patent is a mechanistic study in a contrived
21 animal model. It doesn't provide us instruction for
22 treating vitiligo clinically. It gives us some
23 ideas of their interest in therapeutic pathways to
24 investigate, but only that.

25 The way I read the '505 patent is that it

1 covers all humans. And that's not -- that's not
2 what was investigated in the '505 patent.

3 Q. What else would a person skilled in the
4 art need to know to use the described antibody ChMB7
5 in human vitiligo then?

6 MR. MILLS: Objection to form. Asked and
7 answered.

8 A. I do think I've tried to explain that, but
9 let me explain further that in the patent, it gives
10 us very little information about that antibody such
11 that as a clinician, it's not useful. It's such a
12 broad description.

13 Q. Is it your understanding that human
14 testing would be required before the ChMB7 antibody
15 is used to treat vitiligo in the clinic?

16 MR. MILLS: Objection, form, lacks
17 foundation, incomplete hypothetical.

18 A. Well, as I explained before the break
19 about all the different levels of testing, I have
20 none of that information about this research
21 antibody.

22 Q. Beyond the structure of ChMB7, is there
23 anything else that a person skilled in the art would
24 need to know to use that particular antibody for the
25 treatment of vitiligo?

1 MR. MILLS: Objection to form, foundation,
2 incomplete hypothetical, asked and answered.

3 A. Well, I want to be clear that I'm not
4 simply pointing out that we don't know anything
5 about the structure of this antibody. We only know
6 that it was an FC fragment. There's a small
7 description. We know that it's designed for mice
8 and rats and it would not be a -- from the
9 description, it would not be a molecule that we
10 would want to use in people.

11 Q. Were there other CD122 antibodies that
12 were humanized antibodies known as of 2017?

13 MR. MILLS: Objection to form, foundation,
14 scope.

15 A. There's at least one other that I'm aware
16 of that is referenced in the Xing article, 1007,
17 called TMB-beta 1.

18 Q. Is that also a mouse monoclonal antibody?

19 A. Since these experiments were done in --
20 since these experiments in Xing were done in mice, I
21 would anticipate that the antibodies and cellular
22 products there used were compatible with mice. I
23 don't see the specific reference here about the
24 origin of that antibody, but because when you give
25 an antibody it needs to be compatible with the

1 organism, it would make sense that it's a mice -- a
2 mouse antibody.

3 Q. So referring to the ChMB7 antibody and the
4 CD122 antibody in Xing, what would a person have
5 needed to know to use other anti-CD122 antibodies to
6 treat vitiligo in humans?

7 MR. MILLS: Object to the form,
8 foundation, incomplete hypothetical, asked and
9 answered.

10 A. Your question supposes that we would use
11 these antibodies in humans. And because these
12 are -- they seem -- would appear to be mouse
13 antibodies, that would not be compatible with
14 humans. So these would not be antibodies that would
15 be useful in humans.

16 Q. Was it known as of 2017 how to humanize an
17 antibody?

18 MR. MILLS: Objection to form, foundation,
19 outside the scope.

20 A. In 2017 we had humanized antibodies to
21 different targets, but it's not like -- you know, to
22 humanize an antibody, it's not like just making a
23 little change. It's a completely different
24 molecule.

25 Q. As of 2017 how did you treat vitiligo

1 patients in the clinic?

2 A. Most common way that I treat vitiligo
3 patients is using topical corticosteroids.

4 Q. How do you diagnose vitiligo in human
5 patients?

6 A. I look at them visually.

7 Q. Visually?

8 A. And also I can use a UV lamp that helps
9 brighten the depigmented skin.

10 Q. Did you take biopsies of patients to
11 determine if any certain genes were expressed?

12 A. In the clinic we wouldn't typically look
13 at genetic expression in patients for vitiligo. So
14 the answer would be no, we wouldn't be taking any
15 biopsies for gene expression.

16 Q. Are you familiar with JAK inhibitors for
17 the treatment of vitiligo?

18 A. I am -- I am today.

19 Q. Were they used in the clinic as of 2017
20 for the treatment of vitiligo?

21 A. The first topical JAK inhibitor was only
22 approved last year.

23 Q. And what disease indication?

24 A. For atopic dermatitis and later vitiligo.

25 Q. As of 2017 would a medical practitioner

1 not have used a JAK inhibitor for the treatment of
2 vitiligo?

3 MR. MILLS: Objection to form, incomplete
4 hypothetical.

5 A. In 2017 there were JAK inhibitors
6 available in research and very early in use in other
7 therapeutic areas. So in the case of Xing, for
8 example, they were able to use that -- those
9 molecules topically, but that was in a very -- that
10 was in a research model. Those were not available
11 to treat patients for vitiligo under FDA approval.

12 Q. Does Xing provide enough information for
13 using a JAK inhibitor in the context of treating
14 humans with AA?

15 MR. MILLS: Objection to form, foundation,
16 incomplete hypothetical, scope.

17 A. Well, Xing in Figure 4 shows an example of
18 treating a patient with a JAK inhibitor who had
19 alopecia areata. And to the extent that this
20 provides instruction for a clinician, it provides
21 one example of a patient that improved with a JAK
22 inhibitor, which is not adequate to treat all
23 patients with JAK inhibitor.

24 Q. Would a person skilled in the art as of
25 2017 also have understood Xing to have provided

1 enough support for the treatment of vitiligo -- I'm
2 sorry -- for the treatment of AA using IL-15
3 inhibitor?

4 MR. MILLS: Objection to form, incomplete
5 hypothetical.

6 A. So regarding what Xing teaches about
7 alopecia areata, it is actually, for me, really
8 interesting. What Xing teaches is that they were
9 able to use CD122 inhibitor to prevent alopecia
10 areata in mice.

11 What they didn't show you data for is that
12 they -- those blocking antibodies for CD122 did not
13 reverse the alopecia areata, which is very
14 interesting because that has to do with the site of
15 the pathology, being in the hair follicle, not in
16 the -- because we're not talking about the skin, the
17 epidermis, where the melanocytes are as in vitiligo.
18 We're talking about deeper in the dermis of the skin
19 where the hair follicle resides. And the antibody
20 that they used was not able to penetrate that hair
21 follicle.

22 What's very interesting to me as a drug
23 developer is that a topical JAK inhibitor was able
24 to penetrate the hair follicle and affect the hair
25 follicle where the antibody wasn't and cause hair to

1 regrow. Right? So we're talking about hair
2 regrowth. Antibody couldn't get to the hair
3 follicle. Small molecule did. It's very
4 instructive about how important the selection of the
5 therapeutic is with regard to the target tissue.

6 Q. So you mentioned prevent -- the term
7 "prevent accumulation" in Xing. On page 4 of Xing,
8 it states that, "Systemically administered blocking
9 antibodies to either IL-2 or IL-15 receptor beta
10 prevented AA in grafted mice and blocked the
11 accumulation of CD8-positive NKG2D cells in the
12 skin."

13 How is that different than depleting a CD8
14 T cell?

15 A. Can you tell me where on the page you're
16 reading that?

17 Q. Page 4 on the right-hand column, there is
18 a sentence starting "Systemically administered."

19 A. Okay. So what's happening in this
20 particular model is the mice will develop alopecia
21 areata naturally. They're programmed to do that.
22 So what we know about alopecia areata is that these
23 activated cells, activated T cells -- they give them
24 a long name, but they're just the same thing --
25 they're activated and they go and destroy the hair

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1 follicle and the hair falls out. These mice are
2 programmed to do that.

3 And this is saying that if we block those
4 antibodies or block -- using blocking antibodies to
5 either IL-2 or IL-15 R beta, it prevented these
6 accumulation of these activated cells. So it was
7 able to block the cells that come in to kill the
8 hair follicle. And in that way, the mice didn't
9 produce any hair loss. It's doing that outside of
10 the hair follicle.

11 Q. So these mice did not have established
12 lesions?

13 A. Right. They run around and they're just
14 normal looking and then their hair falls out.

15 Q. In paragraph 34 of your declaration, in
16 the first sentence you refer to Xing and state that,
17 "The use of specific CD122 antibodies in a
18 CD8-dependent mouse model of autoimmune skin disease
19 (sic) to treat autoimmune skin lesions by depleting
20 CD8 T cells was known in the art."

21 What do you mean by "depleted" in
22 paragraph 34 of your declaration?

23 A. I think that's just reflected in the
24 paragraph that we were looking at with Xing, that
25 these -- they're kind of saying the same thing.

1 Q. So your understanding is that the terms
2 "prevented" the accumulation of CD8 T cells is the
3 same as "depleting" CD8 T cells?

4 A. Well, I think we understand the difference
5 between preventing things and accumulating things.
6 But in the paragraph that we were talking about, it
7 says block the accumulation of CD8 cells so that
8 instead of those cells accumulating, their numbers
9 became fewer because we had antibodies to those.

10 So whether they didn't accumulate or they
11 were depleted, their numbers were reduced, and
12 that's what's shown in the Xing paper.

13 Q. But your understanding is that Xing does
14 not show depletion of CD8 T cells in an established
15 lesion?

16 MR. MILLS: Objection to form.

17 A. Let me be more specific about that because
18 what you're asking is kind of misunderstood, I
19 think. It's that if you already have alopecia
20 areata and those hair follicles are already
21 destroyed, the antibodies that reduce or affect the
22 activated T cells are not able to change the
23 situation in the hair follicle, meaning it doesn't
24 allow the hair follicle to come back because we
25 still have the same problem there. The antibody

1 hasn't gotten into the hair follicle to make a
2 change.

3 So the mouse, once they develop the
4 alopecia areata, might not get any more spots but
5 won't heal the -- won't recover from the ones that
6 they do have.

7 Q. Is there any data in Xing that shows
8 actual depletion of CD8-positive T cells?

9 MR. MILLS: Objection, form.

10 A. Can you explain what you mean by
11 "depletion"? Because I think of depletion could be
12 in the tissue as opposed to in the animal itself,
13 its skin versus not skin.

14 Q. Well, I'm trying to understand what you
15 mean by "depleting" because I don't see "depletion"
16 anywhere in Xing. They only talked about preventing
17 the accumulation. So if you're preventing the
18 accumulation, I'm trying to understand how that
19 corresponds to depletion of CD8-positive T cells.

20 MR. MILLS: Objection. Asked and
21 answered.

22 A. I think I've answered your question as
23 best I can.

24 Q. In paragraph 37 of your declaration, the
25 last sentence of paragraph 37 states that,

1 "Optimally, treatment would eliminate existing
2 lesions." Why is this the case?

3 MR. MILLS: Objection, form.

4 A. Well, in this paragraph we were talking
5 about basically two things. There's one we're
6 stopping the progression of the disease, so no new
7 spots. Right? And then the other thing is that
8 even better than not having new spots would be that
9 we get rid of the spots that the patient has because
10 vitiligo is a very disfiguring, socially impactful
11 condition, and it would be optimal if the treatment
12 would get rid of all that. I think anyone would
13 agree with that.

14 Q. Is your understanding from Xing that it
15 shows stopping the progression by preventing the
16 accumulation of CD8-positive T cells versus
17 eliminating existing lesions?

18 MR. MILLS: Objection, form.

19 A. My understanding of Xing is that the
20 administration of these -- you know, of antibody
21 allowed for the prevention of lesions so that they
22 didn't -- lesions that were programmed to naturally
23 occur did not occur. And further, that once they
24 did begin to occur, that it prevented them from
25 developing new lesions.

1 Q. On paragraph -- I'm sorry. On page 6 of
2 Xing on the left-hand column, second paragraph down,
3 they looked at treatment with a JAK inhibitor, and
4 in that case they found, "Systemic therapy resulted
5 in substantial hair growth all over the body." And
6 they go on to say, "and that persisted two to three
7 months after the cessation of treatment."

8 So the JAK inhibitor was able to eliminate
9 existing lesions even after the drug had stopped?

10 MR. MILLS: Objection, form.

11 A. That's what I understand here, that it
12 says, "Systemic therapy resulted in substantial hair
13 regrowth all over the body, reduced the frequency of
14 CD8-positive T cells," and it goes on, "all of which
15 persisted one to three -- one to three months after
16 cessation of treatment."

17 Yeah, I take it at its word there.

18 Q. Is that consistent with how JAK inhibitors
19 act in the clinic for the treatment of vitiligo?

20 MR. MILLS: Objection to form.

21 A. Well, in 2017 we didn't know about how JAK
22 inhibitors would do in the clinic in vitiligo, in a
23 practitioner's office.

24 Q. Today are they effective in reversing
25 established disease in the treatment of vitiligo?

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1 MR. MILLS: Objection, form.

2 A. Today we have one topical JAK inhibitor
3 for vitiligo that's an FDA-approved JAK inhibitor
4 for vitiligo and it's very slow to reverse the
5 course of vitiligo. And my understanding of the
6 clinical research is that vitiligo can return after
7 the medication is discontinued.

8 Q. The drug you're referring to, is
9 that topical -- that's topical administration?

10 A. Yes, it is.

11 Q. And the paragraph we referred to in
12 paragraph -- second paragraph on page 6 of Xing,
13 that refers to systemic treatment. So, trying to
14 understand why you're referring to topical treatment
15 when this is referring to a systemic treatment.

16 MR. MILLS: Objection, form.

17 A. I'm confused. I'm talking about a topical
18 treatment that's available in the dermatology clinic
19 today. Is that what you're asking about? This
20 paragraph is referring to mice.

21 Q. So from Xing, is your understanding that a
22 JAK inhibitor as of 2017 -- let me start over.

23 Did a JAK inhibitor that was administered
24 systemically for vitiligo in 2017, was that able to
25 reverse vitiligo?

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1 MR. MILLS: Objection, form, incomplete
2 hypothetical.

3 A. So under 1032 is a research letter
4 pertaining to a patient who had both vitiligo and
5 alopecia areata who was treated with an oral JAK
6 inhibitor. And so I -- you know, which was very
7 interesting, and it worked for this patient. So I
8 think that the answer is that in 2017 we knew that
9 an oral JAK inhibitor could be interesting in at
10 least this type of vitiligo.

11 I want to caution that vitiligo and
12 alopecia areata are not simple things. They're not
13 baskets of just one simple thing. They can be quite
14 complex and they could have different etiologies.
15 So just having a JAK inhibitor that treated one
16 individual doesn't allow you to extrapolate for all
17 individuals.

18 MS. ROBERTS: Can I have Exhibit 1032,
19 please?

20 Q. In Exhibit 1032, on the right-hand column
21 towards the bottom, it states 12 weeks after
22 discontinuing ruxolitinib, while the hair growth was
23 maintained, much of the regained pigment had
24 regressed.

25 So based on Exhibit 1032, there was no

1 showing of a JAK inhibitor that could result in
2 durable reversal of a patient's vitiligo. Is that
3 correct?

4 MR. MILLS: Objection to form, incomplete
5 hypothetical.

6 A. I think you're using one specific case and
7 generalizing that to all vitiligo. But to answer
8 your question, I would say that in this particular
9 case, this one patient for which we don't have any
10 other information here, that it appears that 12
11 weeks after discontinuing ruxolitinib, while his
12 hair growth was maintained, much of the regained
13 pigment had regressed, which is really interesting
14 to me in the whole research project that we don't go
15 into, in the light of Xing. But anyway, very
16 interesting.

17 Q. So as of 2017, you're not aware of any
18 publications that show durable reversal of treatment
19 of vitiligo?

20 MR. MILLS: Objection to form, incomplete
21 hypothetical.

22 A. Yeah, I -- there might be something there.
23 Off the top of my head today as I sit here, I don't
24 have anything that I can give to you for that.

25 Q. As of April 2017, what was known about the

1 involvement of CD8 T cells in human vitiligo?

2 MR. MILLS: Objection, form, scope.

3 A. Let me answer your question by saying that
4 in April of 2017, there was a beginning of an
5 understanding for the role of CD8-positive T cells
6 and IL-15, IL-2, interferon-gamma in the role of
7 vitiligo. Some of this I've described in my
8 paragraph 39.

9 And, you know, we understand that in this
10 abstract under the Tab 1020 entitled, "Vitiligo
11 patients have increased numbers of autoreactive
12 melanocyte-specific CD8-positive T cells in the skin
13 and blood which are directly responsible for
14 melanocyte destruction," was, for example, one of
15 the things.

16 There were a lot of other things. But one
17 of the things that we understood for human vitiligo,
18 they appeared to have increased levels of these
19 CD8-positive cells and then all the other things
20 that kind of go along with it.

21 We saw that at increased levels in the
22 lesions of vitiligo as compared to normally
23 pigmented skin. So it gave us a clue that we --
24 that those things were having something to do with
25 these lesions.

1 Q. Are you aware of any forms of vitiligo
2 that are not caused by the involvement of
3 CD8-positive T cells?

4 MR. MILLS: Objection, form.

5 A. Well, we don't have a complete
6 understanding of vitiligo today, so I don't have an
7 example to give you except that we have something
8 called segmental vitiligo which appears to be
9 somehow related to nerve involvement, which might
10 not have anything to do with these inflammatory
11 cells.

12 Vitiligo is -- could be caused by other
13 things including trauma from scarring. So there's a
14 lot of reasons that we could have vitiligo outside
15 of CD8-positive T cells.

16 Q. Have you investigated if there are any
17 other references supporting other roles besides
18 CD8-positive T cells in human vitiligo?

19 MR. MILLS: Objection, form.

20 A. If you're asking if I've done
21 investigations, you know, laboratory investigations,
22 I've not.

23 Q. Have you done any investigation of other
24 references that support noninvolvement of
25 CD8-positive T cells in vitiligo?

1 MR. MILLS: Objection to form.

2 A. I haven't done a specific investigation
3 about non-CD8 vitiligo except that as a person of
4 skill in this area, I'm aware of types of -- other
5 types of vitiligo that I would not expect to have
6 activated T cells involved.

7 Q. And despite these different causes, do all
8 these different forms of vitiligo result in
9 depigmentation?

10 A. The central pathology of vitiligo is the
11 loss of the pigmenting cell called the melanocyte.
12 And to the extent that we have a loss of melanocyte,
13 we may call it vitiligo.

14 Q. Would the active lesion for the spot of
15 vitiligo, would they include similar chemokines, for
16 instance, between different causes of vitiligo?

17 MR. MILLS: Objection to form, incomplete
18 hypothetical.

19 A. I think that the different causes for
20 vitiligo would have different etiologies, and they
21 may or may not have similarities. I have not seen a
22 reference that compared those.

23 Q. The vitiligo mouse model that's described
24 in Harris of Exhibit 1006, what's your understanding
25 of the commonalities between the vitiligos in the

1 mice and human vitiligo?

2 MR. MILLS: Objection, form, incomplete
3 hypothetical.

4 A. Well, let's talk about the mouse model
5 that's in Harris which is a contrived model that
6 uses radiation to wipe out the immune system of the
7 mouse. So there's nothing common there to begin
8 with.

9 They then put back in the activated T
10 cells in a virus to infect those T cells with a
11 substance that's going to make them go after the
12 pigmented cells. So there's nothing similar there.

13 There's then the use of the antibody,
14 Ch- --

15 Q. MB7?

16 A. -- 7, yeah -- must be somebody's
17 initials -- to reverse what they put in. So we put
18 that antibody in and it kills the cells, and then
19 the skin, the melanocytes can come back. So there's
20 nothing really common about that.

21 Q. To clarify, the Harris Exhibit 2006 --
22 1006 does not describe the ChMB7 antibody. That's
23 only used in the patent. In the abstract of Harris,
24 it states that they have melanocyte-specific CD8
25 cells which recapitulates the human condition.

1 So how does the mouse model in Harris
2 recapitulate the human condition of human vitiligo?

3 MR. MILLS: Objection, form.

4 A. It appears from reading the Harris article
5 they're very pleased to have a model that caused the
6 depigmentation of the skin but not the hair
7 follicle, because they mention a couple of other
8 models where there was depigmentation of both the
9 hair and the skin.

10 I think Harris is particularly proud of
11 his model, or the group is, not him personally, but
12 they're pleased that they've developed a model that
13 depigmented skin but not hair. And to the extent
14 that there's any similarities with humans, maybe
15 that's the only similarity I find.

16 Q. Are you aware of any other mouse models of
17 vitiligo, human vitiligo as of 2017?

18 MR. MILLS: Objection to form.

19 A. There's a mention of those in the Harris
20 paper on their page 1869, right-hand column, last
21 paragraph.

22 Q. Other than the mouse models described on
23 page 1869 of Harris, are you familiar with any other
24 mouse models of human vitiligo?

25 MR. MILLS: Objection, form.

1 A. I think these were the ones that were
2 known at that time.

3 MR. MILLS: We've been going for over an
4 hour. Are we ready for a break?

5 MS. ROBERTS: One more question again?

6 MR. MILLS: Do you want to take one more
7 question?

8 THE WITNESS: Sure.

9 MS. ROBERTS: It's related.

10 Q. Besides the skin or the -- let me start
11 over.

12 Besides the change in hair follicle and
13 skin pigmentation in the Harris mouse model, are you
14 familiar with any other features that are common
15 between the Harris mouse model and human vitiligo?

16 MR. MILLS: Objection to form.

17 A. Well, the other thing that might be
18 similar is that it would appear that these activated
19 T cells are involved in the production of the skin
20 lesions.

21 Q. Anything else besides the activated T
22 cells?

23 A. Well, with -- you know, with along the
24 activated T cells comes all the other things like --
25 that come along with that, interferon-gamma and

1 that -- IL-2, IL-15.

2 Q. Any chemokines that would be shared
3 between the two?

4 A. Could be.

5 MR. MILLS: Ready for the break?

6 MS. ROBERTS: Yeah.

7 (Recess from 11:24 to 11:37)

8 BY MS. ROBERTS:

9 Q. In paragraph 36 of your declaration, the
10 second half on page 15, you state that, "From the
11 perspective of a medical practitioner, the '505
12 patent's data from the mouse model would not enable
13 treatment of natural or spontaneous vitiligo,
14 especially not in humans."

15 Is it your understanding as of 2017 that
16 Xing's CD122 antibody would have enabled treatment
17 for human alopecia?

18 MR. MILLS: Objection, form, incomplete
19 hypothetical.

20 A. Well, I think we covered some of that
21 because we discussed how Xing's antibody was not
22 helpful to regrow hair. Right? So it was helpful
23 for them to prevent hair loss, but once that hair
24 loss occurred, the antibody didn't regrow the hair.

25 Q. Turning to Exhibit 1032. I'm sorry.

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1 Sticking with Xing, let me start over.

2 From the perspective of a medical
3 practitioner as of 2017, would Xing have enabled
4 treatment of human alopecia areata with a JAK
5 inhibitor?

6 MR. MILLS: Objection to form, foundation,
7 incomplete hypothetical, outside the scope.

8 A. Well, you're asking me a legal term, and
9 I'm not a legal expert. But you used the word
10 "enabled," and I understand enabling to mean
11 something very specific legally. Because I'm not an
12 expert in whether or not Xing enabled anything, I
13 can't give you a clear answer on that. I can talk a
14 little bit about what Xing informed me as a POA and
15 what it tells me as a clinician.

16 Q. In paragraph 36, you use the word
17 "enable." You state that the patent's data from the
18 mouse model would not enable treatment. How do
19 you -- how do you use the word "enable" there?

20 A. My declaration says, "From the perspective
21 of a medical practitioner, the '505 patent's data
22 from the mouse model would not enable treatment of
23 natural or spontaneous vitiligo."

24 Is that what you're referring to?

25 Q. You stated that the term "enable" is a

1 legal terminology that you're not familiar with.
2 How do you use that term in that paragraph of your
3 declaration? What do you understand it to mean?

4 A. No, I didn't say I wasn't familiar with
5 it. I didn't say that at all. I said that I'm not
6 a legal expert on enabling, and you asked me about
7 enabling.

8 Q. Based on the work in Exhibit 1032 --

9 In paragraph 36 of your declaration, what
10 do you consider to be enabling treatment of natural
11 or spontaneous vitiligo?

12 A. I'll take you back to paragraph 16 where
13 enablement's defined. I understand that a claim is
14 unpatentable for lack of enablement if the
15 specification does not contain a sufficiently full,
16 clear, concise, and exact description of the manner
17 and process of making and using the full scope of
18 the claimed invention to enable POSA to make and use
19 the invention without undue experimentation at the
20 clinical date. However, experimentation to make and
21 use the invention is allowable if it's not undue.

22 You know, the '505 patent does not allow
23 for a sufficient, full, clear, concise, exact
24 description of the manner and the process of using
25 the scope of the invention that's claimed, because

1 the claim is for all patients with vitiligo. And
2 what is done is in mice, in a mechanistic animal
3 model. And that's an interesting science
4 experiment, but it's not enough information to have
5 a clinician go and treat a patient like the patent
6 claims.

7 Q. If you apply the same meaning that you use
8 in paragraph 36 of your declaration of the term
9 "enable," from the perspective of a medical
10 practitioner as of 2017, would Xing have enabled
11 treatment of human alopecia with a JAK inhibitor?

12 MR. MILLS: Objection to form, foundation,
13 incomplete hypothetical, scope.

14 A. Using the definition that I read
15 previously in paragraph 16, I get much more -- I get
16 much closer to enablement with Xing because Xing
17 actually explains to me what's going on in alopecia
18 areata with regard to antibodies and activated T
19 cells and treatment.

20 So I can make -- as a clinician, I can
21 make a bridge from the laboratory model clearly to
22 mice that responded to a topical JAK inhibitor.
23 They also make a bridge to a human who had alopecia
24 areata who was given oral JAK inhibitor and grew
25 hair.

1 So, for me, it doesn't require me to do
2 undue experimentation to try to figure out if this
3 would be a good idea for me to go do more research
4 on.

5 Q. What is your opinion, yes or no, whether
6 Xing enables a treatment of alopecia areata with a
7 JAK inhibitor?

8 MR. MILLS: Objection, form, foundation,
9 incomplete hypothetical, scope, asked and answered.

10 A. I think I just answered that.

11 Q. Could you state yes or no whether Xing
12 enables treatment of alopecia with a JAK inhibitor?

13 MR. MILLS: Same objections.

14 A. Well, as a clinician and not a legal
15 expert, I believe that Xing is sufficiently full,
16 clear, concise, and provides a description of the
17 manner and the process to treat alopecia areata with
18 a JAK -- with an oral JAK inhibitor.

19 Q. Again using the same definition of
20 "enable" as applied in your declaration, do you
21 consider the treatment method described in
22 Exhibit 1032 using a JAK inhibitor for the treatment
23 of AA also enabled? I'm sorry, for vitiligo?

24 MR. MILLS: Objection to form, foundation,
25 incomplete hypothetical, outside the scope.

1 A. To clarify your question, you're asking me
2 about 1032 with regard to it enabling the treatment
3 of vitiligo with JAK inhibitors?

4 Q. Correct, with a JAK inhibitor.

5 A. Okay.

6 MR. MILLS: And my objections are to form,
7 foundation, incomplete hypothetical, outside the
8 scope.

9 A. I hesitate to answer your question because
10 you're really -- there's almost two different
11 things. It's almost as though that you can't
12 compare the enablement that I get from Xing to this
13 one-patient experience in a research letter. While
14 it's interesting, it doesn't provide me more
15 information than Xing. There's a patient here with
16 alopecia areata and this patient's received an oral
17 JAK inhibitor and he's responsive to that, and this
18 individual responds as though I would expect, being
19 a POSA looking at Xing.

20 Knowing what would be known in 2017 with
21 alopecia and vitiligo, it's not new information to
22 me that this patient would respond to the JAK
23 inhibitor with vitiligo because I've already got
24 information from Xing telling me that alopecia
25 areata responds to an oral JAK inhibitor.

1 Do you follow the connection? And this is
2 one patient. So it doesn't explain to me anything
3 mechanistically about how to do that. It's a data
4 point, I think, an individual patient being able to
5 take a JAK inhibitor that's already gone through the
6 FDA process, has already answered a lot of questions
7 prior to that.

8 Q. So again, yes-or-no question. Does
9 Exhibit 1032 -- what is your opinion whether
10 Exhibit 1032 enables a treatment of vitiligo with a
11 JAK inhibitor as of 2017?

12 MR. MILLS: Objection to form, foundation,
13 incomplete hypothetical, outside the scope, asked
14 and answered.

15 A. As I -- I think I've answered your
16 question as best I can.

17 Q. Do you have a yes-or-no answer?

18 MR. MILLS: Same objections.

19 A. I try not to provide yes-or-no answers.
20 I like to explain.

21 Q. Can you please turn to paragraph 29 of
22 your declaration. Before we go there, I'm going to
23 ask one other question related to Xing.

24 Would Xing, in your opinion, have enabled
25 the treatment of human vitiligo with an IL-15

1 inhibitor as of 2017?

2 MR. MILLS: Objection to form, foundation,
3 incomplete hypothetical, scope.

4 A. So that I understand your question, you
5 would like to know if -- what my opinion is
6 regarding Xing with regard to enabling treatment of
7 vitiligo with an IL-15 inhibitor --

8 Q. Correct.

9 A. -- as of 2017.

10 And I think it's not as direct to treat
11 vitiligo based on Xing. However, as a POSA, I would
12 have used the antibody that -- maybe if I were Xing,
13 I would have used the antibody that I had, a CD122
14 antibody, to go in and use the Harris mouse and
15 treat the Harris mouse, and that might then enable
16 me to make that bridge from alopecia and using CD122
17 antibody.

18 The reason it's not so clear is that in
19 Xing, they were able to prevent but not treat
20 alopecia areata with the CD122 antibody. So it was
21 not clear from Xing using just the antibody if we
22 could go and treat another similar skin disease.

23 These experiments are not routine and
24 they're complicated, and so I could argue that it
25 would require me to do undue experimentation. I'd

1 have to go and do some of these things to figure out
2 if that antibody might work or not in vitiligo.

3 Q. Okay. Turning back to paragraph 29 of
4 your declaration. Here you're referring to
5 dependent claims and certain administration to them,
6 and you state that, "Each of these modes of
7 administration were routine and common in the field
8 of vitiligo treatment at the time."

9 Can you explain that in more detail?

10 A. Well, let's take them one by one. So
11 clearly, putting topical products onto vitiligo skin
12 is done with corticosteroids in another other -- in
13 other topical agents. Subcutaneous injections are
14 injections that are below the skin into the fat
15 under the skin. So understand that, because it's
16 very similar to injecting that into the dermis or
17 intradermal, which is that thick part of the skin,
18 and then using a microneedle to puncture the skin.

19 So all three of these deliver drug or
20 whatever you wish to deliver in the area of the
21 skin, sometimes a little lower in the case of a
22 subcutaneous and a little higher than that with the
23 intradermal.

24 And then the microneedling is a strategy
25 to break up the barrier function of the skin to

1 deliver an agent very topically, and it's probably
2 the type of delivery that would be closest to where
3 the pigmenting cells are.

4 So these are all ways that we treat skin
5 disease daily. And with regard to vitiligo, we
6 might -- a clinician might use any of these to
7 deliver a therapeutic, a steroid, for example.

8 Q. With a known therapeutic for vitiligo,
9 would each of these routes of administration have
10 been expected to result in similar efficacies --

11 MR. MILLS: Objection to form.

12 Q. -- in treating the vitiligo?

13 MR. MILLS: Objection to form, foundation,
14 incomplete hypothetical.

15 A. I don't know that we have a comparison of
16 these methods that's, you know, published in the
17 clinic. But I can tell you that rather than getting
18 injections, patients would rather have a topical
19 product.

20 Q. And a topical administration would be
21 expected to be effective as well as a subcutaneous
22 injection? Is that correct?

23 MR. MILLS: Objection to form, foundation,
24 incomplete hypothetical.

25 A. For vitiligo, I don't have a comparison

1 for those except my clinical experience, and a
2 subcutaneous injection would be usually more
3 beneficial than a topical.

4 Q. As of 2017 would you have expected each of
5 these routes of administration to be effective in
6 vitiligo with an IL-15 inhibitor?

7 MR. MILLS: Objection to form, foundation,
8 incomplete hypothetical.

9 A. I don't have a molecule like that, so I
10 couldn't provide you with a comment on that. I'd
11 have to guess what that was, and I'd prefer not to
12 do that.

13 Q. For administration of a JAK inhibitor,
14 would each of these methods of administration would
15 have been expected to be effective for the treatment
16 of vitiligo as of 2017?

17 MR. MILLS: Objection to form, foundation,
18 incomplete hypothetical.

19 A. In 2017 we knew that there was an oral
20 product that had shown some promise based on the
21 articles we've discussed. That's not one of the
22 modes of administration listed here. So in 2017 I
23 don't know that we knew what might be effective in
24 people.

25 Q. Do you have any opinion as of 2017 whether

1 a person would have reasonably expected a topical
2 administration of an IL-15 inhibitor would treat
3 vitiligo?

4 MR. MILLS: Objection to form, foundation,
5 incomplete hypothetical, scope.

6 A. A person of ordinary skill, POSA, would
7 probably know that if a IL-15 inhibitor involved a
8 large molecule like an antibody, it would not get
9 through the skin topically, so it wouldn't be
10 effective or it would unlikely be effective.

11 Q. What's your opinion as of 2017 whether a
12 person would have reasonably expected subcutaneous
13 administration of an IL-15 inhibitor to treat
14 vitiligo?

15 MR. MILLS: Objection to form, foundation,
16 incomplete hypothetical, scope.

17 A. Well, a subcutaneous administration of an
18 IL-15 inhibitor, if that inhibitor was a antibody,
19 which is what most of the inhibitors we've been
20 talking about today are, it may or may not be
21 effective in vitiligo because that antibody might
22 not get to where it needs to be on another part of
23 the body. It's just unknown whether that might be
24 effective or not.

25 It would be something that a POSA would

1 attempt or try. It would make sense to try that.
2 But my opinion about whether that would work or not,
3 you know, is irrelevant until it's just -- it's been
4 tried.

5 Q. What's your opinion as of 2017 whether a
6 person would have reasonably expected administering
7 to the epidermis within the lesion an IL-15
8 inhibitor for treating vitiligo?

9 MR. MILLS: Objection to form, foundation,
10 incomplete hypothetical, scope.

11 A. I think if we are able to get the
12 inhibitor to the epidermis where the melanocytes
13 are, we would have the best chance of treating the
14 vitiligo. And again, it would depend on what kind
15 of inhibitor, is it a antibody, is it a small
16 molecule. But either way, it would be something
17 that you might try. It would make sense for a
18 person of ordinary skill to try that.

19 I think what is important about this,
20 because we can go through every single
21 administration, is just that there's no instruction
22 in the patent about these other methods of delivery.
23 There was intraperitoneal injections and there was
24 subcutaneous injections. But these others were
25 reasonable and logical things to try, but those

1 weren't used in Example 5, at least.

2 And there's -- the Patent '505 makes a
3 claim for administering it this way, but there's no
4 evidence that that was used in coming up with this
5 animal model.

6 Q. But you acknowledge that each of these
7 modes of administration were routine and common in
8 the field of vitiligo treatment as of 2017, correct?

9 MR. MILLS: Objection, form.

10 A. That's what I say in paragraph 9, each of
11 these modes of administration were routine and
12 common in the field of vitiligo at the time.

13 Q. As of 2017 can you explain what IL-15
14 inhibitors or IL-15 inhibitor -- receptor inhibitors
15 were known for various autoimmune diseases?

16 MR. MILLS: Objection to form, scope.

17 A. Again, as of 2017, I am not a historian
18 but a clinician. In dermatology, we did not have
19 anything like that in '17 to use on patients
20 clinically that were approved by the FDA for
21 dermatology conditions.

22 Q. Are you aware -- sorry.

23 A. I'm aware of -- I'm aware that that was a
24 target, and possibly there are other drugs that I'm
25 not aware of in other fields that were IL-15

1 inhibitors.

2 Q. Are you aware of any that were in clinical
3 development as of 2017?

4 MR. MILLS: Objection to form and scope.

5 A. In 2017 I was not aware of those. I don't
6 know.

7 Q. Did you investigate any references that
8 might have described IL-15 inhibitors that were
9 known in clinical development as of 2017?

10 MR. MILLS: Objection to form, scope.

11 A. The patent that we discussed earlier,
12 1011, it discusses IL-15 inhibition in these
13 antibodies. So to the extent of this patent, I
14 researched that. But, you know, my focus is on the
15 patent at hand with regard to the '505.

16 Q. Other than the patent in Exhibit 1011, did
17 you consider anything else as to what was known
18 regarding IL-15 inhibitors that were in preclinical
19 development?

20 MR. MILLS: Objection, form, scope.

21 A. There may be other IL-15 inhibitors that
22 were in preclinical development. I'm not aware of
23 what they were.

24 Often, when molecules are in preclinical,
25 their progress is not disclosed for competitive

1 reasons.

2 Q. Was there anything else then that you
3 considered to what was known about IL-15 inhibitors
4 for the treatment of other diseases more generally
5 as of April 2017?

6 MR. MILLS: Objection, form.

7 A. Well, the things that I considered in
8 my -- in the preparation of my opinion, you know,
9 are attached here. And in that, IL-15 was looked at
10 for other diseases. We went through and talked
11 about that long list that we named off. And there's
12 a lot of other conditions that you might look at
13 that to see if there's benefit in different
14 diseases: psoriasis, atopic dermatitis. There was
15 allergies and asthma mentioned. The list could go
16 on and on.

17 Q. So by 2017, IL-15 -- potential
18 therapeutics targeting IL-15 were known for various
19 different autoimmune and dermatology conditions that
20 we discussed. Is that correct?

21 MR. MILLS: Objection to form, foundation,
22 incomplete hypothetical, scope.

23 A. I think I answered your question.

24 MR. FELDSTEIN: Why don't we take a break.

25 (Recess from 12:20 to 12:31)

1 MS. ROBERTS: Dr. Plott, those are all the
2 questions we have for you today, so thank you for
3 your time.

4 THE WITNESS: You're very welcome.

5 E X A M I N A T I O N

6 BY MR. MILLS:

7 Q. Let me ask a couple of limited questions.

8 Dr. Plott, do you recall being asked some
9 questions about the site of pathology in Xing versus
10 the Harris mouse model?

11 A. Yes, I remember talking about that.

12 Q. In the Xing paper, what was the site of
13 the pathology?

14 A. In Xing it's in the hair follicle because
15 it's concerning alopecia areata. In Harris, it's
16 concerning vitiligo, and that's in the epidermis
17 with pathology involving the melanocyte.

18 Q. Please take a look at Figure 2 in the
19 caption in the Xing reference, Exhibit 1007.

20 A. Okay.

21 Q. And specifically take a look at Panel H of
22 Figure 2.

23 A. Okay.

24 Q. Does Panel H of Xing Figure 2 have data
25 about the effect of the TM-beta 1 antibody on

1 CD8-positive T cells in the skin of mice?

2 A. It does.

3 Q. What does that data indicate?

4 A. This is showing us that the -- if you look
5 at the two boxes in that figure, that the control
6 animals that were not treated have a high amount of
7 activated T cells. Those are indicated in the box
8 that's labeled 25 as opposed to the animals that did
9 have the antibody, were treated with an anti-IL-15
10 receptor beta. There, the activated T cells are
11 almost nonexistent. That's the box indicating 0.03.
12 These numbers indicate, you know, cell counts and
13 cell numbers.

14 Q. Based upon your expertise and knowledge,
15 does Figure 2 of Xing provide you with any
16 conclusion as to whether the TM-beta 1 antibody
17 employed in Xing was effective at depleting
18 CD8-positive T cells from the skin of the mice?

19 MS. ROBERTS: Objection to scope.

20 A. Well, it clearly depletes those cells
21 because here in the control, which had no treatment,
22 we had a lot of cells. And then when we've treated
23 them, those are all gone.

24 And this item tells us that those are
25 staining of skin biopsies, right? So those cells

1 are being depleted from the skin.

2 Q. And Dr. Plott, do you recall being asked
3 questions about the Harris mouse model in
4 Exhibit 1006?

5 A. Yes.

6 Q. Do you recall referring to the Harris
7 mouse model in Exhibit 1006 as a contrived model?

8 A. I use those words because it's kind of a
9 made-up thing, you know. They eliminate the mouse's
10 immune system and then they put these cells back in
11 that are T cells that are activated to kill the
12 melanocytes. And of course they do what they're
13 programmed to do. And then they block them with
14 their antibody that they use in here and, you know,
15 the vitiligo gets better. So it's kind of not too
16 surprising that you get those results based on what
17 was done.

18 Q. And you also -- do you recall testifying
19 earlier about the obviousness of applying the
20 antibody in Xing to the Harris mouse model in
21 Exhibit 1006?

22 A. Yeah, I think that it's a natural next
23 step. If I have the Xing article in my hand and I
24 know, gosh, I'm a researcher in vitiligo and what I
25 know about what's happened with Harris's article, it

1 makes just sense, like I want to get that antibody
2 and I want to use it in this model. And I think
3 that that would be something that a person of
4 ordinary skill in the art would do.

5 Q. And from your perspective, based on your
6 expertise, what would be your expectation that would
7 result upon administering the TM-beta 1 antibody to
8 the Harris mouse?

9 MS. ROBERTS: Objection to scope.

10 Q. Let me withdraw and re- -- and issue a new
11 question.

12 A. Yeah, y'all were talking over each other,
13 so --

14 Q. Yeah. From your perspective and based on
15 your expertise, would you have -- what expectation
16 would a person of ordinary skill in the art have
17 regarding the effect of administering the TM-beta 1
18 antibody disclosed in Xing on the CD8-positive T
19 cells in the skin of the mouse in Harris?

20 MS. ROBERTS: Objection to scope.

21 A. Well, the antibody that's administered in
22 Xing is going to act in the Harris model to -- my
23 expectation would be to prevent the development of
24 vitiligo. It prevented the hair loss in Xing, and I
25 think that it would prevent the mice in Harris from

1 developing their disease.

2 Q. Do you recall testifying regarding the
3 irradiation of the mice in the Harris mouse model?

4 A. Yes, I do.

5 Q. So why did you mention that the Harris
6 mice were irradiated?

7 A. It's important to understand the context
8 of that immune system when we're talking about the
9 Harris model, because after eliminating the immune
10 system by radiation, we're giving the animal an
11 activated immune system that's going to attack the
12 melanocytes.

13 When that happens and the mouse develops
14 vitiligo, it's not so unexpected as a POSA that
15 giving an antibody to block that response would
16 reverse the vitiligo.

17 Q. Thank you. Do you recall being asked
18 questions about the disclosures of the '505 patent?

19 A. Yes.

20 Q. And you were asked questions about whether
21 the experiments -- let me withdraw that question,
22 sir.

23 You were asked questions about the working
24 examples in the '505 patent. Do you recall that?

25 A. Yes. There were six examples.

1 Q. How many working examples in the '505
2 patent that administer a inhibitor of IL-15 or a
3 potential inhibitor of IL-15 signal?

4 MS. ROBERTS: Objection to scope.

5 A. There's -- that's only discussed or
6 mentioned in the patent under Example 5.

7 Q. So that sole working example of purported
8 IL-15 inhibition in the '505 patent, do you have an
9 opinion as to whether that example is representative
10 of treating the full scope of what's claimed in the
11 '505 patent?

12 MS. ROBERTS: Objection, scope.

13 A. As I had said in my opinion, the way that
14 I read the '505 patent is that the claim includes
15 humans and any organism that really has vitiligo but
16 that the scope of what's been done is the mouse
17 model that I've previously described, and it's
18 limited to that. It's an interesting science
19 experiment. It is a mechanistic study that would
20 then prompt investigators to do more work, and it's
21 a long ways from something that you would then take
22 into humans.

23 MR. MILLS: Thank you. No further
24 questions.

25 MS. ROBERTS: No further questions from

1 us. Thank you.

2 MR. MILLS: Thank you. The deposition is
3 over. The witness reserves the right to review the
4 transcript.

5
6 (Deposition concluded at 12:43 p.m.)

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WITNESS NAME: DATE OF DEPOSITION:
R. TODD PLOTT, M.D. SEPTEMBER 22, 2023

[illegible]

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1 I, R. TODD PLOTT, M.D., have read the
2 foregoing deposition and hereby affix by signature
3 that same is true and correct, except as noted
4 above.

5
6 _____
7 R. TODD PLOTT, M.D.
8

9 STATE OF _____)

10 COUNTY OF _____)

11 Before me, _____, on this
12 day personally appeared R. TODD PLOTT, M.D., known
13 to me (or proved to me under oath or through
14 _____) (description of identity card or
15 other document) to be the person whose name is
16 subscribed to the foregoing instrument and
17 acknowledged to me that they executed the same for
18 the purposes and consideration therein expressed.

19 Given under my hand and seal of office
20 this _____ day of _____, 2023.
21

22 _____
23 NOTARY PUBLIC IN AND FOR

24 THE STATE OF _____

25 My Commission Expires: _____

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REPORTER'S CERTIFICATE

I, KAREN L. SHELTON, Texas CSR No. 7050,
RDR, CRR, do hereby certify;

That R. TODD PLOTT, M.D., the witness
whose deposition is hereinbefore set forth, was duly
sworn by me and that this transcript is a true
record of the testimony given by the witness;

I further certify that I am neither
counsel for, related to, nor employed by any of the
parties or attorneys in the action in which this
proceeding was taken. Further, I am not a relative
or employee of any attorney of record in this cause,
nor am I financially or otherwise interested in the
outcome of the action.

Certified to by me on this the 24th day of
September, 2023.



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Page 80

1 JAD A. MILLS

2 jmills@wsgr.com

3 September 25, 2023

4 RE: Forte Biosciences, Inc. v. University Of Massachusetts
5 9/22/2023, R. TODD PLOTT, M.D.(#6083971)

6 The above-referenced transcript is available for
7 review.

8 Within the applicable timeframe, the witness should
9 read the testimony to verify its accuracy. If there are
10 any changes, the witness should note those with the
11 reason, on the attached Errata Sheet.

12 The witness should sign the Acknowledgment of
13 Deponent and Errata and return to the deposing attorney.
14 Copies should be sent to all counsel, and to Veritext at
15 clientservices-yom@veritext.com

16
17 Return completed errata within 30 days from
18 receipt of testimony.

19 If the witness fails to do so within the time
20 allotted, the transcript may be used as if signed.

21
22 Yours,

23 Veritext Legal Solutions
24
25

Page 81

Forte Biosciences, Inc. v. University Of Massachusetts
R. TODD PLOTT, M.D. (#6083971)

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R. TODD PLOTT, M.D. Date

1 Forte Biosciences, Inc. v. University Of Massachusetts

2 R. TODD PLOTT, M.D.(#6083971)

3 ACKNOWLEDGEMENT OF DEPONENT

4 I, R. TODD PLOTT, M.D., do hereby declare that I
5 have read the foregoing transcript, I have made any
6 corrections, additions, or changes I deemed necessary as
7 noted above to be appended hereto, and that the same is
8 a true, correct and complete transcript of the testimony
9 given by me.

10
11 _____
12 R. TODD PLOTT, M.D.

Date

13 *If notary is required

14 SUBSCRIBED AND SWORN TO BEFORE ME THIS

15 _____ DAY OF _____, 20____.

16
17
18 _____
19 NOTARY PUBLIC

[& - 36]

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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