UNITED STATES
INTERNATIONAL TRADE COMMISSION

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In the Matter of | Investigation No.

CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME | 337-TA-1238

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OPEN SESSIONS

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Wuhan Healthgen Biotechnology Corp. v. Ventria Bioscience Inc. IPR2023-00684
Ventria Exhibit 2002

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

Before the Honorable MaryJoan McNamara

Administrative Law Judge

In the Matter of Investigation No.

CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME 337-TA-1238

EVIDENTIARY HEARING

Thursday, November 4, 2021

Volume I

The parties met via remote videoconferencing pursuant to notice of the Administrative Law Judge at 9:30 a.m. EDT.

Reported by: Linda S. Kinkade RDR CRR RMR RPR CSR

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*** Index appears at end of transcript ***

P R O C E E D I N G S

(In session at 9:30 a.m. EDT)

JUDGE MCNAMARA: We are here this morning on certain plant-derived recombinant human serum albumin and products containing same. We have a five-day hearing scheduled. And I did, of course, receive and read each side's prehearing statements, so I have a pretty good idea of the allocation of time.

Let me just remind you of a few things which you already know. Please keep your microphones on mute if you are not speaking. Kindly identify yourself before you speak. I may know who you are. Ms. Kinkade knows who you are. But I like to call the record the silent witness. So it may not know who you are. So please identify yourselves.

Now I would like the Complainant, who is Ventria Biosciences, Inc., to please identify your lead counsel today. And if you have any corporate witnesses with you, I would appreciate your identifying them.

MS. HOEKEL: Good morning, Your Honor. This is Jennifer Hoekel on behalf of Complainant. With me as counsel for the proceeding is Beau Jackson, Tom Heneghan and Andrea Shoffstall, all from Husch Blackwell and all on behalf of Complainants.

JUDGE MCNAMARA: Can you kindly turn on your video each of you for a moment so we can see you and --

MS. HOEKEL: They are all in the room with me, Your Honor, so I'm going to have them step in front of the camera.

JUDGE MCNAMARA: Good.

MR. HENEGHAN: Good morning, Judge. I'm Tom Heneghan.

MS. SHOFFSTALL: Good morning, Your Honor. I'm Andrea Shoffstall.

MR. JACKSON: Good morning, Your Honor. This is Beau Jackson for the Complainant as well. Nice to see you.

JUDGE MCNAMARA: Okay. Do you have any corporate representatives with you this morning?

MS. HOEKEL: We do, Your Honor. We have Scott Deeter as our corporate representative, and he is in our observing room. Our technical person, Ms. Hitchens, is going to go down there and ask them to turn on their computer -- or the video.

JUDGE MCNAMARA: Anybody else on the list of attendees whom you would care to identify?

MS. HOEKEL: On behalf of Complainant at this time, we have Mike Martinich-Sauter, who is also counsel for Complainant.

MR. MARTINICH-SAUTER: Good morning, Judge.

JUDGE MCNAMARA: Where are you?

MR. MARTINICH-SAUTER: I'm participating from

St. Louis.

JUDGE MCNAMARA: Very good. You're an hour behind us right now.

MR. MARTINICH-SAUTER: Correct, Judge.

JUDGE MCNAMARA: Okay.

MS. HOEKEL: Your Honor, for the record, everyone else on the examining team is in Kansas City, and so we're also an hour behind the court time.

JUDGE MCNAMARA: Okay. All right. Is there anyone else you'd care to introduce?

MS. HOEKEL: So I think we have -- on the video now in our observing room is Mr. Scott Deeter, who is the corporate representative. He is sort of waving on the side on the right there.

JUDGE MCNAMARA: I can see him. Good morning, Mr. Deeter.

MS. HOEKEL: And then we also have Crissa Cook, outside counsel for Complainant in the room.

JUDGE MCNAMARA: Good morning, Ms. Cook.

MS. HOEKEL: We have Abby Goodrich, who is our paralegal in the room. And then on the left-hand side is Marcus Curl, who will also be a witness for Complainant as an employee of Complainant.

JUDGE MCNAMARA: Very good.

MS. HOEKEL: And then lastly, and most

importantly, we have Lauren Hitchens, who is running all of our technology.

MS. HITCHENS: Good morning, Your Honor.

JUDGE MCNAMARA: Good morning, Ms. Hitchens.

All right. Very good.

MR. HOWE: Your Honor, you asked for a list of attendees as well. This is Stephen Howe. I'm an attendee on behalf of Ventria out of Milwaukee.

JUDGE MCNAMARA: Very good.

MS. HOEKEL: And Mr. Howe is also counsel with Husch Blackwell, Your Honor.

JUDGE MCNAMARA: I'm a little bit familiar with Milwaukee. I have some family there, and in Kansas City for that matter.

MS. HOEKEL: I'm sorry, Judge. I left one person off. Our remedy expert, Ryan Brennan, is in -- LaMotta -- sorry -- that's a totally different person -- Ryan LaMotta is also in the observing room, and he is our financial expert witness.

JUDGE MCNAMARA: Good morning, Mr. LaMotta.

MS. HOEKEL: With that, Judge, I do believe we have identified everybody on Ventria's side.

JUDGE MCNAMARA: Very good. Now for the Respondent, to whom I'm going to -- how would you like me to refer to the Respondent?

MS. NIEMEYER: Good morning, Your Honor. This is the Elizabeth Niemeyer for the Respondent Healthgen. I would refer to them just as Healthgen. I think that's the most succinct name for them.

JUDGE MCNAMARA: I think so, too. Would you care to introduce your team, Ms. Neimeyer?

MS. NIEMEYER: Yes. And I'm not entirely sure who we will be able to bring up on screen. With your permission, Your Honor, the way we are set up, we are sitting down.

Is that okay with Your Honor?

JUDGE MCNAMARA: Oh, sure.

MS. NIEMEYER: Okay.

JUDGE MCNAMARA: I go up and down during the day too. You'll see different views of my office because I have a standing desk, an electronic standing desk, so I'll be up and down too.

MS. NIEMEYER: Okay. The other thing I'll note, I'll get to the introductions, but, with your permission, I think we're supposed to identify the particular speaker on Webex with the person's name. And what you'll see is we have Finnegan lectern. We can change it to the person's specific name, but we would need to log out and log back in, and I think that creates certain risks. So if that's okay with you, we'll keep it that way.

JUDGE MCNAMARA: I think that's fine. As long as everybody continues with the protocol of identifying him or herself before you speak, we'll be fine with that. What I find is that everybody is so excited to get up and start talking that they sometimes forget to identify themselves. It's a pattern, but to be expected.

MS. NIEMEYER: I understand that, Your Honor. I get comfortable and I sometimes forget to introduce myself.

JUDGE MCNAMARA: So do I.

MS. NIEMEYER: But you're the judge.

JUDGE MCNAMARA: Well, you know.

MS. NIEMEYER: With me now, to our team, is Rob Shaffer. You will be hearing from him today.

MR. SHAFFER: Good morning, Your Honor.

MS. NIEMEYER: You will also be hearing from Max Giannelli and Mike Kudravetz. I know you've met Dr. Giannelli before. And there are Dr. Giannelli and Mr. Kudravetz.

JUDGE MCNAMARA: Good morning.

MS. NIEMEYER: And also with us on our team are Dr. Wong logging in from China --

JUDGE MCNAMARA: So what time is it there in Hong Kong?

MS. WANG: It's about 9:40 p.m. in China.

JUDGE MCNAMARA: Tough place to be in terms of

having had a long day already.

MS. WANG: It's okay. Thank you, Judge.

JUDGE MCNAMARA: You're welcome.

MS. NIEMEYER: Also with us on our litigation team are Dr. Yieyie Yang, Elliott LaParne, and Brooke Wilner. They are in our hearing room which is only accessible to counsel and individuals who are under the protective order.

JUDGE MCNAMARA: Good morning.

DR. YANG: Good morning.

MS. NIEMEYER: As you can see, our client representative, Dr. Yang with Healthgen, also joining from China. Also on our team we have Bella Downey and Ashley Dial, who are part of our support team, crackerjack people. And then we also have our experts, Dr. DeFilippi and Mr. Brett Reed.

JUDGE MCNAMARA: Right. And I just want to make sure I'm seeing Dr. DeFilippi. I certainly read all of your names, and, of course, some of you have come up more than once, not surprisingly.

Dr. DeFilippi, are you there? Can I see you, please?

MS. NIEMEYER: I think we can put him into a room that has a camera on it so that he and Mr. Reed can pop up.

JUDGE MCNAMARA: Okay. That would be great.

Thank you.

MS. NIEMEYER: We'll get them into that room with a camera right now.

JUDGE MCNAMARA: Okay. Very good. And then while we're waiting for them to come and to see them, I would ask that each side please identify someone who will be responsible for timekeeping. And I would like to receive a joint email at the end of the day listing the amount of time that each side has spent or expended and the amount of time remaining. So I would appreciate it if each side would identify someone to do that.

And since you're up right now, Ms. Niemeyer, is there someone from your side that will be doing that?

MS. NIEMEYER: That would be Elliott LaParne.

JUDGE MCNAMARA: Ms. Hoekel, from your side?

MS. HOEKEL: It will be Ms. Hitchens.

JUDGE MCNAMARA: Also, while we're waiting, I just wanted to mention that each party is responsible for ensuring that whoever should not be in the hearing when we move to confidential business information is identified and asked to leave, and we will wait for that individual or individuals to jump off, and then we'll keep going after that. So please be aware of that. That's another one of those stopping points where sometimes people are so excited about getting in their information that they kind of forget

that we're heading into confidential business information.

Okay. So I think we have -- Ms. Niemeyer, I can see that you have your additional attendees there.

MS. NIEMEYER: I just wanted -- I don't want to avoid getting to the Staff's introduction, but we do have Dr. DeFilippi and Mr. Brett Reed now on screen.

JUDGE MCNAMARA: Very good. Which of you is Dr. DeFilippi?

DR. DEFILIPPI: That is I. You can even call me Dr. Lou, if it rolls off your tongue easier. I have no issue with that.

JUDGE MCNAMARA: Very good. Mr. Reed?

MR. REED: Good morning, Your Honor.

JUDGE MCNAMARA: Good morning. Thank you. Now at least I have faces I can put with names.

Ms. Niemeyer, you still have staff to identify?

MS. NIEMEYER: We have identified the core of our staff. We also have Ryan Fisher, who is our document manager and running the system. We might have some other technical people who come in and out as needed, if there's any glitches that pop up.

JUDGE MCNAMARA: Very good. Glad to hear that.

Okay. So has everyone from your teams or your corporate representatives or expert or other witnesses been identified?

MS. NIEMEYER: Yes, Your Honor.
JUDGE MCNAMARA: Ms. Hoekel?
MS. HOEKEL: Yes, Your Honor.
JUDGE MCNAMARA: Very good. Okay. So let me identify my team. I have with me Jae Lee, who is my senior attorney and at this point my only attorney, but she has been with me a long time, and without her I'm not sure what I would do.
Good morning, Jae.
MS. LEE: Good morning, Judge. How are you?
JUDGE MCNAMARA: Very well. How are you?
MS. LEE: I'm good. Thank you.
JUDGE MCNAMARA: We also have with us Nicole Muhammad. Nicole joined my team this summer, and I am delighted to have her.
Ms. Muhammad, are you there? There she is.
MS. MUHAMMAD: Good morning, Judge. How are you?
JUDGE MCNAMARA: Very well. Thanks. How are you, Nicole?
MS. MUHAMMAD: I'm doing well. Thank you.
JUDGE MCNAMARA: Nicole helped Jae set all of this up. She has fast become instrumental to my team as well. So it's terrific.
All right. So, with that, I think I covered time. We're going to try to stop each day at 5:30. I think

five days is really sufficient for this since we only have one patent at issue, which is the 10,618,951 patent, to which I will refer as the '951. And as I understand it, we still have claims 1, 2, 11, 12, and 13 at issue.

Is that accurate or did I -- a couple have been terminated I know.

MS. HOEKEL: Claim 2 is also out, Your Honor, at this point. Sorry. That's Ms. Hoekel, for the record.

JUDGE MCNAMARA: Yes. Thank you. I keep trying to adding an R to your name.

MS. HOEKEL: You're not the only one, Your Honor. That happens all the time. My mother said that for years after I was married.

Yes. Claim 2 is also out of the case at this point too, Your Honor.

JUDGE MCNAMARA: Very good. So we have claims 1, 11, 12 and 13. Very good.

And I did not introduce Staff. I'm sorry, Mr. Guarnieri. I don't know why I do this, but I do.

MR. GUARNIERI: That's okay, Your Honor. This is Pete Guarnieri on behalf of the Staff, also appearing for Import Investigations. And I'm joined virtually at least by Anne Goalwin from our office as well.

JUDGE MCNAMARA: Good. Oh, you are in your office.

MS. GOALWIN: Good morning, Your Honor.

MR. GUARNIERI: No. I think we are both appearing remotely from home, unfortunately, but it's just us.

JUDGE MCNAMARA: Okay. It's not just you. I think that's not fair to describe yourself in that way. It is you and you are not just you. You're an important part of this as well.

MR. GUARNIERI: Thank you.

JUDGE MCNAMARA: Now I understand that Staff has limited participation.

MR. GUARNIERI: Yes, that's correct, Your Honor. So for the notice that was filed, the only issues that we're going to be participating in will be the remedy issues, which, of course, is continued on finding a violation in the first instance, so we are not going to take a position on the merits of the violation issues, just the remedy issues.

JUDGE MCNAMARA: Very good. But during the course of the hearing, what I may do, so that you are forewarned, Mr. Guarnieri, if there is a dispute over evidence, I may ask for your thinking on the issue, just so that you know so that you're prepared.

MR. GUARNIERI: Absolutely, Your Honor. The Staff is happy to offer its views on evidentiary issues and testifying issues. I know we are happy to assist the court

in any way we can to resolve those. And so certainly that would be fine.

JUDGE MCNAMARA: Very good. What I wanted to mention was that we'll take at least two breaks a day, 15 minutes each, and we'll take an hour for lunch. What I try to do is stop organically. If someone needs a break or we're changing witnesses, but do not hesitate, if anyone needs a break and needs to step away, to please just put that on the record and let me know.

Also, if for any reason you should see someone on the participant list who should not be there -- we occasionally get attendees who aren't supposed to be on -- please just speak up and let me know.

MS. NIEMEYER: Your Honor, may I ask, for the purposes of when we go on the confidential record, how that will be handled and who should take care of it? I know sometimes specific individuals would get moved into a waiting room. I wasn't sure if you would do that or if that's something we should plan to do.

The only person on our list who would not be under the protective order is Dr. Yang. I don't know if he will be -- I was curious who will be moving people into waiting rooms. We will help monitor who is in the room in general, but as far as moving people who might be appearing on Webex into a waiting room.

JUDGE MCNAMARA: We're not going to do that. I have found that using the waiting room ourselves is -- it's a bit clunky. So I would appreciate it -- I know individually it can be certainly not facile to jump on and off, but I think that's what we're going to do.

There is typically not much CBI unless we get into the discrete proprietary information or we get into the domestic industry information. So I think -- I'm not sure when the first of that is coming up. Again, I read the prehearing statements. So just alert me to when that's coming up. But I think for the most part you-all have identified who is on the protective order, and it should be easy to ask those folks who are not to jump off.

MS. NIEMEYER: Okay. Thank you, Your Honor. I'll note that I think part of each side's openings at some point may get into confidential information, and we'll just make sure that those people are not on Webex or not in a room where they can hear or access the information.

JUDGE MCNAMARA: That would be great.

Ms. Hoekel?

MS. HOEKEL: Yes, Your Honor, I was going to say for Complainant we are just -- Andrea Shoffstall will be in charge of that and asking the witnesses who are not under the protective order, the participants who are not under the protective order, to physically leave the room during any

CBI portion of the parties.

I know with respect to both the opening and at least Mr. Deeter's testimony it's fairly contained, and so we shouldn't -- it shouldn't be a popping head situation and people coming and going all the time. We have tried to really organize it in such a way that it's limited and it's contained.

JUDGE MCNAMARA: Okay. That's a good idea. So before we get started, again, I know that we terminated two claims yesterday, one of which I guess was claim 2, and I also -- we issued a ruling, I think it was order 27, on Ventria's revised request for receipt of evidence without a sponsoring witness.

So are there any other issues that you can identify that need to be resolved this morning?

MS. HOEKEL: This is Ms. Hoekel again, Your Honor. I don't believe the Court has ruled on the most recent nonsponsored witness request, so we would like to take that up. I believe the Staff had asked to be heard on that issue as well.

And then before we get into that, I had a couple of other -- we can either take that up now or I had a few other sort of minor housekeeping questions or things we just wanted to kind of put in the agreement that were agreements between the parties. So however Your Honor wants to handle

that.

JUDGE MCNAMARA: Might as well take care of them now, unless they have to do with specific witness testimony that you are signaling me there may be -- with which there may be problems. I like to take those -- I'm not talking about your request for submission of evidence without a sponsoring witness. I'm talking about live witnesses. If we get to a point where they are about to testify and there are objections to testimony, I prefer to take that up at the time the witness appears and starts to testify.

MS. HOEKEL: Okay. That's helpful, Your Honor.

So there is one remaining -- it's four documents, but it's one basic objection to exhibits that will come in through Mr. Deeter. So we can take that up when Mr. Deeter becomes a witness.

So I'll just take up the other housekeeping matters right now, if that's okay, and then we can --

JUDGE MCNAMARA: Fine.

MS. HOEKEL: Just for the record, we have a witness who we thought was going to testify live that we informed Healthgen was not going to be testifying live after all, and that's Ning Huang. And the parties have done depo designations and exhibit designations for that witness. We just wanted to state on the record that we believe those should be entered as the previous deposition designations

and exhibits were.

JUDGE MCNAMARA: Ms. Niemeyer, does Healthgen have any objections to that?

MS. NIEMEYER: No, Your Honor. We agree with that and have a question on how you would like us to address that. That exhibit, the deposition transcripts with both sides designations is RX-6. We have identified the exhibits that travel with it. There was also order No. 19, which admitted certain exhibits without a sponsoring witness.

And we wanted -- we were curious how you would like us to formally move those into the record so that the record reflects that they have been admitted. We could send the court reporter a list of the exhibits that were admitted through order No. 19 and include RX-6 and the exhibits that go along with that, which the parties have discussed and agree upon, but we would appreciate your guidance on that.

JUDGE MCNAMARA: That makes sense to me. Just include them as part of a list of exhibits that you've agreed upon that you're going to send to chambers -- my house -- but also to Ms. Kinkade.

MS. NIEMEYER: Okay. We'll take care of that. Thank you, Your Honor.

JUDGE MCNAMARA: You're welcome.

MS. HOEKEL: Your Honor, the next housekeeping matter was when you would like us to formally move for

exhibits to be admitted. The parties have a stipulated procedure where we're exchanging exhibits in advance. We're doing objections the night before the witness. If there's any remaining objections, we'll take them up with Your Honor. And then otherwise the exhibits will be coming in through the testimony of the witness.

And the question is should we just maybe the next morning -- and then the night after the testimony -- excuse me -- the parties will exchange a list of the exhibits they believe should be entered into the record.

And the question is, then, is that an acceptable procedure, and then can we the next morning just kind of read those lists of exhibits into the record?

JUDGE MCNAMARA: I think your procedure is just fine. I read the stipulation. Typically people either enter into evidence the list of exhibits from that day or the next morning, but I see you've worked it out for the next morning, so that's fine.

You don't have to read all of the exhibits into the record. If you have a joint list that you've agreed upon, you just let us know that you've got the joint list, that it's been agreed upon. And if there is a reserve of any exhibits that are disputed, I'll take it up, but we'll just put the other non-disputed exhibits into evidence without reading them all into the record.

MS. HOEKEL: Thank you, Your Honor. The next housekeeping question we had or clarification is the parties have discussed and understand, obviously, the Court's rule on witness sequestration. We just wanted to make it clear on the record that the parties agree that the expert witnesses are not sequestered after they have done their sort of case-in-chief testimony.

For example, Dr. Wilken will testify tomorrow about infringement, assuming she is directed, crossed, and redirected tomorrow and is concluding her infringement testimony, she will be free to be released from sequestration for purposes of preparing for her invalidity testimony, and similarly with Respondents' expert witnesses.

JUDGE MCNAMARA: Yes. That's the normative rule.

MS. HOEKEL: Thank you, Your Honor.

MS. NIEMEYER: Your Honor, to follow up on that, we had sort of two follow-up questions. One is, I understand witnesses aren't allowed to participate in the hearing until they testify, but our understanding is experts are permitted to attend. It's fact witnesses who are sequestered until they have testified.

JUDGE MCNAMARA: Yes.

MS. NIEMEYER: Following up on that, Ms. Hoekel may have had this already on something to discuss, but it was the order of witnesses, and the sequestration issue.

For example, if we were to finish early and start Ms. Wilken tomorrow, I think all parties agree that that would work rather than having her start today -- or start today and then finish tomorrow where they are unable to work with her. I understand she may have a conflict.

And then with respect to Dr. DeFilippi, and this is on the estimated procedural schedule that was in the parties' witness -- or the parties' prehearing statements, having him start Monday morning, which again might mean ending a little early on Friday.

The estimated time suggests that that is what would happen, but things go fast or things go slow, so sometimes things kind of just change a little bit. Just for planning purposes, because obviously starting Friday evening and not being able to communicate over the weekend would be fairly significant. Just making sure that following at least that order and given the number of issues, that doesn't seem like something that should create any problems for the parties as a time issue.

JUDGE MCNAMARA: And I'm fine with that. These are your hearings. This is your time. So however you wanted to divide that up is fine with me. Whatever the stopping points are is fine with me. If we end early, all the better. So that works well.

And the whole idea -- I've been doing this now

for several years. The whole idea of breaking up over a weekend when I have more than three days of hearing is to ensure that everybody has a chance to rest, recreate, talk with their witnesses if they need to. So I've been doing this for quite some time, and that's why I do it, and so that I have a break, my Staff has a break.

MS. NIEMEYER: Thank you, Your Honor.

MR. SHAFFER: Thank you, Your Honor.

MS. HOEKEL: We appreciate that, Your Honor.

A couple of other quick housekeeping things. One, Dr. Wilken, and we let Respondents' counsel know this yesterday, is not available today. So she will have to be our first witness tomorrow, if we end today in such a time that we would be ready for her testimony.

We did have one other housekeeping matter before we -- one other housekeeping matter, which was it was surprising to Ventria to see Dr. Yang on the participant list today as the corporate designee given that he has not been made available as a witness in the hearing. And we think that but for COVID requiring this to be virtual, that sort of changed things a little bit. Otherwise, to be an observer, you would be in person in the courtroom.

And so we just wanted to point out that we were surprised by that and think that that is a bit unfair and taking advantage of sort of the virtual rules to have

Dr. Yang in attendance.

JUDGE MCNAMARA: Ms. Niemeyer, can you address that?

MS. NIEMEYER: I guess I don't understand what exactly is being alleged here. We didn't say we were bringing him as a witness. They never asked us to bring him as a witness. We identified him as the corporate representative. He is the head of the company. He is joining for purposes of the introduction. I don't understand what is unfair.

They did depose him for three long days. If they wanted to designate his testimony, they certainly could have even move it into evidence. They didn't do that. I don't understand what the supposed unfairness is. It is virtual. People are able to join virtually. It is true that he would not be able to join if this were in person given travel restrictions and quarantine and different concerns that may arise, but it is virtual, so we're able to do that. They have attorneys who are in different offices across the Midwest.

I guess I don't understand what the concern is or how it has any bearing. He will be joining for the introduction to the extent it's on the public record and he is able to join. I just don't understand what the complaint is or how it is remotely unfair. Him and his company has

been sued, so I think he has a right and entitlement to join, and the virtual environment happens to make that more feasible for him.

JUDGE MCNAMARA: Let me ask Mr. Guarnieri what he thinks, and then I'll come back to you for sure.

MR. GUARNIERI: Your Honor, as counsel for Healthgen pointed out, I don't think Mr. Yang has been called as a witness. I'm not aware of any efforts to compel him to testify as a witness. And so to the extent he is here, just like any other member of the public, he is certainly welcome to view the hearing and the public part of the proceeding. I suppose as well, since he is party to Healthgen CBI, maybe he can stay in any part of the record that implicates only Healthgen CBI.

So I'm unclear if there is any -- I share counsel for Healthgen's unawareness of why this would be improper.

JUDGE MCNAMARA: Ms. Hoekel, would you like to respond?

MS. HOEKEL: Yes, Your Honor. Just briefly. He wasn't identified to us as a corporate representative. I think he was identified to chambers and to Your Honor. But the parties' submission of those documents were not exchanged, and so we had no notice until this morning when Dr. Yang appeared in the Webex that he was going to be appearing.

The last thing I would say is Healthgen made it clear that they were not bringing Dr. Yang or making Dr. Yang available as a witness for this hearing. And so, therefore, we didn't prepare to have him as a witness. I guess my point was, if we were in sort of normal times where everyone had to appear in person, then Dr. Yang would be subject to the subpoena power of the court should he be asked to testify, and that's not something that the parties discussed or were made aware of until he appeared on the Webex this morning.

MS. NIEMEYER: We are not calling him as a witness or are not planning to have him testify. To the extent they are not prepared to cross-examine him, that should not be an issue because he will not be giving testimony.

JUDGE MCNAMARA: Isn't it a fundamental right of a party who is sued to have their -- to be at a hearing? It's part of due process.

So my understanding has been that Dr. Yang would not be called as a witness. My understanding is that he is the owner of the company, and regardless of anything else, due process does give him the right to be present certainly for the public parts of this as any member of the public would be. So on two fronts, I certainly have the discretion to restrict the, quote/unquote, public, but I don't

typically. I don't think that complies with what our efforts are to be transparent.

And so he is certainly entitled to be present for the public parts, but I would want to make sure that he is absolutely not given and does not have access to any of the testimony that is being provided.

Has he been provided with any of that testimony, especially that which is proprietary and confidential to Complainant, to Ventria?

MS. NIEMEYER: Your Honor, Dr. Yang has not been given access to anything that he is not entitled access to, no confidential information of the Complainant. To the extent there's third-party confidential information, we have followed the protective order and not provided him with anything that he should not have.

JUDGE MCNAMARA: Ms. Hoekel, is there any other objection or issue that you see that maybe I don't?

MS. HOEKEL: No, Your Honor. I think we just wanted to raise it. It is a very odd situation because of COVID that it sort of permits people to participate when otherwise they would have to physically be present, and that changes the rules a little bit as to things that they would be subject to.

We are certainly not intimating that Dr. Yang was given any CBI information or that counsel wouldn't -- isn't

going to comply with those rules going forward. It's a very odd situation given COVID.

JUDGE MCNAMARA: And I think, I mean, here we are, more than a year out, almost two years out, and we don't even know when we'll be back in a courtroom. So I think everyone has adjusted, not only procedurally how things are done, but also in terms of expectations and changes. Going forward, I think we're going to be in a hybrid world.

MS. NIEMEYER: Your Honor, I'll note, I agree with Ms. Hoekel that we are in an odd situation. I don't think anyone is going to dispute that. I think that's a global phenomenon.

JUDGE MCNAMARA: I think that's very clear.

Okay. Is there anything else that you would like to take up before we start the openings?

MS. HOEKEL: Your Honor, I think -- last thing, we still were hoping to get a ruling on the nonsponsored witness documents. I know that we had refiled that motion yesterday, yesterday evening, and the Staff attorneys had also noted that they thought it was appropriate for that to be a discussion at some point today.

JUDGE MCNAMARA: It is. So let me ask you this. Are there any of those on this list that are still disputed? Because it's still quite a lengthy list, and if we could

narrow it down to those which obviously should not be admitted. I really don't -- I would prefer that you not argue about documents or admission of documents that very clearly fall within rules of being admitted without a sponsoring witness. I just would like you to focus on those that are truly disputed and for which I have to issue a ruling, and I'm hoping that's not all. I took a preliminary look last night. So I'm really hoping that's not the entire list.

MS. NIEMEYER: Your Honor, I can respond to that. The fact of the matter is we do still object to the documents, although the Complainant provided a shorter list and, I'll say, a longer description. I don't think the longer description actually provides a narrative as to exactly how it's being used.

The bulk of these are documents that were -- they were all produced during fact discovery. They were not used in -- for the most part, many of them in contentions and expert reports and the prehearing brief.

For example, for some of them, they say they are relevant to infringement, but they have not previously been specifically identified or relied upon for purposes of infringement, so it's unclear if they are planning to change their infringement positions, why they haven't been relied on before because they could have been. The experts could

have referred to them, cited them, said they show X.

I just don't think admitting them wholesale at this point seems like an appropriate thing when there's no foundation explaining how they are being used such that we then have to respond to them in post-hearing briefs when they haven't been used for any purposes up until now.

I think there may be some that may come in through experts. I'm not sure if they are planning to use any of these with their experts, and, if so, then they have foundation, and that's fine. The issue is really the ones that have never been used for any purpose, that experts may have just listed in a 20-page list of documents that they reviewed, but then didn't use for any purpose.

So I think to take them and just move them in wholesale now, we don't quite understand exactly what the purpose is, when there is no foundation having said here's why they are being used, when there are other documents that they are already relying upon for those purposes.

JUDGE MCNAMARA: Mr. Guarnieri, I understand that you were part of these discussions or the discussions about this filing. So what's your thinking?

MR. GUARNIERI: Thank you, Your Honor. As Your Honor is aware, Staff filed a response to the original request that supported it with a continuing objection about providing better descriptions for the exhibits. I think at

this point the Complainants have sort of blown past the requirement for what they need to describe an exhibit on an exhibit list. So that objection obviously has been withdrawn.

From the Staff's perspective, Your Honor, there are sort of two salient facts here that I think weigh in favor of admitting these exhibits. The first is that, as I understand it, just looking at the list, the vast majority of these documents are Healthgen's documents. These are documents that Healthgen itself either created or received. And so I really don't think there's any excuse for Healthgen to say we don't know what the documents are. They are their documents.

And I think related to that point is, number two, throughout these discussions I have understood Respondents' position to be it's inappropriate to admit these without sponsoring witness because we don't understand, based on prehearing briefs or the prior discussions of the parties, how Ventria as a party intends to use the documents as part of its case.

But I'm not sure that's actually the standard for why documents should be admitted without a sponsoring witness. A sponsoring witness is -- we want to ensure that -- at least from the Staff's perspective, we want to ensure documents don't come into the record that on their

face are just not understandable.

So, as Your Honor knows, sometimes we have very, very technical cases with highly technical documents, source code, schematics for a particular machine or something, and having those kind of documents floating around on the record without any explanation just doesn't make sense. It pollutes the record. It's difficult for the Commission who is reviewing the record on the full papers to look at that and understand what is this document, why is it in the record, and it prompts for arguments later on when parties argue over what it says and there was no witness there to explain it.

The purpose of the sponsoring witness is not, as Respondents seem to be suggesting, for the witnesses to get up on the stand and say, yes, I recognize this document -- for the following claims. Obviously we don't want fact witnesses to do that. The fact witnesses should simply get up and say this is an email, I sent it on this date, I received it on this date, it was a sales contract, et cetera, et cetera.

And so, from that perspective, this list of documents looks, to the Staff at least, the vast majority to be documents that are easily understandable on the face of the document. They are emails about business transactions, certificates of analysis that I understand are provided by

Healthgen to its customers. And as I understand it, again, we're getting now into sort of a merits issue, but there are already certificates that will be discussed by the experts. These are just additional certificates that go towards infringement.

That all being said, I appreciate Your Honor's concern having a list that's too long. I might suggest here that maybe the best thing to do is, while we are examining the witnesses and getting the opening and getting things going, that Respondents go back, actually look through the list one by one, and pick out any documents that they think are specifically objectionable for some reason within the document, and then, if there's documents we need to talk about and bring up that for some reason are controversial, they are not the correct document, they were drafts instead of final, or whatever the reason is, maybe we can have a better discussion about that sublist. Because it's sort of hard to argue in the abstract about a list of documents that, as I said, on their face seem to be uncontroversial, normal, run-of-the-mill business documents.

JUDGE MCNAMARA: Ms. Hoekel?

MS. HOEKEL: Thank you, Your Honor. Yes, Mr. Guarnieri made most of my points for me, that Healthgen hasn't engaged on a document-by-document objection. There has been no -- they have refused to do that on a

document-by-document basis. It's just been these global objections.

A third of these documents are certificates of analysis. The documents, if they are coming in through an expert witness, Your Honor, we have already removed them from this list. But they are documents that the parties have relied on or discussed, and they are Healthgen admissions, so they have been relied on and discussed throughout the case.

To Your Honor's point, if you would like, none of these documents are on anyone's witness list -- I'm sorry -- exhibit list for today's testimony. So if you wanted the parties to regroup tonight and see if there are specific objections that Healthgen has, per Staff's suggestion, we're happy to engage in that. I don't think any of them are being introduced today.

JUDGE MCNAMARA: Here's my thinking on some of this. First of all, this is a much reduced list from the original list that Ventria submitted. So I think that both Healthgen and Staff have had ample time to have had discussions about certainly most of the documents on this list.

To the extent that they have been already identified as having been created by and provided by Healthgen, there's no basis for objection. If the

parties -- if, for example, Ventria wants to use any of these documents as part of cross-examination, as long as they were already on their list, they are certainly entitled to do that, both under Commission rules and federal rules and my ground rules. So I don't see the basis for objection there.

As you know, some of you have participated extensively in other hearings that I've had over the last number of years, and very typically the parties have exhibit lists that are far longer than those they intend or know that they are going to rely upon beforehand. In fact, I've often wondered at the length of some of these lists that are later withdrawn.

So, for the time being, what I would like you to do -- again, I think Ms. Hoekel and Mr. Guarnieri suggestions were good ones -- that you get together sometime later today. And I would like to know explicitly which documents, other than those that Healthgen created or produced -- and I don't care if they are drafts. Drafts are drafts. They are going to be identified as such. And that would go to the weight of the evidence if something changed in the course of the creation of those documents. That's just the way life works.

So I would like you to meet and get back to me tomorrow morning about any of the documents that are still

problematic. And if anything -- you've already said, Ms. Hoekel, that you don't think anything will be coming up today.

MS. HOEKEL: Yes, Your Honor.

JUDGE MCNAMARA: So that should give you time to narrow the objections.

MS. HOEKEL: One question. Let me make one point and one question.

You made a statement about if they come in through cross-examination. Part of the reason we're having to move these in through nonsponsored witness when they are -- 71 of the 81 are Healthgen documents, is that Healthgen isn't bringing a witness other than --

JUDGE MCNAMARA: Right. Good point.

MS. HOEKEL: I just wanted to make that point.

And then the second point is, to Mr. Guarnieri's point, is that what Ventria has had to do then is subpoena, which we have done, trial subpoenas, for the third parties who received these documents, who would only come in and say, yes, I received this document, and I kept it in our filing system. So it's just authentication. They are not relevance witnesses. They are just saying, yes, I received this document from Healthgen.

They are still under trial subpoena, and so we're still having to keep them open and see when they are

available to come during trial. The sooner we can either release them or firm them up on times would be helpful.

JUDGE MCNAMARA: I understand that, which is also why we emailed you about Alphalyse. We recognize that they are in Denmark. I recognize the timing, what was and not done during discovery, and so that's why we gave you a heads-up that we were -- on how the motion was going to be ruled on.

It's not fair to keep people hanging in terms of -- especially -- well, anybody for that matter -- but when they are in a different country and you know they can't show up or their counsel is going to be sitting there and saying, oh, my gosh. But there would have been a lot of problems anyway, timing, there would have been an enforcement issue through The Hague. I mean, it would have gotten -- it was just an impossible situation.

MS. HOEKEL: My question, Your Honor, sorry, to be more precise, is with respect to like stem cell and ESGEN, and the U.S. distributors who are currently under trial subpoena to -- for the sole purpose of authenticating these Healthgen documents.

JUDGE MCNAMARA: I got it the first time, Ms. Hoekel.

MS. HOEKEL: I'm sorry, Your Honor. I thought maybe I had confused the issue.

JUDGE MCNAMARA: No. But what I would like you to do, I would like to release them sooner rather than later. But as a due process issue, and to ensure that Healthgen has had a clear opportunity, and the sooner the better, I said tonight, but if it can be done sooner, to identify those documents about which they have explicit objections, that will have crossed the T's and dotted the I's from a due process perspective.

MS. HOEKEL: Thank you, Your Honor.

MS. NIEMEYER: Your Honor, if I may, that's fine, and we'll continue that discussion. I think they have narrowed the list thus far. Perhaps we can get to something different.

I will note that we have looked at each document, but we can do so with a greater scrutiny.

I also -- just as an aside, I don't think it's salient whether we have a witness, fact witness appearing or not. We didn't think one was necessary for the purposes of our case. They certainly could have used any of these documents with their experts. So I just wanted to note that.

In a related vein, and you had mentioned order No. 29, terminating the claims, we'll note that that order is not final under Commission rules yet, but I don't believe anyone is planning to address those. If for some force

majeure that is reversed, we would have to revisit it. I don't see anything why these claims would be coming back. We're not planning to address those, even though the order is not officially final, but it's one of those orders that I don't think is going to be controversial.

JUDGE MCNAMARA: My understanding was that Healthgen agreed to it.

MS. NIEMEYER: Agreed.

JUDGE MCNAMARA: And Mr. Guarnieri also filed his support. So there should be no reason or issue about its being final or not. It's going to happen. As you know, the Commission doesn't tend to review those uncontroversial dismissals or terminations. So I think that's where we are.

MS. NIEMEYER: Thank you, Your Honor. I just wanted to note that so there's no ambiguity.

JUDGE MCNAMARA: Well, if something happens that there's a force majeure, it's going to affect the Commission every bit as much as it's going to affect all of us. So I think we'll all be in trouble if there's nothing more than we've already got, which is pretty much a force majeure that we've been living under.

MS. NIEMEYER: I shouldn't have spoken so soon.

JUDGE MCNAMARA: You've got it on the record, Ms. Niemeyer, and I think that's good advocacy. You're fine. I'm just thinking here, hey, what more do you want?

I'll put it that way. It's not even what you want. We have no control over what's going to happen. We have no control over -- that should have been obvious to us now for 18 or 20 months. We don't know what variants are coming. So here we are. We're living under a force majeure.

MS. NIEMEYER: We are, Your Honor.

JUDGE MCNAMARA: Okay. So are you ready to go, Ms. Hoekel, with your opening?

MS. HOEKEL: Your Honor, Mr. Heneghan is going to open for Ventria, so I will step aside. Thank you, Your Honor.

JUDGE MCNAMARA: All right. Very good.

MS. NIEMEYER: Your Honor, Mr. Shaffer will be --

JUDGE MCNAMARA: Okay. Thank you very much for letting me know that.

Good morning again, Mr. Heneghan.

MR. HENEGHAN: Hi, Judge. We're just going to adjust our camera a little bit.

JUDGE MCNAMARA: Are you going to be sharing -- I know that Ventria had some demonstratives for this morning.

MR. HENEGHAN: We are. And one thing I wanted to say about our demonstratives we had posted to the Court's Box site, we actually made a couple little changes. We edited two slides, and we removed two slides so that we could group all the CBI together into two chunks.

JUDGE MCNAMARA: That's smart.

MR. HENEGHAN: And the two slides we took out actually appear again later in the CBI section, so we just thought it made sense to do it that way. We really have pretty well defined areas of either Ventria's CBI or Healthgen's CBI, and I'm prepared to alert the folks and wait a second so that they can leave the room.

JUDGE MCNAMARA: Very good.

MR. HENEGHAN: I think we'll be fine with that.

JUDGE MCNAMARA: That's very smart. That's a very smart thing to do.

MR. HENEGHAN: Thank you. I'm ready, judge, if you are.

JUDGE MCNAMARA: I'm ready.

MR. HENEGHAN: Thank you.

As I mentioned earlier in the introductions, I'm Tom Heneghan. I represent Ventria Bioscience in this matter. Our trial team that will be appearing throughout the investigation is Jen Hoekel, Beau Jackson, Andrea Shoffstall, Lauren Hitchens, and me.

On behalf of Ventria in this matter, you'll hear from Scott Deeter and Marcus Curl.

Scott is the president and CEO of Ventria, and he will testify about the domestic industry that Ventria has built from the ground up. He will testify about the

development of Ventria's innovative products, the tremendous amount of research and inventive work that led to the asserted patent in this case, the '951 patent as the Court identified earlier.

Mr. Deeter will testify about the creation of the market for Ventria's domestic industry products and how that has all happened in the United States, from growing the transgenic rice to processing that grain into recombinant human serum albumin and refining it into the final product that Ventria sells.

Mr. Deeter will also testify about challenges that Ventria has faced, including from foreign actors repeatedly targeting Ventria's valuable industry-disrupting technology.

Mr. Deeter is shown here on the left in this slide.

The other witness from Ventria that you'll hear from is Marcus Curl. He is the director of product applications at Ventria and will testify about the development and operation of Ventria's facilities.

Mr. Curl, who works for Ventria's facility in Colorado, will testify about the company's product application teams, which are comprised of scientifically trained professionals who work with customers on ways to incorporate Ventria's blood-free serum products into their

active research and new product offerings.

Mr. Curl will talk about how the domestic industry products are essential components of products in a variety of context, including lifesaving medicines, in vitro fertilization treatments, and cosmetics.

Mr. Curl will also address the unfair competition from Wuhan Healthgen, including key accounts that Ventria has lost or struggled to maintain in light of Healthgen's malicious pricing, and the ways in which Healthgen's products and aggressive marketing have undermined the industry's confidence in rice-derived albumin, the niche biotech sector that Ventria has invested years and many millions of dollars to develop.

We will also call two expert witnesses, Dr. Lisa Wilken and Ryan LaMotta. Dr. Wilken is shown here on the left, Mr. LaMotta on the right.

Dr. Wilken will testify about the technical issues in this matter. She will address infringement of the '951 patent by Healthgen's liquid- and powder-based products. Dr. Wilken will respond to Healthgen's allegations of invalidity of the '951 patent, and she will testify about the Ventria products that establish the technical prong of Ventria's domestic industry.

Dr. Wilken has a Ph.D. in biological and agricultural engineering from Texas A&M University and is a

professor at Kansas State University where she leads the bioprocessing and bioseparation engineering research lab.

Dr. Wilken's research at KSU is focused on transgenic recombinant proteins produced in plants, the exact field of technology covered by the '951 patent.

Mr. LaMotta is an economic and financial analyst who has carefully studied the economic and competitive aspects of this case. Mr. LaMotta personally visited Ventria's U.S. facilities and farmland and has conducted an in-depth study of Ventria's business and the market at issue.

He will explain why Ventria overwhelmingly satisfies the economic prong. Indeed, Ventria possesses the quintessential ITC domestic industry, as it conducts all of its activities in the United States and invests millions of dollars in the U.S. economy every single year, particularly for the products that establish a domestic industry in this case.

Mr. LaMotta will also address remedy and bond and explain how the direct competition between Ventria and Healthgen and Healthgen's malicious pricing justify a bond of at least 100 percent.

This case epitomizes why Congress enacted Section 337. The dispute pits an American company, Ventria Bioscience, a groundbreaking scientific innovator and 100

percent U.S. manufacturer, against its only direct competitor, Healthgen, a company founded by a former employee of Ventria with the support of the Chinese government.

For many years Ventria has faced unrelenting unfair competition and now it requires the -- I'm sorry -- requires the ITC's intervention to withstand the increased onslaught of Healthgen's patent infringement and associated unfair competition from Healthgen's U.S. distributors.

Section 337 was enacted to combat the precise type of pervasive, unlawful activity at issue here.

This case turns on Healthgen's admissions, the expert testimony regarding infringement of the '951 patent by Healthgen, the validity of the '951 patent, and the existence of Ventria's domestic industry.

Ventria is asserting four claims of the '951 patent: independent claim 1 and dependent claims 11, 12, and 13.

Healthgen has conceded that its products meet most of the limitations of those four claims and does not even offer expert testimony on whether Ventria has established the economic prong of domestic industry.

As for the validity of the '951 patent, Healthgen's retained expert admitted under close questioning from Staff at deposition that his anticipation opinion was a

stretch based upon the prior art on which he relied.

The main prior art cited by Healthgen is not related to transgenic recombinant proteins produced in plants, and a person of ordinary skill in the art would not be motivated to combine the references Healthgen relies upon and would not achieve the invention disclosed in the '951 patent even if a POSA did combine them.

So who is Ventria? Ventria is a pioneering biotechnology firm, based in the heartland of the United States, making cutting-edge advances in various lifesaving technologies.

Ventria's products are used in treatments and interventions ranging from vaccines and regenerative medicine to gene therapy, in vitro fertilization, therapeutics for unmet medical needs, cell culture media and beyond.

Ventria is a genuine innovator and an American success story. Ventria is an established and respected leader in the field of plant-based expression of recombinant proteins, including recombinant human serum albumin, which we also refer to as rHSA.

Ventria has invested enormous resources in not only developing and advancing this technology but also in establishing the industry itself and achieving acceptance of the technology by the wider pharmaceutical and scientific

communities.

Ventria is recognized as belonging to only a handfew of the very first commercial ventures in this nation's space.

One of Ventria's core technologies is a genetically engineered plant-based protein production system called ExpressTec. Through ExpressTec, Ventria scientists have harnessed the natural life cycle in growth of rice as a means of manufacturing scalable and extremely pure recombinant proteins, including rHSA.

Commercial protein production relies on purification from natural or transgenic animal sources or human donors or higher cost bacterial, yeast, or mammalian cell culture expression systems.

In the context of cell culture, fetal bovine serum, also known as FBS, and bovine serum albumin, also known as BSA, are two of the most widely used growth supplements for cell culture media and contain components that have been shown to satisfy metabolic requirements for the culture of cells in vitro, including albumin.

However, they're ethical concerns with the harvest and collection of FBS, which is derived from calf fetuses taken from pregnant cows during slaughter, and BSA, as well as safety concerns around using culture components of animal origin, which can harbor zoonotic pathogens.

Similarly, human donor sources of proteins present ethical concerns and involve risk of transmissable disease from bloodborne viruses.

Further, there are countless supply chain limitations with these sources in addition to costs and lot-to-lot variability issues.

Ventria's groundbreaking ExpressTec platform enables the production of important mammalian proteins in a plant-based expression system at a commercial scale without the ethical, zoonotic or logistical concerns of the other sources.

Ventria's rHSA products also enable the manufacture of medicines, such as immunotherapy used in cancer treatments, gene therapies used to treat inherited diseases, medicines for inflammatory and infectious diseases, and regenerative medicines.

Another use of Ventria's RHSA products is the production of vaccines including for Ebola and COVID-19.

Ventria's RHSA products are also used in the production of surgical sealants and cosmetics.

All of Ventria's operations and investments occur within the United States, primarily at Ventria's facilities in Junction City, Kansas, and Aurora, Colorado, as well as at farmland in rural Kansas where the rice is grown.

Ventria has approximately 50 employees, all of

whom live and work in the United States.

Over the past 20 years Ventria has invested many millions of dollars in the United States, and only in the United States, to establish and grow a fully encapsulated end-to-end business that handles every stage of product development and production.

This includes the R&D that led to the patented technology, gene discovery research, plant breeding and nursery operations, field production, milling and dehusking of the rice, and manufacturing products to meet biopharmaceutical product specifications.

All of this activity is funded by 100 percent U.S. spending that flows directly into the American economy.

Who is Wuhan Healthgen? Respondent Healthgen is a corporation organized under the laws of the People's Republic of China and based in the East Lake High-tech Development Zone in Wuhan, China. Healthgen was found by Daichang Yang -- I apologize, Dr. Yang. I have trouble with your name sometimes -- who previously worked in the United States at Ventria as a senior scientist and lab director.

After moving back to China and establishing his business there, Dr. Yang has been selling the accused products into the United States in violation of Ventria's '951 patent.

Discovery in this investigation has confirmed that Dr. Yang was part of China's Thousand Talents Program and that Healthgen has the support of the Chinese ministry of foreign commerce and maintains close ties to high-ranking officials within the Chinese Communist party.

In addition to running Healthgen, Dr. Yang has worked as a professor at Wuhan University. Healthgen generally operates and/or sells products under the name Oryzogen. That's O-r-y-z-o-g-e-n. Healthgen manufactures and sells a variety of recombinant biological products derived from rice. One of Healthgen's principal products is rHSA, derived from rice, and generally marketed under the name OsrHSA.

OsrHSA is a brand or trade name for rice-based rHSA manufactured by or on behalf of Healthgen in China and sold into the United States in violation of the '951 patent.

You will not be hearing from any live fact witness from Healthgen. Healthgen has declined to bring Dr. Yang or any of its employees to the ITC to testify in this investigation and is relying on its retained experts and attorney argument in this proceeding.

The only testimony in this proceeding from any Healthgen employees is the deposition testimony Ventria designated and Healthgen's counter-designations to that testimony.

You will also not be hearing from any of the other Respondents in this case. The five U.S. distributors Ventria named as Respondents in this investigation declined to participate in defense of Healthgen. Two of them settled immediately and the other three simply did nothing and have been found in default.

Healthgen has no allies in this investigation.

Allow me to briefly address the technology at issue here. Recombinant proteins are proteins that result from the expression of recombinant DNA within a host cell or organism that is different than the original source of the DNA.

The DNA for the gene of interest in this case, human serum albumin, is placed into a vector for transferring the genetic material into a host cell or organism, in this case rice, or protein expression.

Typical downstream processing of recombinant proteins includes recovery and purification. Recovery includes harvesting the rice seeds, prep processing and grinding, extraction or solubilization of the recombinant protein, clarification of crude extract and pretreatment and conditioning. Purification includes capture steps for concentration and separation of the recombinant protein from critical impurities and polishing operations to remove plant and process-derived contaminants.

Operations and conditions are dictated by the physical chemical properties of the recombinant protein and the unique characteristics of impurities from the production platform, in this case from the rice plant.

Thus, downstream processing of rice-derived recombinant proteins such as rHSA differ significantly from that for recovery and purification of HSA from serum or recombinant HSA from other production platforms, such as yeast or tobacco.

Recovery is the most varied aspect of the process because recovery methods depend primarily on the production platform, in this case rice.

rHSA is commonly used as a cell culture medium, meaning it provides an environment for the culturing or development of cells. Cell culture is key to advancement in biomedical research, development and production of therapeutics and vaccines, physiological and life science research, testing of chemical compounds in drugs on various cell types, tissue engineering, et cetera.

Cell culture media provide necessary components to support cell growth and maintenance and includes amino acids, salts, vitamins, sugars and other nutrients.

Albumin, including recombinant human serum albumin or rHSA, is extensively used in cell culture because it is capable of binding diverse ligands, reversibly as a

carrier, including lipids, amino acids, hormones, peptides, et cetera, and providing these molecules to cultures for improving cell growth and productivity.

Albumin also binds, sequesters, and stabilizes small molecules and ions, such as reactive oxygen and nitrogen species, and it serves as an antioxidant.

Supplements are media additives used to augment chemically defined serum-free or reduced-serum cell culture media and provide components typically present in serum, such as chelators, vitamins, curative transport proteins, such as albumin, hormones, growth factors, et cetera.

Albumin from human serum or fetal bovine serum may be contaminated with adventitious agents, such as viruses, and that poses a risk to the cell culture system itself.

As a naturally derived product, it is also widely recognized as having inherent lot-to-lot variability and supply chain issues.

Furthermore, the use of complex media, rather than defined media, may lead to variability in culture results. Use of recombinant albumin derived from animal-free or serum-free sources eliminates those risks while also supporting cell growth through binding and delivering molecules to the cells in culture.

Endotoxin is a component found in the outer

membrane of some Gram-negative bacteria that is released upon cell death and lysis and can be present in cell culture media. Endotoxin may remain in a product stream after sterile filtration steps, which effectively remove intact all contaminating cells or larger debris fragments. It is a human pathogen, which can also negatively impact the growth or performance of cell cultures and cause significant variation in experimental cell culture data.

Endotoxins have many documented in vitro effects on cell growth and function and may commonly -- and many commonly used cell culture systems are known to be sensitive to even low endotoxin levels. Thus, it is desirable for endotoxin to be removed during downstream processing operations and evaluated in the final product, particularly for components used in cell culture supplements, such as rHSA.

rHSA is a protein. Protein aggregates are protein, protein interactions that range from the interaction of two protein monomers, known as a dimer, up to large multimers in particulates.

Aggregates are formed through covalent or noncovalent bonds and can be soluble or insoluble and reversible or irreversible. Aggregates can be analyzed using numerous methods, including microscopy and imaging methods, light scattering, electrophoresis, spectroscopy and

chromatographic techniques with varied separation and detecting principles.

Electrophoretic analysis is an effective separation technique commonly used for evaluating protein purity in aggregation.

SDS-PAGE is an analytical technique that separates proteins under an electric field based on molecular weight.

Aggregates will have a higher molecular weight than the monomeric or single unit and, thus, will not travel through the porous gel as far.

Molecular weight can be determined by comparison to molecular weight markers that contain a set of proteins with known molecular weights. Relative amounts can be determined based on band volume or band intensity based on protein staining.

Addition of a reducing agent to SDS-PAGE for protein sample preparation, termed reducing SDS-PAGE, allows for discrimination between protein aggregates formed by disulfate bonds, which is a type of covalent bond, and those formed by other nonreducible covalent interactions.

Reducing SDS-PAGE is well recognized and accepted as an analytical tool and can be used for quantification, characterization during product development, and quality control.

SDS-PAGE is an analytical technique used by Healthgen in the characterization of its products, by Ventria in the characterization of its products, and is described in the specification of the '951 patent.

Companies selling products in the cell culture medium space, like almost any company selling anything, provide specifications to their customers describing the technical attributes of their products. Specifications are the benchmark product attributes that characterize the product and ensure quality and consistency.

Select specifications such as purity for specific lots of product are identified on a Certificate of Analysis that accompanies each product, product attributes that have been measured.

In the case of rHSA products, Certificates of Analysis provide represent -- about attributes such as total protein, purity, and endotoxin levels for each production lot of a product. The method of analysis is typically included along with the measured attribute in the Certificate of Analysis.

A customer or end user, in the case of rHSA typically a scientist, relies on the Certificate of Analysis as a quality assessment tool and to ensure that the product from a given production lot has been tested and meets the specifications provided on the Certificate of Analysis.

This information is critical to product safety, composition and application. Frequently certificates of analysis for rHSA will include results from SDS-PAGE testing that will indicate the amount of aggregates contained in the product. I will discuss SDS-PAGE and Healthgen's reliance on that analytical technique a little later when we get into Healthgen's confidential information.

For now, suffice it to say that Healthgen has provided certificates of analysis to its customers and distributors for years that rely upon SDS-PAGE testing.

Now I would like to shift our focus to the patent at issue in this case and what it covers.

The '951 patent is entitled "Cell Culture Media Containing Combinations of Proteins." It issued on April 14th, 2020, and is owned by Ventria pursuant to an assignment from the inventors Steven Pettit, Mary Ann Santos, and Ning Huang, all of whom were employees of Ventria when the inventions covered by the '951 patent were discovered.

The '951 patent relates generally to compositions and methods used to improve the growth of cell cultures. The '951 patent indicates that cell cultures have a myriad of important uses in the biological sciences, as mentioned before, such as in vitro cell culture and vaccine production, all of which are fed with and sustained by cell

culture media-comprising nutrients, for example, proteins, that are essential for their growth.

The '951 patent describes compositions and methods for improving the growth of cell cultures comprising recombinant plant-based proteins that possess certain desirable properties, including low levels of endotoxin and low levels of aggregation, including wherein said recombinant plant-produced proteins are recombinant human serum albumin derived from transgenic rice.

The '951 patent further notes that animal-derived media components, such as FBS, pose safety and ethical considerations that have brought about efforts to provide alternative sources for cell culture media and media components.

The invention disclosed in the '951 patent was the result of extensive research at Ventria directed toward the development of a recombinant albumin produced from transgenic rice having low endotoxin without introducing detergent contaminants that would be detrimental to cell viability.

Endotoxin has an unusually strong interaction with albumin, such that any endotoxin contamination in the process will be tightly bound by albumin leading to uniquely higher contamination levels in recombinant albumin.

Techniques are extensively researched and

eventually developed to reduce or remove endotoxic contamination in the final products as reflected in the specification of the '951 patent.

The chart shown on this slide is taken from the specification of the '951 patent and shows the result of experiments demonstrating the low endotoxin level.

JUDGE MCNAMARA: Pardon me. Mr. Heneghan, sorry to interrupt your flow here, but I don't see a number on this demonstrative. It's number 29. It was hidden. But if you're referring to tables -- I've seen this before, of course, in the briefing -- but please just reference when you can the demonstrative number, particularly where it contains what is exhibit information, and this is going to be one of them.

MR. HENEGHAN: Certainly, Judge. I'm happy to do that.

This is Table E4 from the '951 patent. It's slide 29 of our opening presentation.

Those same discoveries are also claimed in the '951 patent as shown in slide 30, which has both the cover page of the patent as well as the claims at issue or at least claim 1 at issue here on the right-hand side, and then the dependent claims 11, 12, and 13.

Judge, the next area of discussion will be Healthgen's accused products, and this topic includes some

information that Healthgen believes is confidential business information. And, therefore, I'm going to ask Mr. Deeter and Attorney Cook and anyone else who -- from the Ventria side who is not under the protective order to step out of the room so they don't hear this part of my opening.

JUDGE MCNAMARA: Very good.

MR. HENEGHAN: Can we pause for just a moment?

JUDGE MCNAMARA: Sure. Could those individuals whom Mr. Heneghan identified please step out. And I'm watching the participant list, as should your team, Mr. Heneghan.

MR. HENEGHAN: I'm sorry, Judge. What was that?

JUDGE MCNAMARA: I'm watching as people leave the participant list, so you-all should be monitoring it as well, and if there's anyone else from Healthgen's side who should not be listening to this, please ask them to jump off now and call out their names.

MR. HENEGHAN: Actually, Judge, this is Healthgen's CBI, so it's fine for them to remain.

JUDGE MCNAMARA: Okay. But sometimes in these hearings I've had a couple of people pop up who shouldn't be on, and it turns out they were connected with in-house counsel or other folks. So just please make sure that there is no one here. I would like that affirmation.

MR. HENEGHAN: Maybe it would help if I explain

how we're doing this, Judge. We have a room where those folks are observing, and Ms. Shoffstall is in charge of making sure they leave that room. I think she is on now and can confirm that in fact the folks who should not hear Healthgen CBI have in fact left the room.

MS. SHOFFSTALL: Thank you, Tom.

Your Honor, this is Andrea Shoffstall for the record. I can now confirm that we have -- all Ventria non-protective order personnel have left the room, and I can now show you the screen of the room as well just to confirm everyone here in the room is under the protective order and able to listen to the CBI information.

JUDGE MCNAMARA: Okay. Very good. And that's the procedure we're going to follow throughout so that there are clear confirmations or affirmations by counsel on the record.

MS. SHOFFSTALL: Understood. Thank you, Your Honor.

JUDGE MCNAMARA: Okay.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

MR. HENEGHAN: Just so you know, I only have one other brief little CBI part that involves one slide right near the end. So there will just be one more brief break and that will be the end of the CBI stuff.

JUDGE MCNAMARA: Just let us know. You have so far.

MR. HENEGHAN: Thank you.

I'm now going to address Healthgen's claim that the '951 patent is invalid, as either anticipated or obvious. Healthgen claims that the '951 is anticipated by one of two references, either Van Urk or Berezenko, and they also claim the '951 is obvious over Deeter in view of Van Urk and Berezenko.

None of these theories comes close to overcoming the presumption of validity of the '951 patent, and certainly not by clear and convincing evidence, the burden that Healthgen must meet when validating the '951 patent.

Healthgen's challenge is made even more difficult because two of the three references on which they rely, and a fourth reference, Huang, to which they make passing reference, were all before the United States Patent Office and were considered when the patent was allowed.

For their anticipation arguments, neither

reference expressly or inherently discloses every limitation of the '951 patent.

For their obviousness arguments, there is no evidence that a person of ordinary skill in the art would be motivated to combine the references in a manner suggested by Healthgen or would have a reasonable expectation of success if they did.

At best, Healthgen's argument is a result of hindsight and is further undermined by numerous objective indicia of nonobviousness, all of which adds up to the conclusion that the '951 patent is valid.

Healthgen relies on its retained expert, Dr. DeFilippi, to advance their invalidity claims. As demonstrated by the joint technology stipulation filed by the parties, the highly technical discussions during the Markman phase of this matter, and the subject matter covered by the '951 patent, this is a highly specialized field and one in which Dr. DeFilippi has little or no actual experience.

As to the overarching technology, Dr. DeFilippi has no experience producing or purifying recombinant proteins expressed in plants. He has done no work or research developing any genetically modified plants.

We're now on slide 55.

He has done no research in the field of

production of recombinant human serum albumin in transgenic plants. He has never worked with a plant-derived recombinant human serum albumin other than in this investigation.

While he acknowledges that scientific knowledge about the topics he discussed in his report has changed over time, he did not do any independent research or investigation to determine if his understanding and beliefs about the issues in this case were current or accurate. None.

His opinion should be given little, if any, weight.

Starting with Dr. DeFilippi's anticipation opinion based upon Van Urk, the asserted claims of the '951 patent are directed to a composition derived from a plant, transgenic rice. Van Urk discusses a composition derived from yeast, which is a fungus, not a plant. Dr. DeFilippi acknowledges that rice... in the example of producing rHSA in a transgenic plant of any kind much less rice. He simply states without authority that it's not necessary.

Fundamental elements and limitations of the '951 patent are simply not present in Van Urk and therefore the '951 patent is not anticipated by Van Urk.

The analysis is almost identical for the anticipation argument based on Berezenko, also a yeast

reference and related to Van Urk. Dr. DeFilippi made the same argument about Berezenko's failure to provide a working example of producing rHSA in a transgenic plant of any kind much less rice. According to him, it's just not necessary.

Berezenko fails as an anticipatory reference for the same reason as Van Urk. The Patent Office agreed, allowing the '951 patent after considering Berezenko.

In an interesting dichotomy, Dr. DeFilippi relies on reducing SDS-PAGE analysis to support his opinion on Van Urk. When confronted at deposition about this seeming contradiction to his criticism of SDS-PAGE in his infringement opinion, Dr. DeFilippi acknowledged that his invalidity opinion was a stretch. No more so than his obviousness opinion.

In an attempt to fill the holes in the anticipation argument, Healthgen attempts to advance an argument on obviousness by combining Van Urk and Berezenko with Deeter. However, Deeter also does not disclose the claimed recombinant mammalian albumin of the '951 patent, and in particular it does not disclose a plant-produced recombinant mammalian albumin composition having less than 1 EU of endotoxin per milligram of albumin and less than 2 percent aggregated albumin as claimed in claim 1 of the '951 patent.

There is also no evidence, other than

Dr. DeFilippi's hindsight, that a person of ordinary skill in the art would have been motivated to combine these references or would have had a reasonable expectation of success if they had.

Finally, if the analysis were to even get that far, there is substantial evidence of objective indicia of nonobviousness that Healthgen cannot overcome. As stated in the '951 patent specification, the plant-derived cell culture component of the invention surprisingly enhanced cell growth and unexpectedly improved activity and stability.

Ventria has received industry acclaim for its work in this field, and Dr. DeFilippi has recognized that the '951 patent met a long-felt need for rHSA produced in rice that had endotoxin below 1 EU per milligram of albumin. One of the limitations of claim 1 that Healthgen admits is met by the accused products and concedes is met by Ventria's domestic industry products.

Healthgen cannot meet its burden to prove invalidity by clear and convincing evidence under any of its theories.

To conclude, I would like to briefly address remedy and bond.

In this case Ventria seeks the remedy of a general exclusion order. The evidence will show that a

limited exclusion order directed solely to Healthgen will not prevent these infringing products from reaching the United States market either through sales and import by companies other than Healthgen or by Healthgen disguising its identity.

And before I discuss bond, this next slide shows some Healthgen CBI, so I'll ask Mr. Deeter and Attorney Cook to step out of the room for just a moment. Ms. Shoffstall will confirm when they have left.

JUDGE MCNAMARA: Okay.

MS. SHOFFSTALL: Hi, Your Honor. This is Andrea Shoffstall. We have -- all participants not subject to the protective order have now left the room and I will confirm via video.

JUDGE MCNAMARA: Thank you.

MS. SHOFFSTALL: Also, we do not have anyone else on the line as well.

JUDGE MCNAMARA: Okay. Thank you very much.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

MR. SHAFFER: This is Rob Shaffer from Finnegan for Respondents.

Healthgen is here, Your Honor, and very much appreciates its day in court because, frankly, we took umbrage to Ventria's rhetoric in its pretrial brief and some of the implications we just heard in its opening.

But let me be clear where Mr. Heneghan was not. The timeline is dispositive on the side show issues.

Dr. Daichang Yang, Healthgen's principal founder, left Ventria in 2005 to go back to China to work at Wuhan University. The earliest possible invention date for the '951 patent is 2009, four years after Dr. Yang returned to China to teach.

These other entities and people that Ventria may discuss throughout this trial have absolutely no relationship with Dr. Yang or connection to Healthgen, and the side show should be really ignored as wholly irrelevant.

What is important, Your Honor, is that the evidence will show that Healthgen's accused products do not infringe. Respondents will also prove that Ventria's one asserted patent is invalid. In fact, three of the four claims are anticipated by a single prior art reference in Van Urk, a reference that was not before the Patent Office.

At bottom, there's simply nothing new to their purported claimed invention. And to the extent that they attempt to argue something new in their patent, well, it's going to be something that's, frankly, just not claimed by the asserted claims.

Healthgen is an innovative company. It uses its own proprietary platform to develop recombinant human serum albumin products that it provides to clients in the United States.

Two of Healthgen's products are accused of infringement in this case. The first product shown here on the left is what we will refer to generally as the powder form. That's the lyophilized powder. It's a recombinant human serum albumin used for mid-grade cell cultures.

The second product shown here on the right is the clinical grade liquid product used to treat patients in the many applications that Mr. Heneghan talked to with Ventria's products. Same thing, many clinical applications for use in patients.

And we'll refer to that generally, Your Honor, as the liquid form.

On slide 4 we have the '951 patent, and there are now only four asserted claims. This is claim 1 and the remaining asserted claims 11 through 13 depend from it.

There's not a lot to claim 1. There's the

preamble, a cell culture media of which improving the growth of cell is not limiting. Then you have a recombinant mammalian albumin produced in transgenic plant. That has two quantitative requirements, Your Honor, to it, and that's less than 1 EU of endotoxin and then less than 2 percent aggregated albumin. That's the entirety of the claim.

I want to discuss a little bit the two quantitative claim requirements. They are more important concepts, because Ventria, as we just heard, attempts to make much more of their patent than there really is. There's no real improvement to the activity of the claims here. They are simply quantitative measurements.

And on infringement, Mr. Heneghan is right. The dispute does center on the highlighted limitation we have here, less than 2 percent aggregated albumin. And as shown at the bottom of slide 4, the aggregated albumin has been properly construed in this case to mean non-monomeric albumin. And as applied to the claim term, less than 2 percent aggregated albumin means less than 2 percent non-monomeric albumin by weight.

Again, nothing more than qualification of aggregated albumin by a percentage.

If we could have slide 5, please, Mr. Fisher.

These concepts will be explained in more detail by Dr. Louis DeFilippi, Healthgen's expert on technical

issues, including state of the art in 2009, infringement and validity. He does have decades of experience working on protein production, analysis purification, including recombinant production of proteins and albumin, Your Honor, and he is a well-respected expert consultant in the field of recombinant proteins produced in cell culture.

And the evidence will show that all asserted claims are not infringed because this less than 2 percent aggregated albumin is not met.

Dr. DeFilippi is going to explain the difference between monomeric albumin and the different forms of aggregated albumin as they are found in all recombinant human serum albumin products. The preferred form of albumin is monomer or monomeric albumin. That's the single molecule shown here on slide 7 on the left.

And it is not included -- this is a very important concept. It is not included in the claim term aggregated albumin. Monomers of albumin can bond together to form aggregated albumin, which is shown to the right of the line on slide 7. And an example of aggregated albumin is a dimer, which is two molecules of albumin binded together -- bound together.

Albumin -- aggregated albumin can also exist as trimers, which is three albumin monomers bound together shown here on slide 7 on the right. And if I could extend

the page out some more, Your Honor, I could show you what you'll see in the documents are referred to as multimers or polymers. Those are multiple monomeric albumins bound together.

And then we also have another form of albumin aggregation shown here and labeled as a partially degraded dimer. Indeed, any albumin found above the molecular weight for a monomeric albumin is counted as an aggregated albumin. And that's in accordance with the claims -- the Court's claim construction on aggregated albumin.

But the important thing to remember here is that all of these forms of aggregated albumin, shown here on the right of the line, collectively referred to as aggregated albumin, is what differentiates these from monomeric albumin, and they all count towards the claim limitation.

And it is the aggregated albumin, not the monomeric albumin, that is the key here. And to prove infringement Ventria must show that the total percent of aggregated albumin in Healthgen's accused products is less than 2 percent. And we will show that they cannot do this without distorting the issues and/or using inappropriate test methods to determine that quantification.

In the bottom column box at the right we talk about the types of bonds that can be included, and that's going to be an important concept, Your Honor, when we get to

SDS-reducing-PAGE, which is Ventria's preferred method. It's not really a contentious point, but it's an important one. Because bonds, these aggregated albumins, can be held together by covalent disulfide bonds.

And the method that they prefer to use, that Ventria is pointing a person of skill in the art or reasonable competitor to use here in reducing SDS-PAGE, as you will see from the experts who agree, and even Ventria's own witnesses agree, that these include bond-breaking agents as the SDS-reducing-PAGE does. And they break apart those disulfide bonds that hold together the aggregated albumin.

What is the result of that? The aggregated albumin breaks apart into monomeric albumin, and that results in artificially lower percentage of aggregated albumin that would be measured by an appropriate technique to quantify it.

Reducing SDS-PAGE is certainly an acceptable technique in the field, but not for purposes of measuring aggregated albumin. And we'll talk about that in some more detail.

But the point here, Your Honor, is, of course, reducing SDS-PAGE is known and a valid technique, but the question for Your Honor is an appropriate technique for measuring what.

Mr. Heneghan didn't explain that in detail, but I

will. And, of course, Ventria and Healthgen use SDS-reducing-PAGE, but to show what, and we're going to go through that too. And the evidence is overwhelming that the appropriate technique is a different technique referred to as SEC-HPLC, because it is known to a person of skill in the art that relevant peer-reviewed literature also makes clear on this point further teaching that reducing SDS-PAGE is not a viable method to quantify as a percentage aggregated albumin.

Your Honor, let's take each of the accused products in turn starting with Healthgen's powder product. And the takeaway here is that no matter which testing method is used to quantify aggregated albumin in Healthgen's powder products, the results unequivocally show that the aggregated albumin is greater than 2 percent by weight, and that means that the less than 2 percent aggregated albumin claim limitation for all the claims is not met.

The powder products do not infringe.

At this point, Your Honor, I'd like to go on the confidential record because we get into some CBI.

JUDGE MCNAMARA: Whose confidential record is it?

MR. SHAFFER: Yes, Your Honor. In terms of the proofs here, the first two are Ventria's, and then Healthgen, so they are a little bit interspersed throughout, but, I apologize. The Ventria folks certainly can stay on

for the next two slides, and then at slide 15 we go into some Healthgen CBI.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

THE REPORTER: We're back on the public record, Your Honor?

JUDGE MCNAMARA: Yes, we are. Thank you, Ms. Kinkade.

MR. SHAFFER: May I proceed, Your Honor?

JUDGE MCNAMARA: Yes. Go ahead.

MR. SHAFFER: Thank you. Thank you, Ms. Kinkade.

We're on slide 21, and this is the Mahler 2009 reference. Dr. Giannelli just confirmed that for me. It's JX-60. It's entitled "Protein Aggregation: Pathways, Induction Factors and Analysis."

On page 6 of the Mahler reference, Your Honor, it includes table 1 shown here. Table 1 is entitled "Frequently Used Methods for the Analysis of Protein Aggregation."

It has a number of categories associated with it and it's really important here on this slide, the very first one is quantification and/or size estimation, quantification and/or size estimation. And it lists a number of acceptable test methods for either quantifying or estimating the size of aggregated proteins or aggregated albumin.

And the first one listed here is SEC-HPLC, which Mahler reports as frequently used to quantify aggregates.

And that's exactly what we're talking about here, Your Honor, for purposes of quantifying albumin aggregates as a percentage of the overall product.

SDS-PAGE, I'll note, it's not reducing SDS-PAGE, but SDS-PAGE is also listed, and, notably, it's not reducing, which is even one step further removed, but even without the reducing agent and just SDS-PAGE alone, Mahler does not categorize it as an acceptable method for quantifying aggregates. It's only for size estimation.

Now Ventria's own Dr. Alfano, vice president of product development, explained at his 30(b)(6) deposition all about reducing SDS-PAGE. And he used the words, bond-breaking agent, that reducing SDS-PAGE contains a bond-breaking agent, like, for example, DTT, and, because of that, the covalent or disulfide bonds that form the aggregated albumin would break apart these dimers or trimers and turn them into monomers. And, in short, Dr. Alfano admitted that reducing SDS-PAGE cannot accurately quantify the percent of aggregated albumin.

You're not going to hear from Dr. Alfano at this trial. Ventria decided not to bring him, so we have designated his testimony, Your Honor.

On slide 24, the '951 patent also describes SEC-HPLC as well as reducing SDS-PAGE.

But the '951 patent doesn't support Ventria's use

of reducing SDS-PAGE at all to test the percent of aggregated albumins in this case. A person skilled in the art, reading the '951 patent disclosure, would understand that SEC-HPLC would observe aggregated albumin, like dimers, although even the '951 patent itself does not go that extra step to actually quantify anything at all and you're not going to find any quantification data in the patent.

But it also talks to reducing SDS-PAGE. Mr. Heneghan was right. Disclosed in the '951 patent, it may be used to look at the overall albumin impurity. And that's exactly what we've been saying all along, Your Honor.

Of course reducing SDS-PAGE is an appropriate test method, but it only looks at the total percent of albumin. That's it. Nowhere in this reference, in this section of the patent, or anywhere else is a person of skill in the art going to understand reducing SDS-PAGE to be a preferred method to measure the quantification of aggregated albumin.

Slide 25, please. Thank you, Mr. Fisher.

So Healthgen, for the purposes of this litigation, contracted an independent lab to test Ventria's plant-derived human serum albumin products for the technical prong of domestic industry. And there are six products at issue. Optibumin, as Mr. Heneghan rightfully mentioned, is one of them. And we don't dispute that Optibumin is covered

by the claims. It is. It has aggregated albumin at less than 2 percent. And, notably, the evidence that they rely on to show that, and that we agree represents less than 2 percent albumin, was measured by SEC-HPLC.

Anyway, shown here are Exbumin and Cellastim, two of the products, but, in fact, it's more than that, Your Honor. Cellastim is actually found in four Ventria products under different trade names. So what we have represented here are five of the six Ventria products.

The lab used SEC-HPLC, and that's shown by the middle column, as the more appropriate technique to quantify aggregated albumin. And the results all show that the aggregated albumin of Ventria's products all contain percentages of over 2 percent aggregated albumin, ranging from 3.65 percent to 4.6 percent, as shown on slide 25 in the middle column.

Now the lab was also asked to run these same exact samples by use reducing SDS-PAGE with its bond-breaking agent, which is Ventria's preferred test method. The results really were not surprising at all. Ventria's Dr. Alfano was exactly right. The albumin aggregates in these products were broken down by the reducing agent, which resulted in a percent of aggregated albumin significantly lower than the percent of aggregated albumin measured using SEC-HPLC for the same sample.

This is telling, Your Honor, because if a competitor were running these tests and using a well-accepted method, like SEC-HPLC, to test its product for aggregated albumin, in view of the claims of the '951 patent, to determine whether or not it infringed, well, its product might not meet these limitations of less than 2 percent aggregated albumin if they choose SEC-HPLC. But if they choose Ventria's preferred method of SDS-PAGE, they may get a very different percent of aggregated albumin, one that may meet the less than 2 percent claim requirement.

Two very different results for the same sample. That's exactly what happened here, Your Honor.

And Ventria asserts in this case, we just heard it from Mr. Heneghan, that SDS-PAGE -- reducing SDS-PAGE is an acceptable test method to quantify aggregated albumin. But this shows the different test methods yield significantly different results. And if Ventria is right that the '951 patent teaches the use of reducing SDS-PAGE in addition to SEC-HPLC, well, then the '951 patent is indefinite under the Nautilus standard. A skilled artisan would not understand with any reasonable certainty the scope of the claimed invention, because under one test method they would infringe and under a different test method they would not.

I want to be clear here, Your Honor, because --

JUDGE MCNAMARA: I'm sorry to interrupt you. I may have missed it, but I didn't see that argument in your brief.

MR. SHAFFER: You're right, Your Honor. My next sentence will make that clear.

JUDGE MCNAMARA: Then you can't argue that now, Mr. Shaffer.

MR. SHAFFER: I understand that. I want to be clear. We're not making an indefiniteness claim. We're not making an indefiniteness claim at this point, but we're submitting that a person of skill in the art would know, based on this, to use SEC-HPLC. We are not in any way submitting the claims are indefinite. It was not in our brief, Your Honor.

JUDGE MCNAMARA: I am moving to strike. I am sorry. I am sua sponte moving to strike that part. You cannot do that. I won't permit that during the hearing. I won't permit that illusion. I won't permit that tying together and then a disclaimer. It's a clever rhetorical technique, but I'm not going to permit that.

MR. SHAFFER: Understood, Your Honor. The point is made, and I think the facts are clear, but if we could go back --

JUDGE MCNAMARA: The point is not made. I've stricken a part of it.

MR. SHAFFER: Okay. I'm sorry, Your Honor.

I just want to be clear that the test results are the test results, and the test results using SEC-HPLC are higher on the same sample than they were using reducing SDS-PAGE. That's the point I'm trying to make by this slide. I'll forget the Nautilus analysis and I'll move on, Your Honor.

JUDGE MCNAMARA: Well, I'm glad, again, because I've already stricken it.

MR. SHAFFER: All right. With that additional background, let's look at Healthgen's clinical grade liquid product. The evidence will show Ventria's infringement proofs are insufficient. It basically relies on the wrong test.

Here, Your Honor, I need to go on Healthgen confidential business. If we could ask Ventria to kindly remove Mr. Deeter and anyone else.

JUDGE MCNAMARA: Okay. I guess Ms. Cook and Mr. Deeter should leave, and would you please confirm that, Mr. Heneghan.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

JUDGE MCNAMARA: Thank you, Ms. Kinkade.

MR. GUARNIERI: It is a pleasure to be appearing in front of you again, Your Honor.

JUDGE MCNAMARA: Good to see you. It's good to see you.

MR. GUARNIERI: It's been a little while. Sorry we're not in our courtrooms back at the ITC.

JUDGE MCNAMARA: I hate to tell you, but at the moment I'm kind of glad. I understand they are sweeping the building for little varmints.

MR. GUARNIERI: We may not be the only occupants of the building when we return.

JUDGE MCNAMARA: So I understand. Yes.

MR. GUARNIERI: So, Your Honor, I let chambers know, I don't have any slides this morning. Actually I worked for a partner once who said he couldn't put his kids to bed without a PowerPoint presentation, but I think I'm going to be able to get through my opening without them.

My remarks will be brief. As we went over this morning during the prehearing conference, the Staff is only partially participating in this investigation. So I'm really only here to address the issues of remedy, which would be the exclusion order, the cease and desist order,

and bonding. And then, of course, once we're done with our trial and it moves on to the Commission, the public interest issues, I don't expect will come up during this hearing.

And, of course, an important point there as well is that these issues are all contingent on finding a violation. If there's no violation, then the remedy is not going to be an issue. And so along those lines as well, I'd like to offer a correction to the Staff's prehearing brief. Counsel for Respondents very helpfully flagged this for me.

On page 19, footnote 17 of the Staff's prehearing brief, the beginning of the footnote could be read to imply that the Staffs has taken a position on whether Ventria has shown a violation. That certainly wasn't the intention. The footnote really should have read, to the extent Ventria is successful in showing a violation. And I'm going to try and make sure I speak that way for the rest of the hearing so that Your Honor is aware I'm not taking a position on the merits and everything that the Staff has taken a position on is contingent on finding a violation.

So on the issue of the violation, the first is what sort of exclusion order should we have. As you know, Ventria is seeking a general seclusion order in this case. The Staff's view is that the evidence is going to support a limited seclusion, not a general seclusion order.

There are a lot of -- as Your Honor is aware from

the prehearing briefs, there are a lot of facts that go into that analysis. I think the salient one that I'd like to raise, and it might be the most important point, is that Ventria is the only source -- I'm sorry -- Healthgen is the only source of the accused products.

Your Honor is familiar with cases we have all the time where there are hundreds or maybe thousands of listings on various e-commerce sites like Amazon or Alibaba. This is not one of those cases. All the goods in question, the infringing goods in question, all ultimately come from Healthgen.

I also appreciate Your Honor's remark at the prehearing conference about the issue of whether or not the products are appropriately labeled, whether or not there's some confusion over what the source is when they are imported.

That's obviously an important factor, because CBP has to be able to enforce the order. If Customs and Border Patrol can't enforce a limited exclusion order, that's obviously a factor that weighs in favor of granting a GEO.

I will say that my understanding of the evidence as it sits right now is that most of that evidence is likely to come in through deposition designations, the documents that were attached to those designations and maybe other paper record. I obviously don't know exactly what the

private party witnesses are going to say, but I'm not sure we're going to hear that much today about the different identities of or possible different identities of how the products are imported. I could be wrong.

In part, that is, as has been pointed out, Healthgen doesn't have any witnesses, and so the testimony will come in through some of the deposition designations of those witnesses, but we're not going to hear from them today at least.

I should also point out that we do have some defaulting Respondents. Obviously they are not here. They haven't participated. They have already been found in default. As to those, a limited seclusion order would be the appropriate remedy.

There is also a false designation of origin claim. It's at issue in the sense that it's asserted against the defaulting Respondents. We didn't hear about it in the opening. Good reason it's not asserted against Healthgen, so I can't imagine it's going to come up during our hearing, but that is another remedy issue that we'll have to deal with at least in post-hearing briefs.

Then we move on to cease and desist order or CDO. Since I want to keep this on the public record, I just will say that I think the evidence will show that Healthgen does not have commercially significant inventory or significant

domestic operations, which Your Honor knows is the standard the Commission generally uses to determine should we grant a CDO or not. I think the Staff's view is that the evidence will show that a CDO is not going to be appropriate against Healthgen.

But, again, getting back to defaulters, those -- they are all domestic entities, so the Commission generally assumes that domestic entities have domestic inventory, and so a CDO against a defaulter would be appropriate. We may hear some testimony on that, I expect, from the economic experts, if anybody.

And then, finally, the bond. Mr. Heneghan touched briefly on the bond during his opening. Without -- again, without going into some of the pricing information, which is CBI, I think, as Your Honor is aware from the briefs, and Mr. Heneghan alluded a little bit to it in his opening, the pricing is complicated in this case. There's a lot of factors that go into it. It's not a simple case where you have one single good with one price sold at retail and that's that and you can do an apples-to-apples comparison between the pricing of the infringing goods and the domestic industry goods.

I think this is a case where the pricing is going to be complex. And in that situation, and Your Honor has had plenty of these cases before, the Commission generally

uses 100 percent bond rate. It's just not practical to make a price comparison or a price differential. The Staff's view is that's going to be the appropriate thing to do here as well, given how complex the pricing is, a 100 percent bond rate would be appropriate.

Your Honor, unless you have further questions of the Staff, that is the extent of my opening remarks. I'm happy to sit back down again. I think we can take a lunch break and proceed with the witnesses after lunch, if that's acceptable to the private parties.

JUDGE MCNAMARA: That's acceptable to me and I assume it's -- and I see you were already sitting down anyway, Mr. Guarnieri, so an interesting expression. But, in any event, that works. We agreed on that beforehand.

It's just about 12:45. So I will see you back here at 1:45.

(Whereupon, the proceedings recessed at 12:41 p.m.)

AFTERNOON SESSION

(In session at 1:45 p.m.)

JUDGE MCNAMARA: I think we had enough time for lunch, I hope.

MR. HENEGHAN: Yes, we did.

MS. NIEMEYER: Your Honor, I had one housekeeping matter I wanted to bring up.

JUDGE MCNAMARA: Sure. I'm ready to go on record. Is everyone else?

MR. GUARNIERI: Yes, Your Honor.

JUDGE MCNAMARA: All right.

MS. NIEMEYER: Good afternoon, Your Honor. This is Elizabeth Niemeyer. I just wanted to note for the record, since you asked a couple of times about the attendance of Healthgen witnesses at the hearing.

One, there are definitely significant travel restrictions on people coming to and from China, and there are also restrictions on witnesses being permitted to testify virtually or in any other capacity from China.

So, with those restrictions, making someone come back and forth is really not feasible even going someplace where they might be able to travel or testify like Macao. So I just wanted to make sure that was clear as to why testimony wasn't designated from his transcript. That would be a question for Ventria. I don't believe we had the

authority to do that. But I did want to make clear that there are significant restrictions on their ability to travel and then just legality restrictions on even being able to testify from China.

JUDGE MCNAMARA: I'm well aware of those, but I am also well aware of the fact that you can apply for specific business visas that can take you to Macao if they are applied for in advance. And we have known the date for this hearing for quite some time.

I am certainly aware of all of the conditions of lockdown, and I am also aware of the exceptions to lockdown, just so that you're aware of that as well, because I do have concerns about this, not surprisingly. So there we are.

MS. NIEMEYER: All right. That's fine, Your Honor. I just wanted to make sure that was clear on the record. We're comfortable with the record and the evidence as it is. We just wanted to make sure that was clear.

I believe we will be turning to Complainant's case-in-chief, and I will pass the baton to Dr. Giannelli, who will be handling it from our side.

JUDGE MCNAMARA: Very good. Thank you, Ms. Niemeyer.

Dr. Giannelli, I guess, Mr. Heneghan, are you starting with Ventria's first witness?

MR. HENEGHAN: I am not. Ms. Hoekel will be

presenting Mr. Deeter, but I had a question.

I recall at the end of the opening you had mentioned you might have some questions about the admissions issues. I didn't know if you wanted to take that up now or if that's for another time.

JUDGE MCNAMARA: I think that's for another time. I think it was pretty clear both from the opening and from the briefs what the admissions are. I will go through those before the end of the hearing so that we're very clear on what they are and what this comes down to.

It's pretty clear to me it comes down to the 2 percent albumin, and then, of course, the invalidity prior art references. But I have some questions about the testing and how some of the language was used as well. The types of tests, I probably will have questions -- I'll wait to hear what the questions are for the experts -- but obviously there are different types of testing and they measure different things and they measure different -- well, they each have -- they are quantitative measurements; they just measure different things.

That was a semantic argument that I believe was raised during the opening. What it's really going to come down to is what the tests measure and how they measure. I'm sure that we will get into that. And then at the end, what I probably will go through for this hearing is, again, have

the parties agree on what has already been admitted as fact, and I already have a list of those things, but I want to hear you out, because, as we know, people can debate those things, but it appears there are already agreements on both sides as to certain claims, their content, and certain facts.

MR. HENEGHAN: Understood. Thank you for the clarification.

In that case I will step aside and Ms. Hoekel will take over. Thank you.

JUDGE MCNAMARA: Thank you very much.

MS. HOEKEL: Good afternoon, Your Honor.

JUDGE MCNAMARA: Good afternoon, Ms. Hoekel.

MS. HOEKEL: We'll turn on the witness video now. Complainants are ready to put on their first witness. We would call Scott Deeter.

SCOTT DEETER,

having been first duly sworn and/or affirmed on his oath, was thereafter examined and testified as follows:

JUDGE MCNAMARA: Please state your full name.

THE WITNESS: Scott Edward Deeter.

JUDGE MCNAMARA: Thank you. Go ahead, Ms. Hoekel.

DIRECT EXAMINATION

BY MS. HOEKEL:

Q. Mr. Deeter, can you introduce yourself to the court with your name and your title and who you work for?

A. I'm Scott Edward Deeter. I'm CEO of Ventria Bioscience.

Q. How long have you been with Ventria Bioscience?

A. I started in 2001.

Q. How long have you been with CEO of Ventria Bioscience?

A. Since that time.

Q. Can you please tell the Court about your educational background?

A. Sure. I received my Bachelor of Science in economics and math at University of Kansas, and then went to University of Chicago for graduate school, and received an MBA at Chicago, and then received a Master's in Economics from London School of Economics.

Q. We're going to start by talking a little bit about the history of the company.

If I can have the demonstrative slide 1, please.

MS. HOEKEL: We're sharing it, Your Honor. It's just taking a minute.

Can everyone see the demonstrative slide 1?

Q. When was Ventria founded?

A. Ventria was formed from a predecessor company

called Applied Phytologics in 2001.

Q. What state was Ventria formed in?

A. California.

Q. What was the purpose of forming Ventria?

A. Really it was to commercialize plant technologies that used the sun, the soil, air and water as the raw materials and the plant as the factory to make recombinant protein.

Q. And did that process have a trade name that Ventria used?

A. We called the technology ExpressTec.

Q. And when was ExpressTec commercialized?

A. We started commercializing ExpressTec in the early 2000s.

Q. What was ExpressTec primarily -- which plant was ExpressTec primarily being used in in Ventria?

A. We selected rice.

Q. Why did you select rice?

A. For a variety of reasons. Rice was selected because it's safe. It's one of the first foods fed to children because of its safe profile. Also, it's called self-pollinating, so it eliminates the flow of genes in the environment, because it pollinates itself, and because we could store the protein in the seed very cost-effectively to reduce the cost of manufacture of the target recombinant

protein, and also because we can scale up production of rice very readily.

Q. Why was the company formed in California originally?

A. Originally the technologies that we pulled together to create ExpressTec came from in-house developed technology. University of California at Davis had some technology that we licensed, and University of California at Berkeley also had technology that we licensed exclusively.

Q. You mentioned Applied Phytologics. What was the business of Applied Phytologics?

A. Applied Phytologics was a predecessor company that had developed what's called a germination expression platform, the ability to express the protein during the germination phase or the malting phase. And the idea was to create a malt syrup that had the target recombinant protein in the syrup, and by way of malting create the recombinant protein, versus ExpressTec, which is using the rice grain itself.

Q. And were those companies merged?

A. Applied Phytologics became Ventria.

Q. So --

A. We turned back the technology of the germination expression back to University of California at Davis. We did keep one promoter technology from Davis, but all the

other technology was turned back.

Q. And so who was the surviving entity of that merger?

A. It was Ventria Bioscience.

Q. What is the business of Ventria Bioscience today?

A. Today Ventria has both a therapeutic as well as a cell culture media. Our business, our cell culture media business, is called InVitria, and it's a division, not a legal entity, but a division of Ventria, so it's synonymous, but just for branding purposes we use the two.

Q. And at some point Ventria changed its name; is that correct?

A. We did change to add Ventria Bioscience Inc.

Q. And why was that?

A. We incorporated in Delaware.

Q. Do you recall what year that was?

A. Approximately 2013.

Q. And why did you incorporate in Delaware?

A. It was more common for companies that were growing, like us, to be incorporated in Delaware, to have more certainty around the legal corporate law.

Q. You mentioned InVitria a moment ago. What is the business of the InVitria division?

A. InVitria is a division, and it's targeting cell culture processes primarily for cell and gene therapies,

cell culture gene therapy type products, as well as vaccines, to eliminate the concerns with using blood-derived or serum-derived products.

Q. Can you explain to the Court just briefly what cell culture is?

A. Cell culture is a biotechnology that allows for the production of cells, mammalian cells typically, and those cells then make a product, and that product becomes either a vaccine or that product may become a medicine for cancer or a genetic inherited disease.

Q. We'll talk about this a little more in detail later in your testimony, but can you tell us what the products of InVitria are?

A. We make a series of recombinant proteins and supplements and media. So those three categories of products. One of our products is a recombinant human serum albumin, and we also make other recombinant proteins.

Q. Where is Ventria incorporated currently?

A. Currently incorporated in Delaware.

Q. And where --

JUDGE MCNAMARA: Just a minute, Ms. Hoekel. Pardon me.

I can't see Mr. Deeter. I've set this up as a stacked, so I can view. All I'm seeing -- I can see you. There is Mr. Deeter now. I was just seeing your slides, but

I wasn't seeing any movement either in the slides. So I do see Mr. Deeter now.

MR. GUARNIERI: Your Honor, I had this problem earlier too when I was watching Mr. Deeter's feed for the Staff. I resolved it by right clicking on Mr. Deeter's video and there's an option to put him on the stage. I think that should pin his video.

MS. HOEKEL: I'm going to have Ms. Hitchens put the slide back up and see if you can still see Mr. Deeter when we're sharing something.

JUDGE MCNAMARA: Thank you. I am seeing you but I am not seeing Mr. Deeter.

MS. HOEKEL: I think it's because of the way we have the sound system. We're all on one sound system, so it's defaulting to mine. I'm wondering if counsel muted theirs --

I don't know if this is okay with Your Honor, but if the other counsel muted theirs unless they are making an objection --

No, never mind, my technical person explained that's not going to work.

JUDGE MCNAMARA: I don't know if we can do this, but what I'd like -- Nicole, I see --

MS. MUHAMMAD: Try layout and do side by side.

JUDGE MCNAMARA: I did. That's not working for

me.

MS. HOEKEL: Your Honor, Ms. Hitchens believes she can fix this if we gave her ten minutes. I apologize for the delay.

JUDGE MCNAMARA: We can do that, because I need to be able to see everybody who is speaking, and I need to see the slides as well.

Sure, we can do that. None of the ways in which I've tried this are working.

MS. HOEKEL: I apologize, Your Honor.

JUDGE MCNAMARA: No worries. It happens.

(Brief interruption.)

MS. HOEKEL: Your Honor, I think we're ready to get back on the record whenever you are.

JUDGE MCNAMARA: We are ready. Thank you. All of us are ready, I think.

BY MS. HOEKEL:

Q. So I think where we were was talking about Ventria facilities. And where are the facilities of Ventria currently?

A. Currently we have a facility in Junction City, Kansas where we do our manufacturing and our quality team is there. We also do our molecular biology, greenhouse process development, and then we also have a rented a facility in Colorado on the Anshutz Medical Campus where we do

subculture product development.

Q. Do you have any facilities in California anymore?

A. No.

Q. Why did Ventria leave California?

A. We wanted to go to a state where we could scale up, and at the time the chairman of all state Departments of Agriculture was in Kansas. He was the chair of all state Departments of Agriculture, biotechnology committee, and Kansas had a very sophisticated approach to plant biotechnology.

Governor Sebelius at the time was involved in recruiting us to Kansas. And it had a very close relationship because of that to the USDA's regulatory framework for plant biotechnology, which gave us certainty in terms of how the regulatory framework would work in Kansas. And so Kansas worked with the USDA collaboratively to implement the regulations that were important to the early steps of the company.

Q. I believe you told us that Ventria's core technologies are plant-based expression recombinant protein products; is that correct?

A. That's correct.

Q. And does Ventria use ExpressTec in producing that product?

A. Yes.

Q. Can you give the Court sort of a high-level understanding of what ExpressTec is?

A. ExpressTec is a tool set that includes multiple genetic elements that allow us to design the expression of a target protein using a synthetic gene that we insert into the plant tissue, and that tissue is expanded and then developed into a maturing plant. And the protein is expressed in the seed, where it can be stored for multiple years and maintain the quality of that protein in the rice seed. And the ExpressTec technology allows those genetic elements to come together to be able to make that happen.

Q. I'm going to ask you to look at the first exhibit that we're going to talk about in your testimony, and that's Exhibit CX-1082.

A. Okay.

Q. Do you recognize Exhibit CX-1082?

A. Yes, I recognize it.

Q. What is this?

A. This is from our website where we used a case study to describe ExpressTec and how it is applied to the InVitria product line.

Q. I'm going to ask to put up demo slide 3 and ask you, Mr. Deeter, how did ExpressTec benefit Ventria?

A. ExpressTec is a platform technology so that it can make multiple types of proteins. In this case, in this

slide, we're making a human serum albumin protein recombinantly that is using a genetic gene that is inserted into the embryonic tissue of rice, and that embryonic tissue is selected for the presence of the gene, and then that tissue is grown into the first-generation rice plant, where we then select from there the highest amount of recombinant human serum albumin in the seed.

And it's expressed in the white part of the seed there in this picture. That's called the endosperm where the starch in the rice is located. And so that's a nice storage vehicle for the protein, because it has the ability to maintain the quality of that target protein over time.

And you can see that we store it in a very low-cost way at high scale using typical grain storage shown on the second box there.

And then when we're ready we can then take it from storage and we remove the outer husk of the rice, we remove -- we then add aqueous, an extraction buffer, and we solubilize all the protein, including the recombinant human serum albumin, and then we purify that protein and clarify that solution.

That becomes, then, the liquid protein, the target recombinant human serum albumin, and then we can package that or make it into a powder and package it.

Q. Mr. Deeter, you're familiar with the products

that Ventria is claiming in this case are covered by the '951 patent, correct?

A. Yes, I am.

Q. And what are the brand names of those products?

A. The brand names of those products are Cellastim, Exbumin, and Optibumin. Those are the three recombinant protein products. We also have an albumin included in ITSE + A that is Cellastim, and we have three media products, one for vero cells called OptiVERO, one for HEK cells called OptiPEAK HEK-293, and one for T lymphocytes for cancer therapies called OptiPEAK T lymphocyte. Those three medias also contain albumin.

Q. Is ExpressTec used in the expression of those products?

A. It is used to make the protein components.

Q. Of each of those products?

A. Of those products, yes.

Q. And when did Ventria first start selling a rice-derived albumin?

A. We started the selling around 2007, early in 2007. I want to say April, May, of 2007 is when we had our first sales.

Q. What was the brand name of that product?

A. That was Cellastim.

Q. Has Cellastim as a product evolved over the

years?

A. Yes. We made a lot of advancements over the years to improve the quality and the utility of the albumin product line.

Q. Let's look at demonstrative slide 4, please.

Prior to Ventria's use of rice for derived albumin, what were other sources common for cell culture albumin?

A. The most common standard is fetal bovine serum, which comes from a pregnant cow that's slaughtered. The fetus, the blood from the fetus is drained and used as a cell culture product that includes the albumin. Also from the blood of both cattle as well as humans albumin can be extracted. Those are the primary sources of blood-derived albumin and serum.

Q. Were there sources for recombinant albumin?

A. There was a yeast-derived albumin that was manufactured as well.

Q. What are some of the benefits that Ventria has a rice-derived albumin compared to other hosts for albumin?

A. Compared to the blood or fetal bovine serum type origin, there's a significant benefit of using rice because it's a plant, number one; number two, it doesn't harbor the viruses and pathogens that may come from the blood supply. So any type of virus that might come from blood, HIV would

be one, and the case of COVID actually could be an issue, or in the case of cattle blood, there was -- there's a big concern and still is today about prion contamination that causes mad cow disease in cattle and Creutzfeldt-Jakob disease in humans. And so there was a need to have a scalable and effective source of albumin that did not come from a blood source.

And the yeast-derived product was available, as I mentioned, but it's very, very expensive, and it limited the market opportunity for that product, because it was just too expensive.

Q. May I ask to put up demonstrative slide 5 for a moment.

Are there supply chain and availability benefits to rice over other hosts?

A. Rice is attractive in a scalability sense because, as you might think about growing rice, you know, it involves water, it involves land, air, and a rice plant, and the energy source is the sun. And so we can, because of our yield of recombinant albumin in the seed, that was a key advantage, we could make a large amount of albumin per acre of land. And it's a significant advancement for scalable manufacturing of recombinant protein.

Q. I'm going to ask Ms. Hitchens to pull up Joint Exhibit 117, JX-117.

Mr. Deeter, do you recognize Exhibit JX-117?

A. Yes.

Q. What is this?

A. This looks to be one of our selling sheets or product brochures that was used for the marketing of the product.

Q. And can you tell me which -- about what year this document is from? We can look at the second page, if that helps you.

A. Okay. It looks like the last quarter of 2006 approximately. It says that's when the product would be available.

Q. There's a revision date at the bottom of this page. It's really small. Do you see that?

A. Let me see. Is that -- July of 2006.

Q. Does that comport with your recollection of when Ventria started offering Cellastim?

A. Yeah, this would have been when we were beginning the activities to think about the marketing of the product.

Q. And when, again, was Cellastim first sold?

A. In early 2007.

Q. How did the market first receive rice-derived albumin in 2006-2007?

A. Initially it was a struggle. We had a lot of -- there was a lot of interest conceptually to the idea that we

talked about for plant-derived and rice-derived albumin. The challenge was making a high-quality product consistently.

Q. Did you have any issues with Cellastim in 2007 with respect to the quality of the product?

A. Yeah. We had customers who set specifications related to our product, most notably the performance and the endotoxin levels of the product and the quality of the product.

Q. What kind of steps did you have to do to gain market acceptance?

A. We needed to lower those impurities.

Q. And was that something that was easy for Ventria to do, difficult for Ventria to do?

A. It was very difficult.

Q. How long did that take?

A. It took us several years and a lot of trial and error, mostly error. There was a lot of effort made to try different strategies to improve the quality of the product. It was a classic case of the scientific method. We would have a hypothesis. We would test it. Most of the times it didn't work or it didn't achieve our objective. And so it was difficult to reach the goals that the customers had for the product in the early days.

Q. Did Ventria encounter any application acceptance

issues?

A. You mean by the customer?

Q. By the customer. Did the customer come to Ventria with any problems with how do we use this?

A. Yeah, there was a lot of -- it's actually why we started our cell culture lab was so that we could replicate the problems that the customer was seeing.

You know, I was pretty naive when we started, myself and our team of scientists that worked on this. We thought we could just extract and purify the protein and sell it and everything would be great and we would scale up and go.

What we learned, though, as the customers tested the product, it didn't work for them as expected. And so what we had to do was develop our own cell culture lab, and we hired cell culture scientists, virologists, people that had expertise in this area so they could teach us how the protein was used, how it compared to fetal bovine serum, how it compared to human serum albumin, and how it compared to bovine serum albumin.

And so that cell culture lab was really a key to us understanding the performance of the product. And then we also had to understand how to improve processing, different processing methods, that would work to get, not only the performance, but also the endotoxin targets that

the media industry and the injectable drug industry required so that you're not injecting either the cell or the human with a high level of endotoxin, which could be toxic.

Q. Did you employ additional people when you added the cell culture teams?

A. Yes. We had -- Ning was our VP of R&D, and he really was the lead scientist, and working for him was Steve Pettit and Mary Ann Santos, Dana Lee. We hired several people to develop the cell culture lab so that we could replicate what the customers see.

Q. Were these primarily scientists?

A. Yeah, all scientists.

Q. We haven't introduced the patent yet, but some of the names that you gave me, were those inventors on the '951 patent?

A. Yes.

Q. And did that include Ning Huang?

A. Yes, Ning was our VP of R&D.

Q. Is Mr. Huang retired?

A. He retired from the company, yes.

Q. Let's talk about the market for rice-derived has. Currently how big is the U.S. market for rice-derived has -- rHSA?

A. It's impossible to state exactly, but I believe it's around $50 million.

Q. And how does the price of Ventria's rHSA compare to non-rice-derived has?

A. So blood-derived albumin is lower priced than the recombinant product, so the recombinant product has the benefit of being blood-free so it doesn't have the concerns about pathogen contamination. It has more consistency and more scalability. And so, for those reasons, we're able to obtain a premium price.

Q. So there are other U.S. manufacturers of cell culture albumin products, correct?

A. Yes.

Q. Do those -- do any of those U.S. manufacturers use rice as the host?

A. No.

Q. How many players are there in the U.S. market for rice-derived human serum albumin?

A. We have several distributors that distribute product and then we have one manufacturer in the United States, which is Ventria.

Q. Are there other manufacturers that sell into the United States that sell rice-derived human serum albumin?

A. Yes.

Q. How many?

A. One.

Q. Who is that?

A. That's Healthgen.
Q. How did you learn about Healthgen?
A. The first time I heard about the company I actually knew it as a different name called Ori Bio. We got a phone call from one of our first customers that we had been working with several years to develop albumin for their applications, and they said that they were contacted by a company that was selling rice-derived albumin, and they gave us the company name. We were pretty close to them because they are our collaborator. And I researched Ori Bio. They gave me the name Ori Bio, and realized that it was our former employee Daichang Yang.
Q. How do you know Daichang Yang?
A. He worked for me and for the company from 1999 until 2005.
Q. What did he do at Ventria and/or Applied Phytologics?
A. He was a scientist in a lab.
Q. In 2009 did you have any concerns about Dr. Yang's company?
A. I'm sorry.
Q. In 2009.
A. In 2009? When we first learned of it?
Q. Yes, sir.
A. Yes. I was very concerned about that.

Q. Why were you concerned?

A. We were concerned because the claim that was being made was that the product was identical to our product, and we didn't know how he had obtained the product.

Q. Were there any other concerns in 2009 when you looked at the website?

A. Yeah, we -- what we did, we investigated first the Ori Bio website and noticed that the presentations that were made on the Ori Bio website were our presentations. All of the data was identical to our data. We learned that the colors were changed to depict a different color, and the brand name was Ori Bio, but they were exactly tracking with our data. That was our first concern.

Of course, we learned that Daichang Yang was the founder and the CEO and chairman of the board of the company. That was concerning.

We then did further investigation and found out that he had filed a patent, and that patent was filed in China in 2005, and that was only two months after he left Ventria in May of 2005.

Q. Okay.

A. And it's impossible to have generated the data in the patent in two months. He was the sole inventor on the patent.

Q. We'll come back --

A. That would have been impossible to do in two months. And we then noticed that the gel images that were showing the protein in the patent were identical to the color images in the actual gels that we had in our lab notebooks in Ventria.

Q. Really quickly, why was it your opinion that it was impossible for, I think you said it was impossible, to do the patent in two months, what do you mean by that?

A. It takes the rice longer to grow than two months.

Q. And what are you -- what is the two months you're referring to?

A. He left our employment in May of 2005. He was covered under a confidentiality agreement, an employment agreement at that time. He told us that he was going to -- back to China to become a professor at Wuhan University, which we supported and encouraged. We thought it was exciting for him. But it would have been impossible for him to set up his lab and produce the data in the patent in two months.

Q. That's because of the growing time of rice, in part?

A. Because of the timeline that it takes to grow rice.

Q. I'm going to put up an exhibit and ask you if you recognize it. It's CX-711C.

For the Court, this is a document that was marked as CBI, but we're not concerned about maintaining it as CBI, Your Honor, so we can stay on the public record for this.

Q. If you can look, Mr. Deeter, at CX-711C and tell me if you recognize this document?

A. This would have been the employment document for Daichang Yang to join Applied Phytologics, which was the predecessor company to Ventria Bioscience.

Q. Was Dr. Yang under a confidentiality provision as part of his employment with Ventria?

A. Yes.

Q. So Dr. Yang left Ventria, you said, in 2005?

A. In May of 2005, yes.

Q. What was Dr. Yang's contribution, if any, to Ventria's rHSA technology while he was employed at Ventria?

A. Part of Dr. Yang's role was to order the gene, the synthetic gene from Blue Heron, the synthetic gene provider that we use, a third-party provider, to start the process of inserting that gene into the rice, and working for Ning, that was one of his roles, and so he was involved at the beginning of the project.

Q. When you learned about the Ori Bio company, other than looking at the website that you talked about and other than finding the patent, did you do anything else at that time in response to that information?

A. We did a quite extensive investigation, one of which was to look at our own website because we were curious where all of our -- why our presentations ended up on the Ori Bio website.

What we discovered was from early in 2009 through the end of the year there was an IP address affiliated with Wuhan University that downloaded 504 pages of our website and all of our documentation on the website. And that was in our data logs from our servers.

We also discovered that the gene sequence that was used in the patent in China by Dr. Yang was an incorrect listing in GenBank, he listed the incorrect sequence, and actually it was the identical sequence that we used, and we ordered from the synthetic gene company Blue Heron.

Q. Did you file a lawsuit as a result of that investigation?

A. We did file a lawsuit against Daichang and his company.

Q. Do you recall what year that was filed?

A. Off the top of my head, you know, '11, '12, 2012, 2013, something like that.

Q. What was the outcome of that lawsuit?

A. It was a very disappointing process, to say the least. It was my first time going through something like that. A very expensive process. And we got to a point

where we saw no beneficial outcome except to settle. And it was a very hollow victory for us to do the settlement.

Q. Did Dr. Yang participate in that case through discovery?

A. We tried to subpoena Ori Bio/Healthgen and Dr. Yang, but the subpoenas were not served by the government in Beijing.

Q. I'm going to ask you to look at another document that is CX-887C.

Again, for the record, this is a document marked confidential business information. It would be confidential business information of Ventria, but, Your Honor, again, we're waiving that confidentiality designation and can remain on the public record.

MS. GIANNELLI: Your Honor, I believe that this document also implicates confidential information of Dr. Yang, Dr. Daichang Yang, who was a party to the agreement. I'm not sure that Ventria has the sole authority to waive the confidentiality of CX-887C.

JUDGE MCNAMARA: I think your point is well taken, Dr. Giannelli.

MS. HOEKEL: That's fine. We can go on the confidential business record very briefly, Your Honor.

JUDGE MCNAMARA: So you're going to go first to the Ventria confidential business record?

MS. HOEKEL: It's one document, Your Honor.

JUDGE MCNAMARA: But I don't think Dr. Yang has waived his right to the privilege on this or his right to the confidentiality.

MS. HOEKEL: What I meant to say by that was that this would be confidential business information as to the public, but it would -- I think what Dr. Giannelli's concern was, was that we don't waive Dr. Yang's objection to this information being confidential business information, so I think we should go on the confidential business record.

I guess what I meant to say by that is I don't think either Ventria employees or Healthgen employees need to leave for this because it's their information.

JUDGE MCNAMARA: Do you agree with that, Dr. Giannelli, just to be sure that we've got this clear on the record?

MS. GIANNELLI: I agree with that, Your Honor. In fact, I believe Mr. Deeter, the witness, may be a signatory to the agreement. We certainly have no basis that the witness couldn't be questioned on the document.

JUDGE MCNAMARA: Thank you very much. So this is confidential as to everyone.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. HOEKEL:

Q. After the lawsuit, when was the next time you heard about Dr. Yang's businesses?

A. After the lawsuit -- well, I would say we started hearing more and more activity in 2018-2019 time frame, when we started to notice from customers again that they were being marketed and were actually using in one case the Healthgen product.

Q. What did you understand the Healthgen product to be at that time?

A. Recombinant human serum albumin derived from rice.

Q. Were you -- did you learn about the country of origin of that product?

A. We did from -- our customer told us that it was a foreign source and it was from rice. And so we did further investigation and noticed that there were several distributors of the same product.

Q. Did anyone at Ventria ever speak to anyone in this time frame from Healthgen?

A. One of the Healthgen salespeople contacted our scientists to sell their product to us. That was Dr. Alfano.

Q. In 2019 was Ventria working on its Exbumin product?

A. Yes, we were working with a large vaccine company, Merck, in the U.S., to develop the Exbumin product for use in vaccines in their vaccine program for -- in cell culture and buffer solutions to stabilize virus.

Q. And was Exbumin granted any regulatory approval as part of that process with Merck?

A. Yes. It was approved as an excipient, one of the first excipients approved in several decades, I'm told, that it was the first recombinant albumin approved as a final formulation excipient as part of the approval of Merck's ERVEBO Ebola vaccine.

MS. HOEKEL: Your Honor, I have a couple of exhibits that I want to show the witness that we had some dispute with Healthgen counsel. I think I can moot that objection, Dr. Giannelli, if you have no objections to me showing CX-840, 841, 842, and 843 in the nature of a demonstrative, and we won't move for their admission.

MS. GIANNELLI: We would have no objection to you showing them to the witness.

Your Honor, the issue was that these were foreign-language documents for which no translation has been provided, but we discussed this and it seems that they may just show them to the witness to sort of jog his memory on

things that he observed. So we have no objection to showing them but not moving them into evidence.

MS. HOEKEL: Thank you, Dr. Giannelli.

Your Honor, did you have a question?

JUDGE MCNAMARA: I'm muted.

I guess my question is, if these documents haven't been translated and I can't read them, I guess Mr. Deeter can't read them, there's still -- even though they are demonstratives and they are not being admitted for the truth of the matter, how do I deal with the language barrier? Because I really don't know Chinese.

MS. HOEKEL: Your Honor, essentially they are websites of the Respondent Healthgen. There are a few English words on them that were native to the website. That's the way the website appeared.

And that's all that we're asking Mr. Deeter. He is just going to say he saw these, he saw the product name, he saw the pictures, that's all. That's all we're asking. We're not eliciting any testimony that's in Chinese. None of this in this room can read it either, Your Honor.

JUDGE MCNAMARA: I wish I could.

MS. HOEKEL: Let me put up the exhibit. If we have problems with it, we can take those up. But maybe if Your Honor saw the exhibit it would clarify the use of it.

JUDGE MCNAMARA: Sure.

Q. The first exhibit is CX-840. I'm just going to ask Mr. Deeter --

Sorry, Your Honor, it's not up yet.

It's the way it was printed it cuts off. Maybe Ms. Hitchens can show us the first page and then the second page of the document.

I'm just going to ask Mr. Deeter if he recognizes this document.

A. It looks like the website.

Q. And did you see this website at some point in time?

A. Yes.

Q. And what was it that you noticed about this website that caught your attention?

A. Well, the fact it was rice-derived recombinant albumin, OsrHSA.

Q. What is it about this website that led you to believe it was recombinant has?

A. Well, the statement in English says recombinant.

Q. And what about the picture? Is there anything in the pictures below that you -- that caught your attention?

A. Can you expand that?

Q. He is asking if Ms. Hitchens can blow it up a little bit.

A. Yeah. So the recombinant human serum albumin on

the label from OryzaGen.

Q. If we can look at the next exhibit, which is 841, please.

On the screen, Mr. Deeter, is CX-841. Have you seen this before?

A. Yes.

Q. What is this document?

A. This is a description of the characterization of recombinant human serum albumin.

Q. And you don't speak Chinese or read Chinese, correct?

A. Correct.

Q. How is it that you understand that?

A. This is exactly the chart that's been in our presentations.

Q. The chart that's on page 1 or page 2?

A. The chart below the green.

Q. Okay. If we can go to the first page of this exhibit, 841, please, do you see in the middle where it says, OsrHSA, and then in parentheses it says, recombinant human serum albumin from Oryza sativa?

A. Correct.

Q. What is Oryza sativa?

A. Rice.

Q. We're just going to use --

Dr. Giannelli, we're not going to use any additional exhibits.

You mentioned previously that you became aware that Dr. Yang filed a patent in China for what technology?

A. That was for the expression of recombinant human serum albumin in rice.

Q. And did you believe that those patents were based on work he did at Ventria?

A. Yes.

Q. Why is that?

A. There were several reasons. I mentioned the identical mistake on amino acid difference in the gene. That would be very unlikely to make that same mistake in the patent from what was in our possession.

Number two, the images of the gel, which is like a fingerprint, would be impossible to exactly replicate. We have color images of those gels in our lab notebooks, and he is not able to produce anything other than a replica, a photocopy.

It had the exact same artifacts in the image, the same plotting, and same structure of the banding pattern as well as some mistakes in the banding pattern from the molecular marker.

Q. Do you believe that that information gave Dr. Yang a head start in making recombinant human serum

albumin?

A. Yes.

Q. Mr. Deeter, you understand that part of the Court's task in this investigation is to have an understanding of Ventria's investments in its domestic industry products, correct?

A. Yes.

Q. And we've talked already about some of the challenges that Ventria faced, and Dr. Yang's lawsuit was one of those challenges, correct?

A. Yes.

Q. Were there -- how did that lawsuit affect your business and your ability to invest in the domestic industry products?

A. Well, it was a big distraction really, and it's very expensive to go all the way up to trial and then not have him appear at trial, and to realize that, even if we won we couldn't enforce anything against a Chinese company.

So it was a really tough process. I learned a lot. I guess that's the benefit. I learned a lot about the legal process and about patents and patent prosecution and trade secret theft. But that was, you know, some of the learnings along the way, I guess.

Q. Have you had other -- has Ventria faced other challenges with respect to its trade secrets?

A. Yes. We had a second trade secret theft case related to allegedly stolen seeds, the rice seeds, including the recombinant human serum albumin seeds from our laboratory.

Q. What was the name of the individual who was accused of stealing -- is it stealing seeds, is that what he was accused of?

A. I believe it actually converted from trade secret theft to corporate espionage.

Q. And who was bringing that action?

A. That was brought by the U.S. Department of Justice, by the FBI.

Q. What was the name of that individual?

A. His name was Dr. Weiqiang Zhang.

Q. Did he work for Ventria?

A. Yes. He also worked with Ning.

Q. Was he eventually convicted of anything?

A. Yes, he was convicted.

Q. And you said that he was accused of having taken some proprietary rice seeds; is that correct?

A. Yes.

Q. Why was that important to Ventria's business?

A. Well, the rice seed goes through several years of development to improve its ability to grow how much yield we get from the rice. There's a lot of work to select the best

seeds that will grow the best in the field. We do that every single year, sometimes multiple times a year, to select the best seeds, the seeds that make the most yield. And it includes all the genetic elements that our technology represents.

So all the genetic technologies are included in one seed. So we protect the seeds with the utmost care. And Weiqiang, Dr. Zhang, was a Ph.D. plant reader that we had hired, and he was working to further develop and improve our seeds.

Q. Was there another individual involved in that particular investigation?

A. There was another individual that was an employee of the U.S. Department of Agriculture.

Q. And that involved other companies in addition to Ventria?

A. It was the understanding that both Pioneer Hybrid Corn Seed Company was a party to this as well as Monsanto.

Q. And we're going to go through just a couple of exhibits to ask you if you recognize them and ask that they be placed in the record for the purpose of additionally help quantify the amount of loss and detriment to the Ventria business that's relevant to the domestic industry products. I just want to ask about a couple of exhibits.

The first one is Exhibit CX-516. I'll ask if you

recognize this document, Mr. Deeter?

A. Yes. This looks to be the judgment against -- in the case that we were just discussing.

Q. And this judgment says that -- was it doctor?

A. Doctor.

Q. -- that Dr. Zhang was found guilty on three counts of an indictment, correct?

A. Yes, correct.

Q. And if we can go to page 7 of this document, please.

Does this document indicate whether Dr. Zhang was ordered to pay monetary restitution to Ventria?

A. Yes. The restitution amount is listed on the right, 190 -- I think that's 3,157.

Q. Let's look at Exhibit CX-519, please, and ask if you recognize this document, Mr. Deeter?

A. Yes, I recognize this. I helped prepare the economics here.

Q. And what is this document?

A. This was a document showing the cost and the distraction to our team that participated in the prosecution of Dr. Zhang.

Q. If we can look at page 3 of Exhibit 519, please.

And you said you participated in putting together some of the economic damage information for the Government;

is that correct?

A. Yes, correct.

Q. And what does the Government's memo regarding restitution here provide?

A. Let's see. This is the -- it describes the $350,000 in wages and legal fees for our part of this as well as for our attorney's fees, if I didn't say that.

Q. Next let's look at Exhibit 533. Again, I'm going to ask Mr. Deeter when the document comes up if you can identify this document, please.

A. Yes, this is the Sentencing Memorandum.

Q. And if you look at section A of the Sentencing Memorandum, can you read that first sentence, please?

A. "This evidence contains ample facts to conclude that Zhang purposely sought to cause more than $25 million in loss to Ventria."

Q. If we can look at one last document which is CX-860.

(Clarification by reporter.)

Q. Exhibit CX-860, Mr. Deeter, do you recognize this document?

A. Yes. This was a description of the case brought by the Government.

Q. If we can go to the last page of this document, which is page 12. And if we can drill up the last

substantive entry on page 12.

Do you see this entry, Mr. Deeter?

A. Yes. This is a paraphrasing of the case against Weiqiang Zhang.

Q. This says that he was sentenced to 121 months in federal prison for conspiring to steal samples of rice seeds from a Kansas biopharmaceutical research facility, correct?

A. That's correct.

Q. And is Ventria that research facility?

A. That's correct.

Q. Thank you. Mr. Deeter, I think we have established that in the U.S. market of rice-derived human serum albumin there are only two suppliers, correct?

A. Two manufacturers.

Q. Two manufacturers. And one of them is Ventria and one of them is Respondent Healthgen?

A. That's correct.

Q. Have you -- has Ventria lost customers to Healthgen in the last few years?

A. Yes.

Q. Have you -- have customers told you why?

A. The primary reason was price.

Q. Explain what you mean by "price."

A. They were able to get a cheaper price. Many times we -- we work collaboratively with the scientists,

with the customer, to get the product adopted and utilize a show performance in the the scientists, in the lab of the customer.

And then it moves to their quality team, their regulatory team, who looks at the safety and the regulatory profile.

And then once that is concluded they will move to the procurement group, which the procurement group is more what I call the purchasing department is mostly focused on price. And it's when we get to that stage when we've seen customers switch and we lose customers over price.

Q. Who is the biggest customer Ventria has lost to date?

A. I believe the biggest customer is Kerry. They were our largest customer in 2015, and we effectively have not sold them much in the last several years. But they were our largest customer. We helped them enter the market. We helped them develop this. They are a company that makes hydrolysates that are used in cell culture. They were very interested in our product. It was a collaborative effort.

Our scientists helped show their scientists how to use it and educated them on the use of the product. And they, of course, like any business, they wanted to have as good a price as they could get, and they told me that they were looking at a foreign source of rice-derived albumin, so

I believe that's probably the biggest.

Q. Do you know who Kerry is buying from?

A. I do now.

Q. Who is Kerry buying from?

A. They're buying from Wuhan Healthgen.

JUDGE MCNAMARA: Pardon me, Ms. Hoekel. Would you make sure at the end of Mr. Deeter's testimony that you give the full name of the company and the spelling so that it's correct in the record.

MS. HOEKEL: We will do that, Your Honor. Thank you.

JUDGE MCNAMARA: Thank you. Okay.

Q. I am going to ask that we bring up Exhibit, Joint Exhibit 1, which is the '951 patent.

Mr. Deeter, is it your understanding that this is the patent on which this investigation is based?

A. Yes.

Q. Who are the inventors on this patent?

A. Steve Pettit, Ning Huang, and Mary Ann Santos.

Q. This patent was filed on February 20th of 2009?

A. Right. Yes.

MS. HOEKEL: Your Honor, I think from here to the end of Mr. Deeter's testimony, which is at least another hour, maybe an hour and a half, we're going to be in Ventria's CBI information. There will be some small

portions that aren't, but primarily the exhibits and the testimony at this point will be Ventria CBI.

JUDGE MCNAMARA: Okay. So I think, Dr. Giannelli, you know what to do there, and then to confirm that Dr. Yang is off.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

(In session at 4:04 p.m.)

JUDGE MCNAMARA: Dr. Giannelli, are you ready?

MS. GIANNELLI: Yes, Your Honor.

JUDGE MCNAMARA: All right.

CROSS-EXAMINATION

BY MS. GIANNELLI:

Q. Good afternoon, Mr. Deeter.

A. Good afternoon.

Q. Thank you. You testified that Dr. Daichang Yang used to work for Ventria, correct?

A. That's correct.

Q. Dr. Yang left Ventria in 2005, didn't he?

A. That's correct.

Q. And that's about four years before the earliest application related to the '951 patent was filed on February 20th, 2009, isn't it?

A. That's correct.

Q. And you do understand that the sole allegation remaining against Healthgen in this investigation is for alleged infringement of the '951 patent, correct?

A. That's right.

Q. Now you mentioned a settlement with Dr. Yang from a prior case. Am I correct that that settlement was signed by you in 2013?

A. I believe that's approximately the date. I would have to look at the exact date because I don't have the recollection in my head, but I did sign that document.

Q. And you were part of that prior case, correct?

A. That's correct.

Q. And so you were aware of what was happening in the California court back then, correct?

A. I was aware of the case, that's correct, and we had that filed in California.

Q. So you would have been aware of the various court orders that were issued in that case, correct?

A. I would have been aware of what our attorneys did on our behalf.

Q. I would like to pull up the first exhibit, RX-357, please. This is an order on Defendant Daichang Yang's motion for summary judgment or summary adjudication in the California case, and the order --

Mr. Deeter, can you confirm that this order relates to the case that Ventria had several years ago against Daichang Yang?

A. Off the top of my head, it's hard to tell that, but it appears to be related to that case, Ventria versus Daichang Yang, motion for -- okay.

Q. And in this court order, the Court issued an initial order and then amended it, but I'd like to start by

looking at the Court's initial determination.

On page 9 of RX-357, at the bottom of the page, regarding Ventria's claim that Yang misappropriated two promoter trade secrets.

Mr. Deeter, do you understand the term "promoter" there?

A. I do understand what promoter means.

Q. Okay. And here the Court initially stated that summary judgment in Dr. Yang's behalf was granted. Do you recall that?

A. Standing right here, not the details of it, but I'll take your word for it.

Q. Okay. And so it was Dr. Yang's motion that was initially granted, correct?

A. Again, recalling the exact details of whose motion, you know, today, I'll take your word for it.

Q. If we could go to page 10 of RX-357, I think the picture will become a little clearer for you, Mr. Deeter.

A. Okay.

Q. If we could please pull up the paragraph starting with "Yang indisputably." Here the California court explains that Yang indisputably used a certain promoter, Promoter A, while conducting research for Ventria. The Chinese patent, and that would be Dr. Yang's patent, correct, Mr. Deeter?

A. That's how I would interpret that.

Q. Okay. Now Dr. Yang's patent references research using a different promoter, Promoter B, so that the court states that they are not going to go into the details of the trade secrets, but, in a sentence starting with "on grounds," the court states that on grounds that Ventria cannot establish proof of its ownership of the Promoter B trade secrets in question, Yang moves the court to summarily adjudicate Ventria's claims based on these two trade secrets.

And if we could expand the next paragraph of this page of the court order, please.

The Court concludes that Yang has produced admissible evidence sufficient to meet its initial burden of production and shift the burden to Ventria to produce admissible evidence demonstrating the existence of a triable issue of material fact. Specifically, Dr. Yang has demonstrated that Ventria cannot produce evidence that Yang worked on Promoter B while employed at Ventria.

Mr. Deeter, are these events ringing a bell now that you're seeing them here on the screen?

A. I mean, the details of it, this is a pretty detailed part of a very involved case, so I assume what you're saying is correct.

Q. Okay. And if we could -- we can bring down this

excerpt and blow up the next paragraph that begins with "notwithstanding."

And here the California court in 2013 states, "notwithstanding its responsive evidence, Ventria has failed to demonstrate the existence of a triable issue."

And if we could blow up the next paragraph, please. We can take this one down.

Similar to your testimony just a few minutes ago there's a discussion of the Yang China patent, and the court here notes that Ventria cites evidence that parts of Dr. Yang's Chinese patent materials duplicate verbatim research conducted at Ventria, including an inadvertent mistake. The court, however, here says it does not appear, however, that the Ventria research in question involved the use of Promoter B.

And if we recall from earlier in the opinion, Promoter B would be Dr. Yang's promoter that has no connection to Ventria.

The California court continues, "Hence, although Ventria's evidence arguably supports a reasonable inference that Yang used Ventria's research to obtain the Chinese patent, it does not support a reasonable inference that Yang or anyone else at Ventria used Promoter B to conduct the duplicated research."

Do you see that, Mr. Deeter?

A. Yes, I see that.

Q. And the court then states, "as a consequence, the assertedly duplicated research does not create a triable issue of fact either."

Do you see that, Mr. Deeter?

A. Yes, I do see that.

Q. Okay. And if we could -- we can set this paragraph aside. Please pull up the last two paragraphs of RX-357, page 10.

The court continues to discuss, the expert evidence that Ventria proffered, and here, Mr. Deeter, do you see where it states that Ventria has produced an expert declaration containing an opinion that it is unlikely that the China Patent Application was based on the doctoral research or thesis of Wuhan doctoral student TingTing Ning.

Do you see that, Mr. Deeter?

A. Yes.

Q. So that was what your expert had argued similar to what you've implied here today, correct?

A. I'm sorry. Counsel, could you repeat the question?

Q. It was a messy question, Mr. Deeter. I'll rephrase. Actually let's continue with the opinion.

The court states that, because Yang asserts that Ning's research used Promoter B and that this led to the

Chinese patent, Ventria's expert opinion is intended to undercut Yang's assertion.

Do you see that, Mr. Deeter?

A. Yes.

Q. However, when evaluating your expert witness testimony in the prior California case, the California court concludes that, quote, like Ventria's other evidence, however, its expert opinion is insufficient to create a triable issue.

Did I read that correctly, Mr. Deeter?

A. Yes, you did.

Q. Continuing on the next paragraph, the California court concluded, the expert opinion is insufficient because it does not support a reasonable inference Dr. Yang conducted Promoter B research while at Ventria.

Do you see that, Mr. Deeter?

A. Yes.

Q. And if we can go to the paragraph on the top of page 11 of RX-357 and just blow up that top last paragraph.

The court further states that, even if the expert's opinion can be liberally construed to support an inference that Ning's research was not the basis for the Chinese patent and even if Ventria's evidence collectively supports a further inference that the Chinese patent was based on Yang's research at Ventria, it would still require

conjecture to infer that Yang's research at Ventria included the use of Promoter B, and, therefore, that Ventria somehow owns Promoter B trade secrets.

Did I read that correctly, Mr. Deeter?

A. Yes, you did.

Q. Do you remember these events in the California court, Mr. Deeter?

A. Yes.

Q. This reads like it's the end of your trade secret misappropriation case, doesn't it, Mr. Deeter?

A. No.

Q. This opinion issued in 2013, correct?

A. That's the date. I don't recall exactly, counsel, what the date was of that.

Q. Now the Court, although it had a lot of negative things to say about Ventria's lack of evidence, the Court ultimately -- if we can move to RX-357, page 1 -- the Court ultimately issued an updated opinion, and if we could blow up, on page 1, the bottom quarter or so -- perfect.

Now the Court refers to its June 19th, 2013 Tentative Ruling. Mr. Deeter, you understand that to be the part we were just reading? Is that your understanding?

A. I'm sorry, counsel. What part are you referring to?

Q. So here the court is referring to the June 19th,

2013 Tentative Ruling. Mr. Deeter, I'll represent that the Tentative Ruling where the Court was -- granted Dr. Yang's motion to dismiss, that's the Tentative Ruling we were just reading.

A. Okay.

Q. However, the Court here modifies the judgment, around line 25, and states that Dr. Yang's motion for summary adjudication of the two Promoter B trade secrets is in fact denied. But the reason here, the Court explains, just before you settled with Dr. Yang, the Court states that the Court continues to have some doubts whether or not Ventria's evidence supports a reasonable inference that Yang developed these trade secrets while employed at Ventria, but all doubts must be resolved in favor of the party opposing summary judgment.

So, Mr. Deeter, are you aware that this was the final court order before the parties finally inked their settlement agreement?

A. I don't know the exact dates of each, but I will take your word for it, counsel.

Q. So here the Court is, in fact, referring to the June 19th, 2013 Tentative Ruling. So, with that date in mind, I'd just like to connect that to the date of settlement.

So if we could please pull up CX-887C, which was

the settlement agreement.

And for this we'll need to go on the confidential record, but assuming that no members of the -- so I think that would just be Crissa Cook, if she is still participating, would need to leave for the moment.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

JUDGE MCNAMARA: We are back on the public record, Ms. Kinkade.

BY MS. GIANNELLI:

Q. But you agree that the text here in Deeter from two years prior to the '951 patent in example 3 is identical to the text of example 3 in the '951 patent in substance, correct?

A. Correct.

Q. So given that the same production system appears before the '951 patent, would you agree that the method of producing recombinant human serum albumin in rice grain as disclosed in Deeter cannot be an inventive aspect of the '951 patent?

A. Well, as we mentioned, that the rice grain is one aspect of the invention, and so we have to have the rice grain, but then we also have a lot of extra R&D that went into make the recombinant protein.

Q. You're not an inventor on the '951 patent, are you, Mr. Deeter?

A. No, I'm not.

Q. Let's compare the properties in the recombinant albumin in your patent application with the properties of the recombinant albumin in the '951 patent.

If we could please have RX-32 at page 31, table III, on the left.

JUDGE MCNAMARA: Dr. Giannelli, could you repeat the number of the exhibit?

MS. GIANNELLI: RX-32.

JUDGE MCNAMARA: Thank you.

MS. GIANNELLI: We're going to display table III at the top of page 31.

Q. And then on the right, if it's possible to have two up at once, we would like to display JX-1 at column 66, lines 10-24.

JUDGE MCNAMARA: If they could blow up those sections. It's better than a thumbnail. Just do what you can here.

Q. Mr. Deeter, are you able --

JUDGE MCNAMARA: Go ahead.

MS. GIANNELLI: Sorry, Your Honor.

Q. Mr. Deeter, are you able to see these tables?

A. Yes.

Q. Okay. We have here on the left the properties of the recombinant albumin of your patent application published in 2007, and on the right we have the properties of the recombinant human albumin as published in the '951 patent.

Am I correct, Mr. Deeter, that all the properties of the recombinant albumin in the '951 patent Table E2 were

also disclosed at least two years earlier in your patent application?

A. Those tables appear to describe the same properties.

Q. Now in the third row here, Mr. Deeter, there's a reference to SDS-PAGE. Do you see that?

A. Yes.

Q. You're familiar with SDS-PAGE, correct?

A. I'm not an expert, but I know what it means.

Q. Last, I'd like to look at RX-32, page 32, example 9. And we can drop the side-by-side and just go with RX-32. Thank you.

Mr. Deeter, can you please read the title of example 9 from your 2007 patent application into the record?

A. Sure. "Cell culture media supplemented with recombinant human serum albumin promotes hybridoma cell growth in serum-free media."

Q. And so in this example back in 2007 you were disclosing the use of recombinant human albumin produced in transgenic rice as a cell culture media supplement, correct?

A. Yes.

Q. Could we please look at the bottom of this page, the bottom of page 32 of RX-32? If we could highlight the last sentence, which is the conclusion.

The conclusion in this patent application is that

the example shows that plant-derived recombinant human serum albumin can promote cell growth in serum-free media and replace animal-derived albumin for use in tissue culture.

Did I read that correctly, Mr. Deeter?

A. Yes, you did.

Q. You would agree that rice is a good expression system for recombinant albumin, Mr. Deeter?

A. Yes.

Q. I believe you mentioned some of the benefits earlier, correct?

A. That's correct.

Q. So you would agree that rice has advantages over other expression systems for recombinant albumin, correct?

A. That is correct.

Q. And many of those advantages were in fact known prior to the '951 patent, correct?

A. Many of the advantages using rice were known prior to the '951.

Q. If we could please pull up RX-77C, first page, I'd like to look at one of Ventria's grant applications, Mr. Deeter.

I see here the applicant name on this grant application is Ventria Bioscience; is that right, Mr. Deeter?

A. Yes, that's correct.

Q. And in the top center the date submitted is November 27th, 2006?

A. That's correct.

Q. Am I correct that this is a grant submission that Ventria provided to the Government?

A. I assume this is the actual document, but I don't exactly know because it doesn't say the receipt date, but it's the submitted date. Sometimes when you submit you have to revise, but...

Q. This document would have been authored by Ventria, though, correct?

A. That would be right.

Q. You would agree that Ventria scientists endeavor to be truthful and accurate in their applications for federal funding?

A. Always.

MS. GIANNELLI: I apologize, Your Honor. We are back on the confidential record. It is just Ventria confidential information that's being discussed.

(Whereupon, the trial proceeded in confidential session.)

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C E R T I F I C A T E

TITLE: CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME

INVESTIGATION NO.: 337-TA-1238

HEARING DATE: November 4, 2021

LOCATION: Washington, D.C. - Remote

NATURE OF HEARING: Evidentiary Hearing

I hereby certify that the foregoing/attached transcript is a true, correct and complete record of the above-referenced proceedings of the U.S. International Trade Commission.

Date: November 4, 2021

Signed:

ss// LaShonne Robayo

Signature of the Contractor or the Authorized Contractor's Representative

I hereby certify that I am not the court reporter and that I have proofread the above-referenced transcript of the proceedings of the U.S. International Trade Commission against the aforementioned court reporter's notes and recordings for accuracy in transcription in the spelling, hyphenation, punctuation and speaker identification and did not make any changes of a substantive nature. The foregoing/attached transcript is a true, correct and complete transcription of the proceedings.

Signed:

ss// Raymond G. Bryntesson

I hereby certify that I reported the above-referenced proceedings of the U.S. International Trade Commission and caused to be prepared from my record media and notes of the proceedings a true, correct and complete verbatim recording of the proceedings.

Signed:

ss// Linda Kenkade

UNITED STATES
INTERNATIONAL TRADE COMMISSION

----------x

In the Matter of Investigation No.

CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME 337-TA-1238

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OPEN SESSIONS

Pages: 262 through 518 (with excerpts)

Place: Washington, D.C.

Date: November 5, 2021

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UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

Before the Honorable MaryJoan McNamara

Administrative Law Judge

In the Matter of	Investigation No.
CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME	337-TA-1238

EVIDENTIARY HEARING

Friday, November 5, 2021

Volume II

The parties met via remote videoconferencing pursuant to notice of the Administrative Law Judge at 9:30 a.m. EDT.

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*** Index appears at end of transcript ***

P R O C E E D I N G S

(In session at 9:30 a.m.)

JUDGE MCNAMARA: Let me know what issues you have this morning to address.

MS. NIEMEYER: Your Honor, this is Elizabeth Niemeyer. One housekeeping matter is the parties spoke, we have spoken previously, with regard to the revised request for receipt of evidence without a sponsoring witness, which was filed Friday evening -- today is Friday -- Wednesday evening, sorry -- and we have agreed to withdraw our objection to the exhibits that are on that list.

Our understanding from our communications is that they won't be used for new or different purposes that haven't been disclosed. If that were to happen, we would certainly preserve our right to be able to move to strike or preclude. We don't anticipate that's going to happen based on our discussions.

So based on the totality of the discussions that the parties have had, we withdraw our objections, and those could be moved into evidence.

JUDGE MCNAMARA: Great. Again, I recognize that if there's something that comes up that you see, as you said, that requires an objection or you hear it being used for a different purpose, of course jump in.

Mr. Heneghan, do you agree?

MR. HENEGHAN: We do agree, Judge. We appreciate Healthgen withdrawing those objections. I'm just curious what you want us to do to formally move them into evidence.

Do you want us to provide you with a list, or are you comfortable with the list that's contained in the filing from Wednesday?

JUDGE MCNAMARA: You have to move the actual exhibits in. So I think both sides have been sent Box links. And you should also include a list. Every time you submit exhibits, please make sure you're sending us a list. It's gotten a little bit complicated, but there it is. It's the new procedure because of how we're operating digitally.

MR. HENEGHAN: We'll prepare that list and we'll submit it. I guess we'll just formally move those exhibits into evidence.

So are they admitted then? Or not until we submit the list?

JUDGE MCNAMARA: Well, I think you should submit the list and then move them in as a list, as a group.

MR. HENEGHAN: Thank you.

MS. NIEMEYER: Your Honor, if I may, just as a point of the clarification, I think it will be handled similar to the exhibits that were admitted through Order No. 19, and then the Ning Huang designated transcript and corresponding exhibits, we'll email that list to chambers,

and the court reporter, and then they will appear in the formal transcript as admitted exhibits. So I think that will effectuate the admission.

JUDGE MCNAMARA: I think that's right. That's a good idea, and that's how we'll do it.

(Exhibits, as submitted by counsel and reflected in the attached index, were received into evidence.)

MR. HENEGHAN: I was just about to say the same thing. Just like we do with Order 19.

JUDGE MCNAMARA: That makes sense. It's just that because of the way things have changed in Dockets, we have to have the list actually in Box. The way they are putting exhibits up is different than we're seeing them in Box. And so it's easiest for us to see the exhibits from Box than it is on EDIS at this point.

It's a different method that they're using, so there we are. I think that's the easiest way to go.

So are there any other housekeeping measures that anyone else would like to mention or bring up?

MR. HENEGHAN: Judge, we do have a couple of continued -- Healthgen has a couple continuing objections about exhibits identified for Dr. Wilken, who is the next witness. Our understanding is you want to take that up right before Dr. Wilken testifies as opposed to taking it now?

JUDGE MCNAMARA: I think it's easiest if I see them in context. When she starts to testify and she is addressing a given exhibit or a proposed exhibit, that that's when I think the exhibit -- that's when the objection should come up, because that way we can just discuss around that context, and I'll have --

MR. HENEGHAN: Okay. The only thing I would point out, some of these are demonstratives. So you want to handle those also the same way as they come up or before she testifies?

JUDGE MCNAMARA: Well, I think as they come up. But I guess my question is, in terms of the demonstratives, is the problem -- I guess we're addressing it now -- is the problem with the exhibits that are listed on the demonstratives?

MR. HENEGHAN: Well, Judge, actually Ms. Shoffstall is going to handle those objections. So I'll turn it over to her.

JUDGE MCNAMARA: Very good. Good morning, Ms. Shoffstall.

MS. SHOFFSTALL: Your Honor --

MS. NIEMEYER: Your Honor, I will note -- sorry.

JUDGE MCNAMARA: Ms. Niemeyer?

MS. SHOFFSTALL: I'm much shorter than my colleague. I apologize.

JUDGE MCNAMARA: What, you're apologizing for your height? Don't do that. Seriously.

MS. NIEMEYER: Your Honor, I believe we had sent an email this morning about this, so I'm not sure if there are still objections to discuss now. If there are, it may make sense to take it up before Dr. Wilken takes the stand because we're not entirely clear where we are on the pending objections.

JUDGE MCNAMARA: Okay. So, Ms. Shoffstall, can you address that, then?

That was Ms. Niemeyer for the record, Ms. Kinkade. I think you know that.

MS. SHOFFSTALL: This is Ms. Shoffstall for Ventria.

I will say there are a number of exhibits and issues with the demonstratives that we have agreed to drop, so those have been mooted. There are about, I would say, seven or eight exhibits that are cited within the demonstratives that I think the parties still have some disagreements about.

So, Your Honor, if you prefer to take that up prior to Ms. Wilken's testimony or throughout, we can do that.

JUDGE MCNAMARA: How far apart are they spaced? Do you know? Or do they come sort of in a group?

MS. SHOFFSTALL: I think -- and Ms. Niemeyer can correct me if I'm wrong. I think the bulk probably appear right in the middle of the demonstrative presentation or throughout the middle of Lisa's -- or Dr. Wilken's testimony.

JUDGE MCNAMARA: So let's wait until we get there.

MS. SHOFFSTALL: Okay.

JUDGE MCNAMARA: And then if you still -- what I can always do, you can work it out later on. I can admit them provisionally, and if there is -- if it's a matter of taking them out, we can take them out, if that's where it ends up.

MS. SHOFFSTALL: Okay, Your Honor. I think that sounds good to us.

JUDGE MCNAMARA: Okay. Mr. Guarnieri, are you ready now?

MR. GUARNIERI: Yes, Your Honor. I think we'll need to get Mr. Deeter back up on the stand here. I'm prepared to start whenever Your Honor is ready.

JUDGE MCNAMARA: I can't see him. Okay. Here we go again.

There he is. Good morning, Mr. Deeter. Good morning.

THE WITNESS: Good morning, Your Honor.

JUDGE MCNAMARA: I'm sorry you couldn't have dinner with your colleagues last night, but otherwise I hope it was a good evening.

THE WITNESS: I had a nice dinner with my wife.

JUDGE MCNAMARA: Good. Okay. You are still under oath. I don't have to readminister the oath.

SCOTT DEETER,

having been previously duly sworn and/or affirmed on his oath, was thereafter examined and testified further as follows:

MR. GUARNIERI: Thank you very much, Your Honor.

EXAMINATION BY COUNSEL FOR ITC STAFF

BY MR. GUARNIERI:

Q. Good morning, Mr. Deeter. My name is Pete Guarnieri. I work for the Office of Unfair Import Investigations at the International Trade Commission. You may have met one of my colleagues at your deposition, I believe the former IA, Ms. Bhattacharyya, now Judge Bhattacharyya.

JUDGE MCNAMARA: I must say, I was delighted. I am delighted by that. We have had tea together, and she is just delightful. I know she will be really good.

MR. GUARNIERI: Certainly a loss for our office but a gain, I think, for the Bar.

JUDGE MCNAMARA: Absolutely.

MR. GUARNIERI: We're very happy for her.

JUDGE MCNAMARA: Me too.

Q. Mr. Deeter, I just want to start with sort of a few clarifying questions, and I'll ask for your forgiveness in advance. They may seem a little obvious, but just for the record I want to make sure that a few things are clear.

So the first, you discussed extensively with your counsel yesterday the products that are at issue here, the recombinant human serum albumin, right?

A. Yes.

Q. Okay. And the acronym that is used to describe those products is rHSA; is that correct?

A. That's one of the acronyms, yes.

Q. Just so -- I'm sure the court reporter probably has this already, but that's generally written with a lower case r and then upper case HSA, which we saw on a lot of those documents, right?

A. Yes.

Q. And now the specific products at issue in this case, though, are rice-derived rHSA products, right?

A. Yes.

Q. And am I correct you testified yesterday that the only two manufacturers of rice-derived rHSA products are Ventria and Healthgen? Is that correct?

A. Yes, that is the Healthgen Biotechnologies and

Wuhan Healthgen. I think they are the same or very similar. And then Ori Bio -- there's several names they go by.

Q. Why don't we get to that in a second. Let's assume for the sake of my question that that's the same entity.

Other than Healthgen and Ventria, you're not aware of any other manufacturers of rice-derived rHSA products; is that correct?

A. That's correct.

Q. There are other rHSA products that are not rice-derived; is that correct?

A. Yes, that's correct.

Q. And those would be products derived from yeast, as I understand it?

A. Yes, you're correct.

Q. Now is it possible to tell the difference between rice-derived rHSA products and yeast-derived rHSA products based on the label of the product or just a visual inspection of the product itself?

A. Typically -- the label may or may not say the host, but typically it does say the host and the origin. That's typical.

Q. And the host or the origin, how would that explain what the difference is between rice-derived rHSA versus yeast-derived rHSA?

A. The host may be listed in the Certificate of Analysis or in the documentation that comes along with the -- with the product at the time of shipping.

Q. Just so the record is clear, can you explain what you mean when you say the host?

A. I'm sorry. The host is the rice or the yeast.

Q. The --

A. The host cell, the host organism that produced the rHSA.

Q. Thank you. Now do you recall yesterday your counsel asked you a number of questions about the Healthgen website? Do you recall those questions?

A. Yes.

Q. And if I could ask, Ms. Hitchens, if you're on, would you mind putting up CX-840.

MS. HOEKEL: My understanding is, if there's no C behind it, it is a public document.

MR. GUARNIERI: We'll wait until everyone can see the witness and the document as well as it's pulled up.

Before I continue the questions, just -- Your Honor, are you able to see both Mr. Deeter and the document this morning?

JUDGE MCNAMARA: No, I can't. So I have to figure out, again, how to go back to what I did yesterday. Apparently slipped into -- there he is. I've got him now.

MR. GUARNIERI: Perfect. Let's proceed.

Q. So, Mr. Deeter, can you see CX-840 that's on the screen now?

A. Yes.

Q. Could I ask Ms. Hitchens -- Ms. Hitchens, could you zoom in on the middle of the document? There's a picture of two bottles side by side. Are you able to blow up just those two bottles? Okay.

Now I believe you mentioned earlier that one of the names that the Healthgen products is sometimes sold under is -- is it Oryzogen?

A. Yes, that's what's on this label.

Q. That's -- for the court reporter, that's the O-R-Y-Z-O-G-E-N.

And that's on the -- we see that on the bottle label, the picture here in CX-840, right? Is that correct?

A. Yes.

Q. And then I believe as well -- I know it's a little hard to read, but do you see underneath that there's a green label as well, OsrHSA? It's got a catalog number next to it. Do you see that on the bottle label?

A. Yes.

Q. Okay. Am I correct that OsrHSA is a brand or a trade name that this Healthgen product is sold under to your knowledge?

A. Yes.
Q. And then there was another name you mentioned. Was it Ori Bio?
A. Ori Bio, yes.
Q. To your understanding, are Ori Bio, Oryzogen, OsrHSA, and Wuhan, are these all related entities or brand names?
A. It's my understanding.
Q. Mr. Deeter, are you aware of any other companies that sell rHSA products under the brand name Oryzogen?
A. Other than distributors that the -- that would be distributing this product and affiliated with Wuhan Healthgen, Healthgen Ori Bio, Oryzogen, no.
Q. Fair enough. Maybe I should clarify my question.
Are you aware of any other manufacturers that manufacture an rHSA product under the brand name Oryzogen?
A. No.
Q. Are you aware of any other manufacturers other than Wuhan Healthgen that manufacture an rHSA product under the trade or brand name OsrHSA?
A. No.
MR. GUARNIERI: That's the extent of my questions. Thank you for your time today, Mr. Deeter.
With that, I will pass the witness back to counsel for Complainants for any redirect.

JUDGE MCNAMARA: Ms. Hoekel, will you be doing the redirect?

MS. HOEKEL: Yes, Your Honor. Do you mind if I take just a second to move the camera so I can do it standing?

JUDGE MCNAMARA: Sure. Go right ahead.

MS. HOEKEL: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MS. HOEKEL:

Q. Good morning, Mr. Deeter.

A. Good morning.

Q. A couple of questions in response to questions that Dr. Giannelli posed yesterday. I want to look at --

(Clarification by reporter.)

Q. Mr. Deeter, I'm going to ask Ms. Hitchens to pull up RX-357, which was an exhibit that was discussed in your cross-examination yesterday.

A. Yes.

Q. And you'll recall this was an order on -- it's titled Order on Defendant's Motion for Summary Judgment or Summary Adjudication.

Do you see that?

A. Yes.

Q. Do you recall yesterday that Dr. Giannelli showed you some excerpts from the tentative order that was

attached?

A. Yes.

Q. Prior to this order, which is dated, I believe, July 2nd of 2013, what discovery had you been able to obtain from Dr. Yang in this California lawsuit?

A. You mean evidence that we collected?

Q. Yes.

A. So the evidence involved the patent that was filed for this investigation, the website traffic, the presentations on the website of -- at the time it was called Ori Bio. The downloads of our website, the evidence within the patent that showed the gel images that are like a fingerprint of the gel, that was only a copy, a photocopy, in the patent, but those actual gel images in color are in our lab notebooks in Ventria.

Q. Were those all public documents, Mr. Deeter?

A. No. They were in our lab notebooks.

Q. Let me ask a better question.

Were those documents that Ventria was in possession of prior to the lawsuit?

A. Yes.

Q. Those were Ventria documents?

A. Those were Ventria documents.

Q. Were you able to get discovery from Daichang Yang?

A. No. We were not able to serve our subpoena.
Q. And according to this document on the front page, it says Dr. Yang's motion for summary adjudication of the two Promoter B trade secrets is denied.
Do you see that on the screen towards the bottom of the screen?
A. Yes.
Q. And then shortly after this motion, was the case settled?
A. I believe that settlement was -- I'd have to recall the actual settlement date. Around this time, yeah, I believe that's right.
Q. And it was settled with Dr. Yang making a payment to Ventria; is that correct?
A. That's correct.
(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. HOEKEL:

Q. Again, do you recognize Exhibit 1?

A. Yes.

Q. Joint Exhibit 1. This is the '951 patent. And if we can go to page 72, I'm sorry, column 72, which I believe is page 60 in the exhibit.

If I can have Ms. Hitchens blow up the bottom half of column 72 that starts with "analysis," please.

I know that's still a little small, Mr. Deeter, but can you read the title there, title next to II?

A. "Analysis by SDS-PAGE of Cellastim Batch P0171 (New process) compared to albumin produced by Millipore/Novozymes (Catalog No. 9301-01)."

Q. So does the '951 use -- well, let me go down further into this document and let's blow up the paragraph that starts with "visual inspection of the gel."

Do you see that paragraph?

A. Yes.

Q. When it says visual inspection of the gel, what is gel referring to?

A. The electrophoretic gel.

Q. And that electrophoretic gel in this patent is used in what test method?

A. Fig. 9, I believe, is SDS-PAGE.
Q. And that's what -- okay. We can look back up at that in a minute and show that from the patent.
Ms. Hitchens, let's show the paragraph under analysis of SDS-PAGE just to confirm.
Mr. Deeter, you said Fig. 9, which was referring to the gel below.
What is Fig. 9 referring to in the patent?
A. An SDS-PAGE analysis that shows the purity of the products for the Cellastim new process and old process.
Q. Okay. So let's go back down to the paragraph we were looking at, the visual inspection of the gel paragraph again.
Do you see that paragraph?
A. Yes.
Q. Okay. And, again, what test method is the gel referring to in this paragraph?
A. SDS-PAGE.
Q. And if you could read the sentence that starts "importantly," about halfway down the paragraph.
A. "Importantly, the new process samples have significantly less aggregates at around 250 kilodalton than the old process samples have. (Average number than 2 percent for the old process, greater than 2 percent for the old process, and average less than 1 percent for the new

process.)"

Q. Thank you. And if we look at the next page of Exhibit JX-1, if we can look at the two tables on the top of the page.

A. Yes.

Q. The Table E3, what is the title of that table?

A. "Cellastim Process."

Q. And what do you understand this table to be -- what product do you understand this table to be reporting on?

A. The Cellastim process.

Q. Is that a Ventria product?

A. Yes.

Q. To the left, do you see dates on that table?

A. Yes.

Q. And then in the middle there's a column that says, "EU/Milligrams Dry."

Do you see that?

A. Yes.

Q. What is that column reporting?

A. That reports the amount of endotoxin in the sample.

Q. And that's the sample of what process?

A. Of Cellastim.

JUDGE MCNAMARA: Pardon me just a minute. I was

just checking the transcript, and the correct name of the Table E3 was not mentioned. It is "Cellastim Old Process," and what came up in the transcript was just "Cellastim Process."

MS. HOEKEL: Thank you. I was just about to remind the witness again, Your Honor, to keep his voice up, because I think that's part of the problem.

THE WITNESS: Sorry. I'll do better.

Q. And then if we can look at Table E4 below, and if you can tell us what the title of that table is.

A. The title of this table is "Cellastim New process."

Q. And under the left-hand column, again, what do we see in the left-hand column of that table?

A. The date that those samples were manufactured.

Q. And then do you see the fourth column, again, and can you tell us what the fourth column is reporting?

A. That is the endotoxin units per milligram of Cellastim using the new process.

Q. Counsel yesterday showed you a patent that you're a named inventor on, the Deeter patent.

Do you recall that?

A. Yes, I do.

Q. Would these charts have been reported in the Deeter patent?

A. No.

Q. And why would this data not be reported in the Deeter patent?

A. At the time that we filed the Deeter patent, we did not know how to process the Cellastim to get low endotoxin.

MS. HOEKEL: I don't have any further questions on redirect, Your Honor.

JUDGE MCNAMARA: Okay. Thank you, Ms. Hoekel.

Dr. Giannelli?

RECROSS-EXAMINATION

BY MS. GIANNELLI:

Q. Good morning, Mr. Deeter.

A. Good morning, counsel.

Q. I have just a couple of follow-up questions about the California court litigation.

Now in fact you stated that the discovery from Dr. Yang was limited, but Dr. Yang was, in fact, deposed in that litigation, correct?

A. We -- that's correct. We deposed -- he came to Hong Kong to -- for a deposition.

Q. And in fact Dr. Yang's student at Wuhan University was also deposed in that litigation, correct?

A. That's correct.

Q. If we could please pull up JX-105C, which is the

Certificate of Analysis for Optibumin.

MS. HOEKEL: We need to go back on the confidential record, Dr. Giannelli.

MS. GIANNELLI: Thank you.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

(In session at 10:30 a.m.)

JUDGE MCNAMARA: Good morning, Dr. Wilken.

THE WITNESS: Good morning.

JUDGE MCNAMARA: How are you?

THE WITNESS: I'm doing well. How about yourself?

JUDGE MCNAMARA: Very well. Thank you.

Okay. So I guess I can place you under oath. Could you kindly raise your right hand.

LISA WILKEN, Ph.D.,

having been first duly sworn and/or affirmed on her oath, was thereafter examined and testified as follows:

JUDGE MCNAMARA: Please state your full name.

THE WITNESS: Lisa Wilken.

DIRECT EXAMINATION

BY MS. HOEKEL:

Q. Good morning, Dr. Wilken. Can you introduce yourself to the Court, please?

A. Good morning. I am Lisa Wilken.

Q. And where are you currently employed?

A. I am an associate professor at Kansas State University.

Q. A couple of housekeeping matters.

Did you review the testimony of Healthgen's expert, Dr. DeFilippi, on infringement?

A. Yes.

Q. And did you prepare some slides today to assist with presenting your testimony today?

A. Yes.

Q. And will they assist you in testifying today?

A. Yes.

Q. I understand your slide numbers start with the prefix CDX followed by slide number.

Is it okay if I just refer to them as slide numbers?

A. Yes, please.

Q. We're actually going to start with an exhibit, which is Exhibit CX-970. Dr. Wilken, Ms. Hitchens will pull that up on the screen in front of you.

Go to page 2, please. And if you can just blow up the top of it.

JUDGE MCNAMARA: Somehow I lost Dr. Wilken again. I lost her visually.

MR. GUARNIERI: Your Honor, this is Pete.

JUDGE MCNAMARA: There she is. Okay.

MS. HOEKEL: Thank you, Mr. Guarnieri. I'm helpless with that stuff.

JUDGE MCNAMARA: And now I've lost -- I can see

Dr. Wilken, but I can't see Ms. Hoekel.

MS. HOEKEL: There's a way, Your Honor, and Ms. Hitchens can explain it to you, the layout where you hide everyone that is participating without video maybe. Does that help?

JUDGE MCNAMARA: I think it defaults because I had that up yesterday. Thank you. When I came in this morning it was defaulted.

MS. HOEKEL: Ms. Hitchens told me, because it's a new Webex session every morning, it will default every day.

JUDGE MCNAMARA: Good to know. I should have figured that out. Thank you. Thank you, Ms. Hitchens, wherever you are.

MS. HITCHENS: You're welcome, Your Honor.

MS. HOEKEL: Your Honor, can you see everyone you need to see?

JUDGE MCNAMARA: Yes. Thank you.

Q. Dr. Wilken, can you tell us what this exhibit, which is Exhibit CX-970, is, please?

A. This is my CV.

Q. And is this a fairly current CV?

A. Yes.

Q. Is this a true and accurate copy of your CV?

A. Yes. Minus a few recent presentations and other activities, but yes.

Q. If you can pull up slide 2, please.

Don't worry about slide 2. We can just look at this exhibit. Oh, there's slide 2.

Dr. Wilken, what is slide 2?

A. It provides the qualifications for this respective work.

Q. What is your highest legal of education?

A. I have a Ph.D. in biological and agricultural engineering from Texas A&M.

Q. Where are you currently employed?

A. I am employed at Kansas State University.

Q. And what is your title at Kansas State University?

A. I'm an associate professor and a Mark C. Nyquest - Carl and Mary Ice Cornerstone Teaching Scholar.

Q. And what does it mean to have a named teaching position?

A. That's an endowed position for excellence in graduate and undergraduate education.

Q. And how long have you been an assistant professor at Kansas State?

A. So I was an assistant professor from 2012 to 2018, and since then I am an associate professor.

Q. Thank you. And have you received any awards related to your teaching?

A. Yes. I have 32 awards. I have three national awards, four university awards, and many through the College of Engineering, as well, at Kansas State University.

Q. What kind of teaching awards have you won?

A. So I've won the ASEE, so American Society of Engineering Education, Achievement Education Award, a Young Educator Award from the American Society of Agricultural and Biological Engineering, and I also have three Presidential Awards from Kansas State University, including those for undergraduate research, mentoring undergraduate researchers, and undergraduate advising.

Q. Were those first awards that you mentioned national in nature?

A. Yes. So I have three national awards.

Q. Can you provide us an overview of the kinds of research that you have done that are relevant to the technology of this case?

A. I work in bioprocessing and bioseparation. So we take raw materials that have some recombinant protein or other proteins within that material, and we work on downstream processing. So taking that from an unpurified form to a highly purified form.

Specifically I have worked extensively with the extraction and purification of recombinant protein from plant-based expression systems, and studying some of the

unique plant-derived impurities and the impact of those impurities on various purification techniques.

Q. What courses have you taught during your career?

A. So I have taught freshman and sophomore engineering design courses. I've taught courses in properties of biological materials, biological engineering fundamentals, and bioseparations engineering.

Q. Can you explain what bioseparations is, please?

A. So I develop and teach a bioseparations course that covers, one, analytical techniques used for assessment of downstream processing and purification, as well as studying each of the steps or UNA operations used to purify biological molecules, molecules derived from biological systems, from the beginning steps to the very end.

Q. When you say "biological systems," what kind of biological systems are you talking about?

A. So this could be any cell systems, tissues, plant systems, animal, mammalian, just various biological organisms and cell types.

(Clarification by reporter.)

Q. Dr. Wilken, you mentioned that your research includes properties of biological materials, bioseparations, engineering design.

Have you published any articles in peer-reviewed journals on those topics?

A. Absolutely. We have several publications that highlight some of the challenges and opportunities for working with plant-derived recombinant proteins.

Q. And if we can -- are those materials listed in your --

We're just putting a note in front of Dr. Wilken, Your Honor, that reminds her to slow down. I have one in front of me as well.

A. I am naturally a very fast talker.

JUDGE MCNAMARA: I think that is true of a lot of us. And I think that's a great idea to put that note in front of you. It's like an affirmation in a way.

THE WITNESS: Thank you.

MS. HOEKEL: Just wanted to make sure that was clear, Your Honor.

Q. Let's look at -- do you have publications -- you have publications and you also have speaking engagements that are related to the plant-derived recombinant proteins that we'll be discussing in this case?

A. Yes. I have had speaking presentations at various national meetings related to this work and other research in downstream processing.

Q. Are those listed in your CV?

A. Yes. We have a few additional since then, but otherwise, yes, all of them are listed.

Q. Can you tell the Court a little bit more about your experience with recombinant rice-produced human serum albumin separate and apart from your testimony in this case?

A. So I developed and run a bioseparations engineering lab in the biological and ag engineering department.

Q. Let me stop you there. What is that? Can you explain that in more layman's terms?

A. Biological ag engineering?

Q. The lab. What's done in the lab?

A. Okay. So this is a research lab for training of undergraduate and graduate students, and we also focus on, of course, the research or innovative aspects within the field.

Q. Within the field of what?

A. Downstream process. So bioprocessing, how do we work with the biological systems and purify biomolecules, such as proteins, from these systems.

Q. I apologize. I interrupted you. You were explaining to the Court your experience with recombinant rice-produced human serum albumin.

A. Once I set up and developed the research lab, I've had students working with transgenic rice and specifically extraction and purification of recombinant human serum albumin from transgenic rice. We focus

significantly on the extraction aspect, how do we solubilize effectively this protein while also considering the impurities that may be co-extracted. And also looking at various steps for purification of recombinant human serum albumin.

Q. When you talk about solubilizing the protein, could you break that down a little bit more for us?

A. So we start with a rice flour, and so it's in the solid form, and so before purification we need to solubilize or put that protein in a soluble form. So it's basically in a buffer or water with buffer salts that maintain pH, for example.

Q. And that's part of the lab work you do at Kansas?

A. Yes. That has been the significant focus, because plant-derived -- you know, transgenic plants are unique systems. And so we've been studying some of the impacts of the various impurities from, not only rice, but other transgenic plant systems as well.

Q. And in the lab work that you do, you talked about solubilizing.

Do you also do purification?

A. Yes. Purification as well, because we want to develop processes that are integrating, meaning that we're developing an extraction techniques that are compatible with purification or would make purification easier or more

efficient or effective.

Q. And in your work at the university, have you ever used SDS-PAGE to measure impurities, such as aggregates, in samples of purified albumin?

A. We use SDS-PAGE. It's a standard method. Throughout my under -- or graduate work at Texas A&M, I have many -- probably hundreds of gels, I would say, that I ran. We use those to follow each step of the downstream processing. It's an easy way to assess the performance of both extraction and purification steps. And we -- the research has continued at Kansas state. And so that would be a common technique that my researchers use to evaluate our research.

MS. HOEKEL: At this time, Your Honor, Ventria offers Dr. Wilken as an expert in the areas of biological engineering, bioseparations, recombinant protein purification, plant express recombinant proteins, and human serum albumin.

JUDGE MCNAMARA: Mr. Shaffer, I gather there was no objection and that -- by Healthgen, and that Dr. Wilken has been accepted as an expert?

MR. SHAFFER: No objection, Your Honor.

JUDGE MCNAMARA: Thank you. She is so accepted.

MS. HOEKEL: Thank you, counsel.

Thank you, Your Honor.

Q. Let's look at slide 3 of your presentation, please.

Dr. Wilken, I understand you're here today to provide opinions regarding whether Ventria's domestic industry products practice claim 1 of the '951 patent; is that correct?

A. Yes.

Q. Are you also here today to provide opinions regarding whether Respondent Wuhan Healthgen's accused products infringe claims 1, 11, 12, and 13 of the '951 patent; is that correct?

A. Yes.

Q. Are those -- sorry, Your Honor.

Are those claims summarized on slide 3?

A. Yes.

Q. The claims of the '951 patent?

A. Yes.

Q. So let's look at slide 4, please. And if you can tell the Court what slide 4 is.

A. Slide 4 includes the definition of a POSA or person of skill in the art.

Q. And the -- can you read the definition in the bottom box from the order of a POSA in this case, please?

A. "The parties definitions are similar. Each definition requires a Ph.D. in biochemistry and/or chemical

fields, and at least two years of experience in similar areas. It is expected that the differences among the definitions will have little, if any, effect on the claim construction analysis. Thus, all proposals are appropriate for a person of ordinary skill in the art."

Q. And this was referring to both Ventria's proposed definition and Healthgen's, correct?

A. Yes.

Q. And have you previously reviewed the positions of Dr. DeFilippi and the Staff in this case as to who they regard as a person of skill?

A. Yes.

Q. And do your opinions change depending on which definition of skill is applied?

A. No.

Q. Let's look at slide 5, please. On slide 5, can you tell the Court what you've provided on slide 5?

A. Slide 5 highlights two claim terms, first being recombinant mammalian albumin, and the second aggregated albumin.

Q. Have you considered and adopted the Court's construction of these terms when rendering your opinions?

A. Yes.

Q. If there are any claim terms that are -- that have not been defined by the Court, what definition are you

giving them in your opinion?

A. I'm giving them plain and ordinary meaning.

Q. Let's look at slide 6, please.

Dr. Wilken, as an expert witness, have you formed any opinions regarding whether Ventria's domestic industry products practice claim 1 of the '951 patent?

A. Yes.

Q. What is that opinion?

A. That Ventria's domestic industry products practice at least one claim of the '951 patent and satisfy the technical prong of domestic industry.

Q. Is that claim 1 that you are opining on?

A. Yes.

Q. Have you formed any opinions as an expert witness -- excuse me -- regarding whether Wuhan Healthgen's accused products infringe the accused -- the asserted claims of the '951 patent?

A. Yes.

Q. And what is that opinion?

A. That Healthgen's accused products infringe claims 1 and 11 through 13 of the '951 patent.

Q. Let's go to slide 8, please.

What is slide 8?

A. Slide 8 provides an overview of my testimony.

Q. And so the first part of your testimony is going

to be related to the technology; is that correct?

A. Yes.

Q. Let's look at slide 9, please. Dr. Wilken, the title of this slide is "Albumin."

Can you tell the Court, on sort of high level, what albumin is?

A. So albumin is a protein, meaning it's a polymer of amino acids. The three-dimensional structure is depicted on the right side of the slide. It is a protein normally found in blood, including not in human blood or fetal bovine serum. It has multiple binding sites for diverse ligands. Ligands are molecules which are capable of binding to the albumin protein.

Q. Let me stop you right there. On this slide there is a picture on the right.

Can you tell us what that picture on the right is?

A. So the picture on the right is a three-dimensional structure of albumin, including you'll see the blue peptides or links of amino acids that form the albumin molecule. It is folded into its three-dimensional confirmation or the structure of this protein.

Q. So that's the blue, sort of, ribbon-looking material?

A. Yeah. So the blue material represents the amino

acid sequence within the protein molecule.

Q. What is represented by the red, the little red dot?

A. So this depicts an example of a few of the bindings locations of these diverse ligands that we mentioned, the fact that it combines amino acids, lipids, proteins, hormones, and many other molecules. So it's just a representation showing the function of albumin is -- and the value is of a carrier of these molecules.

Q. And what are -- so what are the little gray, the little gray balls in the figure to the right?

A. So that's modeling the structure of these ligands, and they are bound to the albumin molecule.

Q. So can you tell us about how albumin functions as an antioxidant in a system?

A. So it is a -- it offers a protective mechanism to cells, for example, in a cell culture, by binding molecules that could be detrimental or harmful to the cells. So when stresses are introduced into the cell, so simple cell cultures, the media components, and other sources, so it just helps protect the cells by picking up some of these potentially harmful components.

Q. Let's look at slide 10, please.

And slide 10 is, again, that picture of albumin, correct?

A. Yes.
Q. What are you depicting on this slide?
A. So this is indicating the importance of the structure to the function of albumin.
Q. Why is structure important?
A. So particularly -- it's always important for proteins. Structure is the function, and it must be maintained. And, in particular, since it functions by binding multiple types of molecules, that's derived from its structure. And so we see 1, 2, and 3 indicated here. Those are homologous domains, just means domains of the molecule that are similar.
Q. So, doctor, can you point out to the Court, and Ms. Hitchens can probably blow that up if that's easier, what you were referring to when you said 1, 2, and 3?
A. So you'll see the 1, 2, and 3. Those are the various domains. And throughout the structure there are many binding sites for various types of molecules.
Q. And that's, again, the red dot?
A. Yeah. So that's just an example showing some binding sites within, that they extend throughout the entire protein molecule.
Q. What happens if you alter the structure of an albumin?
A. So if the structure is -- for example, if you

were to remove a portion of that molecule, the function will certainly be impacted, or the ability to bind and transport these ligands or molecules for the cell culture.

Q. Is that because it essentially loses a portion of its structure?

A. Yes. So there's binding sites throughout. It's not one particular site. It's multiple sites to carry multiple ligands.

Q. Let's pull up, just briefly, Exhibit CX-898. And I want to ask if the information that you've shown on these slides 9 and 10 is derived from a peer-reviewed publication.

A. Yes, it is.

Q. What is Exhibit CX-898?

A. This is a peer-reviewed journal publication entitled "Albumin in a mammalian cell culture and implications for biotechnology applications" from Cytotechnology.

Q. Thank you. Let's look at slide 11, please.

Dr. Wilken, the title of this slide is "Cell Culture."

What is cell culture?

A. Cell culture is growth of cells in an environment beyond its natural source. So cells are removed and grown external to the original source in an artificial environment. So nutrients are provided through a media for

those cells to grow.

Q. So when we see pictures like the one you have here of Petri dishes with a gel in it, what is that Petri dish with the gel?

A. So that is depicting the media. So the media is just that liquid, or could even be in a solid form, formulation. That provides the cells with all the necessary nutrients it needs to grow.

Q. Is media another word for cell culture?

A. So cell culture media. It's one component of a cell culture.

Q. And where is cell culture used?

A. Cell culture is used extensively in research development for studying cells, the function of cells, for production of biological compounds, such as proteins, including therapeutic proteins in vaccines.

Q. And so --

A. So research and development as well as industrial production of valuable products.

Q. What kinds of things do we find in cell culture media?

A. So cell culture media should have the, what we call, macro nutrients, so the major elements, carbon, hydrogen, oxygen, that, if needed, that cells need to grow. It also would include vitamins, minerals, and things like

albumin, for example, that is beneficial to the cell culture.

Q. And why is albumin used in cell cultures?

A. So albumin is based on the function of that, based on the binding, the capabilities to bind molecules and deliver them to the cell, or even to pick up molecules that could be detrimental to the cell.

Q. Let's look at slide 12, please.

Dr. Wilken, can you explain for the Court what recombinant proteins are and how they are made?

A. So recombinant is based on the combination, which we see in the word recombinant. So the combination of DNA from two different organisms. So we're going to take the DNA, which is our blueprint for producing proteins, so we're going to take a portion of that from a host. So in this example we're discussing today, that host would be human, human serum albumin, and that DNA is going to be integrated into a rice genome, and that blueprint or DNA is going to direct the host organism, in this case rice, to produce that protein.

The organism that has that recombinant protein is called the transgenic organism, in our case this would be transgenic rice, while the protein, which is nonnative, so it's not originally or typically produced in that system, is considered to be a recombinant protein.

Q. So in the case we're talking about today, it's taking the DNA for a human serum albumin and making -- having the rice produce that protein in the rice, correct?

A. Yes.

Q. And then what is a recombinant protein?

A. So the recombinant protein just means it's a protein that is not typically naturally produced by that organism. So it is a combination, right, you're putting a portion of the DNA to direct the formation of that protein into the host. When that is done, the resultant protein is considered to be a recombinant protein.

Q. Let's look at slide 13, please.

Dr. Wilken, can you provide the Court with some examples of other places that albumin has been -- the recombinant albumin has used -- has been used in other hosts?

A. So recombinant albumin has been produced in various types of bacteria, yeast production systems, as well as tobacco, along with rice.

Q. And do each of these systems have their own benefits and challenges?

A. Absolutely. So each type of cell system or production system is going to have advantages, and there are also some disadvantages to those. They have unique compositions, functions, and these can present unique

challenges and unique opportunities to express and produce recombinant proteins.

Q. Let's just take one example. Can you give the Court some drawbacks of using tobacco as a host for recombinant albumin?

A. Sure. Tobacco is considered what we call a green, leafy tissue. So this is a metabolically active tissue that has high moisture content. And so it also produces protease, which are proteins that degrade other proteins. And so through the expression and purification there's some challenges with producing protein. In addition, solubility can be an issue, as well as some impurities, such as phenolics, or protease, I mentioned, can impact the quality of that recombinant protein.

Q. Can you spell phenolics and explain it to the Court please?

A. Phenolic is P-H-E-N-O-L-I-C. And these are cyclical structures that -- one issue is they impact purification significantly. They can also bind to recombinant proteins, but in a harmful way. So these are derived -- the green color that you see, that comes from some of these molecules.

Q. Let's look at Exhibit JX-24, please. Maybe we can blow up the top of that, Ms. Hitchens.

Can you tell me what JX-24 is, please?

A. This is a publication about human serum albumin produced with recombinant DNA technology that addresses challenges and strategies.

Q. Who are the authors of that particular publication?

A. So we have four authors: Chen, He, Shi, and Yang.

Q. The last author is Yang.

Who do you understand Dr. Yang to be?

A. He is affiliated with Wuhan Healthgen.

Q. And what journal published this article?

A. Biochimica et Biophysica Acta.

Q. Is that a peer-reviewed journal?

A. It is.

Q. Can you tell what year this was published?

A. 2013.

Q. If you can blow that up so everyone can see it a little better.

A. Below the abstract.

Q. Thank you. If we could blow up the last paragraph on page 1 of JX-24, please.

Do you see that paragraph?

A. I do.

Q. What did Dr. Yang and his coauthors have to say about non-rice hosts used to express rHSA in 2013?

A. That none of the hosts that have been used for

production of recombinant human serum albumin have proven to be cost effective on an industrial scale, and that the production faces many challenges in large-scale manufacturing, and that it differs between expression systems.

Q. Do you agree with their assessment of non-rice hosts used to express rHSA?

A. Yes.

Q. Let's pull up slide 14, please. Slide 14 has a cite on the bottom, which is JX-1.

Do you see that?

A. I do.

Q. Do you understand that to be the '951 patent in this case?

A. Yes.

Q. And is this an image from that patent?

A. Yes.

Q. What does this image show?

A. This image shows the impact of expression system on the performance of albumin in a cell culture, and so --

Q. On --

A. -- on the x-axis you see the concentration of albumin from .5 to 10 mgs per mL, and on the y-axis you'll see viable cells. So the idea or the goal is to have the highest amount of viable live cells in the culture.

And there are three different recombinant albumins evaluated here and compared to a negative control.

Q. Where is the negative control shown?

A. So it is the -- it looks like it has horizontal lines, which means it's the control, so they are not going to have any benefit or increase from the initial --

Q. And what is Cellprime?

A. Would you please zoom out slightly --

Q. Sure.

A. -- so I can remind the proper source.

Q. Sure.

A. So Cellprime is a recombinant human serum albumin that's produced in a yeast system.

Q. And what is Seracare?

A. Seracare is a human serum albumin native derived from human plasma.

Q. And what is Cellastim?

A. That is the recombinant human serum albumin produced in rice.

Q. And Cellastim is made by whom?

A. Cellastim is made by Ventria.

Q. And what does this slide tell us about recombinant human albumin expressed in rice?

A. That it performs or has more beneficial activity than the other types of albumin, including that from human

plasma and that from yeast. And we see a -- approximately three-and-a-half-fold improvement in the number of viable cells for the rice-derived albumin compared to the yeast or human plasma derived albumin.

Q. And the Cellastim is depicted in this figure as which bar?

A. Those black bars that you see.

Q. Let's look at slide 15, Dr. Wilken.

What is shown on Exhibit -- I'm sorry. What is shown on slide 15, please?

A. This is a very general overview of the ExpressTec technology from Ventria, which expresses the recombinant human serum albumin into the rice plant. The rice grows and produces the protein within the seed. The seed is harvested and stored prior to the extraction and purification of human serum albumin. And although these are indicated by one box for each step, they can have multiple processes in each of those steps.

Q. Let's pull up Exhibit CX-919, please.

And if you need to page through the exhibit, Ms. Hitchens can do that.

What does this document tell us about ExpressTec?

A. It discusses the expression technology that has been developed by Ventria to express various recombinant proteins in rice.

Q. If you could pull up, Ms. Hitchens, Exhibit CX-1082, please.

Dr. Wilken, what is this document?

A. It is discussing InVitria, which is a division of Ventria, and their expression technology, the advantages and capabilities of the technology.

Q. Let's look at slide 16, please.

And slide 16 is titled "Downstream" Processing."

Can you explain what you're showing in slide 16?

A. So this gives a general idea of the phases involved in downstream processing, which is any step after the production of a recombinant protein in a host system.

Q. What do you mean by any step after the production of a protein?

A. So once that recombinant protein has been expressed or accumulated, then all the steps following to purify that molecule from that host system.

Q. So if we look at the top of this diagram, you have leaf-based system, seed-based system, and bioreactor-based system.

Do you see that?

A. Yes.

Q. So where does this diagram of processing start from a physical structure? With the leaf?

A. So this is comparing the various strategies. So

even within the realm of using plants for production of recombinant protein, there are differences in terms of the processing methods used for downstream processing. And we summarize here generally as leaf-based systems, that would be something like tobacco; we have seed based systems, which would represent something like the transgenic rice discussed; and a bioreactor based system, where there is really two options here: First, you're running the cells in a bioreactor and they could accumulate that protein inside the cell, or it can secrete or move that protein from in the cell to out into the media as it's being produced.

Q. What are some examples of the kind of hosts that would be used in a bioreactor-based system?

A. So in this case we're discussing plant cells, but bioreactors are also used -- this is similar to the yeast technology as well -- where the recombinant human serum albumin is actually secreted to the media. And in this case we see we skip the first, really, you know, two to three steps, because the protein is already in the soluble form, and it can go directly to that pretreatment step.

Q. That's what's shown on the right side of the figure?

A. Yes, that is the right side. For the other systems, the protein is inside, and, thus, requires an extraction. And how we handle even the plant tissue is

going to differ depending on the type of plant system used for the production of the protein.

Q. What are some of the steps in recovery step?

A. So the purpose of recovery is to, one, maximize the amount of recombinant protein that you get out of the system. We also want to quickly remove any impurities that may be detrimental to the stability of the recombinant protein. So we want to have the most amount of our protein, we want to minimize impurities that can impact the quality, and we want to concentrate, we want to quickly reduce volume and have the highest concentration of our product possible.

Q. If we can look at Exhibit CX-896, which you cite on this slide. And let's look at the cover page of CX-9 -- 896.

Dr. Wilken, if you can tell us what this document is, please.

A. This is a book chapter, an invited book chapter that was written by my Ph.D. student, myself, and collaborators regarding the impact of six -- what we identified as six major plant-derived impurities and their impact on our downstream processing or potential quality.

Q. Let's look at page 10 of this document, please, Ms. Hitchens.

Is that the figure that was depicted on the slide we just looked at?

A. Yes.

Q. If you can go to the next page, please, Ms. Hitchens, page 11 of this document.

Under the second paragraph under the heading -- sorry -- under the second paragraph on the page, it starts with "because plants."

Do you see that? What does this Dixon reference say about plant production systems in this portion of the --

A. That plants are, one, very complex and they are unique in their challenges regarding downstream processing, that many of the studies have done a case-by-case, meaning that it's specific to the plant expression system and it's specific to the recombinant protein produced, and that there are unique challenges associated with that combination of recombinant protein in plant system. So there are challenges, the challenges differ, on a case-by-case basis, and that plants have a unique composition that differs from prior technologies that need to be considered when you're developing downstream processing.

Q. Let's look at slide 17 of your presentation, Dr. Wilken.

What is endotoxin?

A. Endotoxin is a lipopolysaccharide, which just means it's a lipid and polysaccharide. Polysaccharide is a polymer of sugars that is derived from bacterial cell wall,

so it's going to be a fragment of the cell wall, that can be introduced throughout the processing steps.

Q. How is that introduced in the processing steps?

A. If there's some contamination by bacteria, which it's very easy to do, throughout the stages of -- from the beginning to the very end of the processing.

Q. Can the -- so in this case we're talking about rice-derived human consumer albumin.

Can the rice seed itself carry with it endotoxin?

A. If there is bacteria that's harvested with the rice, which we know there's bacteria everywhere, then, yes, there could be bacteria associated.

Q. And the rice -- do you understand where the rice is grown that's used in rHSA production?

A. Yes. It's grown terrestrially or in the field.

Q. Is endotoxin good or bad to have in cell culture media?

A. Endotoxin is detrimental to cell culture growth and performance of cells.

Q. Why is that?

A. So it can -- it induces reactions from the cells, and these cells can impact cell growth, and it's a toxin. It's of utmost concern in downstream processing of all recombinant proteins essentially.

Q. Let's look at Exhibit JX-134, please.

And if we can -- do you recognize this document?

A. Yes.

Q. What is this document?

A. This is a document from Corning regarding endotoxins and impacts on cell culture.

Q. Let's look at page 6 of this document for a moment.

Do you see page 6?

A. Yes.

Q. What is being depicted here on page 6?

A. This is showing the potential impacts of endotoxin on a cell culture or cell growth, including potential reactions that it could cause in impacts of those, including reduced cell growth and reduced protein production.

Q. Just in layman's terms, how does an endotoxin affect cell growth?

A. It catalogs a series of reactions from the cells. So it produces, what I would say, an immune response. So it's going to respond to that and cause the buildup of various molecules that impact the cell culture.

Q. We're going to move on to slide 18.

Dr. Wilken, do you understand that aggregation -- and specifically we'll talk about albumin aggregation in a minute -- but do you understand that aggregation is a

disputed issue in this case?

A. I do.

Q. Okay. So I want you to explain to the Court a little bit about what is -- what is protein aggregation?

A. So protein aggregation is the formation or interaction, protein-protein interactions between protein monomers or individual monomer units.

Q. And albumin is a protein, correct?

A. Yes.

Q. And it's found in a monomer state, correct?

A. Yes.

Q. And then what do you call it when two albumin monomers are interacting?

A. So this is an aggregate. And specifically if there's two, that would be called a dimer.

Q. What if there's more than two?

A. Then that's a polymer or aggregate as well.

Q. Okay. Are aggregates a good thing in cell culture? Are protein aggregates a good thing in cell culture?

A. No, not typically.

Q. Why?

A. They could impact the overall function. So it could be a sign of some type of impact of the process that could render the molecule, not only -- maybe not completely

nonfunctional, but potential reduced activity or not functional like a monomer molecule.

Q. Let's look at the figure that you've added to the slide.

Do you see where it says "albumin monomer 1"?

A. Yes.

Q. What is that intended to depict?

A. So this train car here is depicting the full albumin structure. So we saw in a prior slide how albumin is composed of the various domains, and we have ligands that are bound to albumin throughout the structure. So this would represent the full functional molecule of albumin.

Q. And what is depicted on the right-hand side of this figure?

A. This would depict albumin dimer or the formation or interaction between two albumin monomers, which are fully functional. Albumin that come together to form a dimer.

Q. Let's look at Exhibit CX-900, please. Again, if we can blow up the top so that we can all see what Exhibit CX-900 is.

Can you identify this exhibit, please, Dr. Wilken?

A. This is a peer-reviewed journal article entitled "Immunogenicity of therapeutic proteins: Influence on aggregation," from the Journal of Immunotoxicology.

Q. And what is the year on this article?
A. 2013. It was received in 2013 and officially published in 2014 in the journal online.
Q. And if we can --
Did you see what you needed to see, Your Honor? I didn't want to take away the blow up.
JUDGE MCNAMARA: Thank you.
Q. Let's look at the bottom paragraph on the right under the title "Protein Aggregate -- Aggregation," excuse me.
Do you see this excerpt from Exhibit 900?
A. I do.
Q. What does the publication tell us about aggregates?
A. That they can have a range of protein assemblies, they can differ in their biochemical and biophysical characteristics, and it ranges from dimer, meaning that the simplest form would be the formation of two monomer units into a dimer, all the way up to larger aggregates that could be subvisible or even visible.
Q. What does it tell us about the bonding?
A. So there is a variety of different interactions, and, ultimately, they could also vary in terms of their solubility and their ability to reverse into the monomer units as well.

Q. Let's look at slide 19, please.

Dr. Wilken, on slide 19, can you read the title of slide 19, please?

A. It is the construction of recombinant mammalian albumin means aggregated albumin is formed from fully functional albumin monomers.

Q. And is that from the Court's claim construction?

A. Yes.

Q. And can you explain what -- we've talked about the figure on the right. Remind us what the figure on the right depicts. I'm sorry. The figure on the left.

Remind us what the figure on the left tells us.

A. So by definition, albumin is fully functional, and so this would represent all of the albumin monomer intact, meaning that we have all those necessary components of our albumin that are capable of delivering the function that we expect, for example, to our cell culture.

Q. And then if we can look at the figure on the right, what is the figure on the right depicting?

A. The figure on the right is depicting taking a albumin monomer, which retains that functional activity, and that coming together with something non-albumin, meaning that a functional unit either has been removed or other non-albumin related units as well. And so these -- if they come together, form together, this does not result in the

formation of aggregated albumin.

Q. And why is that?

A. Based on the definition of albumin, that it retains the function and that -- in that case that non-albumin component cannot offer the full function without the necessary structure of that particular molecule.

Q. So let me back you up again.

The red box on the right-hand figure that says "non-albumin," do you see that?

A. Yes.

Q. And underneath that you have -- it says one functional albumin unit and one non-albumin unit.

A. Yes.

Q. The one functional albumin unit is referring to what in this diagram?

A. The blue train car that you see with the full -- basically representing that we have the full structure intact of our albumin molecule.

Q. And then the red box says non-albumin.

And can you just break that down for us? What could be included in non-albumin?

A. So non-albumin could be originally albumin that perhaps has been degraded in a way where we have removed sites that render the molecule not functional or unable to perform the jobs of that particular molecule is desired --

is focused to do.

Q. So when we looked at that earlier picture with the blue ribbons and the red binding sites and the gray ligands, how does what you just described as a non-albumin relate to that picture?

A. And so we saw that three-dimensional conformation or structure of the albumin molecule. We know that there are multiple binding sites, so we can't simply remove all of those domains, their binding sites that are very, very close to the terminus, the end of the protein molecule as well. And without that conformation, it's unable to fully perform the function of the albumin.

JUDGE MCNAMARA: Can I ask a question here? Sorry, Ms. Hoekel.

Can I ask about this, Dr. Wilken?

In terms of the non-albumin that you've characterized on the right-hand side of slide 19, could that also include environmental degradation, other endotoxins?

THE WITNESS: Of the albumin?

JUDGE MCNAMARA: Yes.

THE WITNESS: Yes. So this could be albumin -- initially it was full but has been degraded, for example, into something -- if we remove, for example, an entire domain, then that's not able to, by definition, fulfill the functional capacity or the job that that molecule was

intended to do.

JUDGE MCNAMARA: I understand that, but is the degradation resulting from the process itself or from the fact that there have been other environmental factors, for example, it could be anything, any kind of bacteria or anything else that has somehow become part of this process?

THE WITNESS: So to create those -- if we were to remove, for example, part of the domain, that could be done -- one common source of that would be something like a protease, which is a protein that specifically degrades proteins, that would potentially remove a fraction. It could also be due to some processing condition potentially.

JUDGE MCNAMARA: Thank you.

Q. I want to look at slide 20 for a second, for a moment, Dr. Wilken.

Did you have a chance to review certain slides from Healthgen's opening?

A. I've seen this slide.

Q. Okay. Do you have any opinions on Wuhan Healthgen's characterization of aggregated albumin from its opening?

A. So based on our definition of albumin here, we see the monomer on the left, which is the importance of -- we talked before about the importance of the structure of that for its function -- particularly with albumin -- and

that the fundamental unit of aggregated albumin would be the dimer that we see in the middle of those three examples there.

So dimer would be the formation of two of those monomer units and the trimer would be three and so forth.

Q. And would the dimer and the trimer as depicted in this figure satisfy the Court's definition of aggregated albumin?

A. Yes.

Q. What about the picture that is titled "Partially Degraded Dimer"? Would that satisfy the Court's definition of aggregated albumin?

A. I do not believe so. That shows here -- that's the analogy of the train car. Let's say we remove those wheels from the train car and it can't form the dimer molecule. We know the importance of structure and function. And simply, if we were to remove, for example, that domain, which would be represented potentially by that degraded material, that that's not going to meet the definition of monomeric albumin in order to form aggregated albumin.

Q. So the aggregated -- the partially degraded dimer here, that is pictured here on the Healthgen slide, has what looks like a fully formed monomer on the left, correct?

A. Yes.

Q. And then it has -- what is your understanding of

the molecule that is on the right side of the partially degraded dimer?

A. It looks like to me that it's just a large missing part of the protein molecule here.

Q. And that's -- and they call it partially degraded dimer, right?

A. Yes.

(Clarification by reporter.)

MR. SHAFFER: It looks like we might have lost the judge.

MS. HOEKEL: Oh, no. Thank you.

MR. GUARNIERI: We can probably go off the record.

(Brief interruption due to technical difficulty.)

JUDGE MCNAMARA: We can go back on the record. And I'm sorry about that.

BY MS. HOEKEL:

Q. I think, actually, that we can -- let me just ask one last question on this slide.

Dr. Wilken, is your -- is it your -- start that over.

What is your opinion about whether or not a partially degraded dimer meets the Court's definition of aggregated albumin?

A. My opinion is that the picture indicated there,

the partially degraded dimer, does not meet the Court's definition of albumin aggregate. So that would -- the aggregated albumin would include as the basic form a dimer and beyond.

Q. Let's look at slide 21 briefly. If you can explain to the Court what you have shown in slide 21.

A. First, that the adopted construction indicates that any fragment must retain the biological and therapeutic beneficial activity of native mammalian albumin.

Q. The Court's construction of what term?

A. Of recombinant mammalian albumin.

Q. And then --

MR. SHAFFER: Your Honor, objection to the extent that mischaracterizes your construction. That may be her opinion of it, but that's not what it says.

MS. HOEKEL: It's an excerpt from -- copies of the Court's construction.

JUDGE MCNAMARA: It is part of an excerpt of the construction. It's not the complete construction. I get that.

MR. SHAFFER: I just have a problem with the word "fully," Your Honor. Fully is not in there.

JUDGE MCNAMARA: I see.

MS. HOEKEL: I'm sorry. Your objection is not to the excerpt on the page; it's to Dr. Wilken's description of

it.

MR. SHAFFER: I'm happy to take it up on cross, Your Honor.

JUDGE MCNAMARA: I think that's a good idea, yes. Thank you, Mr. Shaffer.

Q. Let's move on to slide 22, please. Slide 22 is titled "Multiple, Suitable Methods For Measuring Protein Aggregation in a Sample."

Can you tell us, generally, about techniques that measure protein aggregation?

A. So there are numerous different methods that may vary depending on, one, separation technique, so, for example, based on molecular weight, and also based on the detection principle.

Q. And is SDS-PAGE one of those techniques?

A. Yes.

Q. Why does a person in this industry choose one method over another, just generally?

A. It depends. There are -- as we mentioned, there's advantages and disadvantages to each, so it could relate to -- some are very routine and basic, some are highly sophisticated and require a lot of equipment, and there's various aspects that you would look at regarding these methods.

Q. Let's pull up Exhibit JX-132, please.

If you can identify JX-132 for the Court, please?

A. This is a review article that summarizes the strategies for the assessment of protein aggregates in product development.

Q. And who is the author, the first named author on this article?

A. den Engelsman.

Q. Is it okay if we refer to it as the den Engelsman paper?

A. Yes.

Q. Let's look at page 3 of Exhibit -- JX-132. And there is a section here that is titled "Techniques to Analyze Protein Aggregates."

If Ms. Hitchens could blow up that paragraph for us.

What does den Engelsman say about techniques to analyze protein aggregation?

A. That there are many techniques that are available. They may differ based on their separation or detection methods. They can be visual or microscopic methods.

Q. And if we look at the second paragraph of this section, it says the various techniques available are summarized in Table III.

Do you see that?

A. I do.

Q. Okay. Can we pull up the top of the Table III, which, I believe, starts on page 4.

Can you flip that, Ms. Hitchens? I don't know if you can maybe blow up just the top of the table so we can see what the table is titled.

And if you can tell us what this table's title is?

A. This is titled, Overview of Analytical Techniques Used for the Analysis of Protein Aggregates.

Q. And this table continues over a couple of pages, so let's look at page 5, please.

Blow up the section that is titled "Detection and Characterization of Protein Aggregates."

Can you call out some of the techniques that are listed in this table under this title?

A. We have SEC and SDS-PAGE listed here.

Q. There are other examples listed, correct?

A. Yes.

Q. Let's talk just briefly about -- what is SDSC?

A. SEC?

Q. SEC. Sorry. What is SEC?

A. SEC is size-exclusion chromatography. So it is a separation method. It uses a separation method based on size.

Q. Can you tell us a bit about what SDS-PAGE is?

A. SDS-PAGE is gel electrophoresis. The gel is a porous material, which will allow separation of proteins in that gel based on their size. If a protein is small, under an electric field, so you have it in an electric field, and that -- proteins will migrate according to size. If the proteins are small, they will migrate well throughout those pores, so they will travel further from top to bottom through that gel. Larger sizes will be impeded and not travel as far through that gel under the electric field.

Q. And is molecular weight another word that we'll see sometimes used the same as size?

A. Yes.

Q. And so does den Engelsman use SDS -- does den Engelsman characterize SDS-PAGE as a suitable technique for characterization -- for detection and characterization of protein aggregates?

A. Yes. In fact, in subsequent tables there are advantages holistically across the methods that indicate that, not only is SDS-PAGE a method, but a very promising or good method based on various traits or aspects.

Q. And then there's also Native-PAGE.

What is Native-PAGE?

A. Native-PAGE is also a gel electrophoresis technique. The intention there is to not have even any

detergent present. So, typically, when you're trying to look at a native structure of a molecule, this technique would separate -- one issue with Native-PAGE is that it will separate both based on size and charge, whereas an SDS-PAGE, we're providing the protein equal charge, so it will migrate only based on molecular weight.

Q. And does SDS-PAGE typically use a detergent?

A. Yes. So the SDS part is -- the SDS is a detergent. And so SDS or the new -- the recent technology, new PAGE, those are both detergents.

Q. And if we look at page 12 of JX-132, under the Conclusions and Recommendations section, what does den Engelsman conclude about aggregation analysis techniques?

A. That there are -- aggregates can be analyzed by many different methods. There's not one single method that would potentially cover all aspects. It really depends on what particular traits or what information we need from the aggregate analysis, and that the results obtained from a method are linked to the method.

Q. Let's look at exhibit JX-60, Dr. Wilken.

A. This is a peer-reviewed journal article that also reviews detection techniques and protein aggregate analysis.

Q. And let's pull up one more document, which is JX-132.

If you can identify when it appears on the

screen, JX-132, please, for the Court.

Oh, I'm sorry, maybe it's JX-60. Can you identify JX- -- I'm sorry -- JX-60, please, page 3. I just want to look at page 3 for a second.

What does page 3 -- we're in the wrong document. We'll just skip this one for now.

Let's look at --

Give me one second, Your Honor. I apologize.

JUDGE MCNAMARA: Sure.

Q. Let's pull up 132 again, which is the Mahler paper. Sorry I jumped around on us. Okay.

On the Mahler article, if we look at page 6. Do we have page 6 of Mahler? We'll come back to that. Sorry.

Let's look at slide 23. Slide 23 is titled "SDS-PAGE."

What are you depicting on slide 23, please?

A. So here we have a collection of the use of SDS-PAGE for a method for aggregate analysis, which includes that in the '951 patent, and other sources as well.

Q. We looked at some of the nonpatent literature already, correct?

A. Yes.

Q. What are the -- what's depicted on the right-hand side of this slide, please?

A. Those are gels, gel electrophoresis, SDS-PAGE.

Q. And then is this an excerpt from the '951 patent?
A. Yes.
Q. If we can look at the '951 patent -- we can just look at it on this page. That's fine, Ms. Hitchens. Maybe we can blow up the box in the middle, which is in column 72, lines 34-57.
Your Honor, we have just put it in here for ease of reference. This is from the '951 patent.
What does the '951 patent tell us about the use of SDS-PAGE?
A. That we could use the SDS-PAGE for analysis of aggregates.
Q. And then figures 9A and 9B on the right, can you explain to the Court just generally what those are?
A. That is the picture of the gel, gel electrophoresis, and the evaluation of the samples for aggregation.
Q. Are those SDS-PAGE gels?
A. Yes.
Q. Let's look at slide 24, please.
Are you familiar with a document -- an exhibit -- we can pull it up for a moment -- JX-30?
We're asking for JX-30 to be pulled up as an exhibit.
Do you recognize JX-30?

You can maybe blow up the top half.

Can you tell us what JX-30 is?

A. It is the Van Urk patent.

Q. Okay. For the Van Urk publication?

A. Yeah. The patent.

Q. Okay. If we can look to page 70 in the exhibit. Do you see -- I apologize. Let's go back to the -- it's the next page. I'm sorry, Lauren. There we go.

Ms. Hitchens, if you could blow up the section of this page that says "SDS-reducing polyacrylamide gel electrophoresis."

Do you see that in Van Urk, Dr. Wilken?

A. I do.

Q. What is that referring to?

A. This is highlighting the use of reducing SDS-PAGE, so the PAGE is the polyacrylamide gel electrophoresis, and that they are using this technique to assess monomer content in their sample.

Q. And where does it say that?

A. In the highlighted portion and also the subsequent that says the proportion of albumin present as a monomer.

Q. What does this section of Van Urk tell us about the use of SDS-PAGE?

A. That it can be used for assessment of monomer and

aggregates within a sample.

Q. Let's move on to your opinions on the DI products.

Ms. Hitchens, if you can pull up slide 25, please.

We're just going to move on in your testimony to talking about the technical prong of domestic industry.

(Request for a brief recess by the reporter.)

JUDGE MCNAMARA: Let me see you back here at about 12:15. And I'm going to be restarting. I have to restart my computer.

(Proceedings recessed at 11:56 a.m.)

(In session at 12:15 p.m.)

BY MS. HOEKEL:

Q. Your Honor, I want to go back to one exhibit that I had started to talk -- have Dr. Wilken talk about and we got ourselves -- the technology failed us for a second. So I want to go back just briefly.

Dr. Wilken, I'm going to ask you to look at Exhibit JX-60.

Can you tell the Court again what JX-60 is, please?

A. This is a peer-reviewed journal article reviewing protein aggregation and analysis related to that.

Q. If we can look at the abstract. If you can

please tell us what the middle of the abstract says with respect to analysis of protein aggregates.

A. Could you zoom in a little bit, please?

Q. Dr. Wilken, remember to keep your voice up too.

A. This includes -- it's a challenge to analyze protein aggregates, and that there is not one single analytical method to cover all aspects of aggregates, and so each method has advantages, but also has limitations specific to each method.

Q. And then if we can look at page 6 of the Exhibit JX-60. There's a table at the top of Exhibit 60.

Do you see that?

A. Yes.

Q. What is the table called?

A. "Frequently Used Methods for the Analysis of Protein Aggregates."

Q. And do you see there's a category to the left?

A. Yeah.

Q. What is that first category?

A. Quantification and/or size estimation.

Q. And do you see SDS-PAGE listed as a method usable for quantification and/or size estimation of protein aggregates?

A. Yes.

Q. We're going to go back to slide 26, please.

Let's go to the next slide.

Can you tell us what slide 26 is showing the Court?

A. This is showing Ventria's domestic industry products, which are made from transgenic rice.

Q. Is it your opinion that all of the products listed on the left-hand side of this slide, Cellastim, Exbumin, Optibumin, ITSE + A, OptiPEAK and OptiVERO are made from transgenic rice?

A. Yes. They have -- they are albumin from transgenic rice or -- so it's one component. For example, in the formulations, they contain recombinant human serum albumin from rice.

MS. HOEKEL: Your Honor, we're going to pull up a confidential record. If we could go on the confidential record, please.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

JUDGE MCNAMARA: Okay. Ms. Kinkade, I'm assuming you've got that.

THE REPORTER: Yes, Your Honor.

BY MR. SHAFFER:

Q. Dr. Wilken, you talked about some studies that Ventria contracted out to SGS Life Sciences, right?

A. Yes.

Q. And you pointed to one of those today, right?

A. Yes.

Q. There are, in fact, two that were done; is that right?

A. I believe so.

Q. And they were Exhibits C and D to your report?

A. I don't remember the numbers directly, so I can't say. Sorry.

Q. All right. If we could have CX-0904, the first page. And this one is dated June of 2021. If we could have that enlarged, please.

Do you see that?

A. I do.

Q. And this test was done a month after the one that you talked to this morning, right?

A. I believe so. I think that was a May document

and this appears to be June, just from remembering, yeah.

Q. That's right. If we could go to page 3, at 1.0 Summary, please, Mr. Fisher, and if we could enlarge that paragraph.

It states, this report summarizes the study results for the purity analysis of recombinant human serum albumin samples by SDS-PAGE under reducing condition.

Do you see that?

A. I do.

Q. It says, SGS Life Science Services performed the assay as instructed by the sponsor and outlined within the report under an experimental design.

Do you see that?

A. Yes.

Q. Okay. So you understand that to mean that as Ventria told or someone told SGS to run this study by using the method of reducing SDS-PAGE, right?

A. Yes.

Q. Did you as part of your diligence in reviewing and reporting on this data look to see how SGS Life Sciences typically conducts these types of tests?

A. I looked at how they performed these studies when I officially -- when I initially got the report.

Q. Okay. You looked to see how they typically quantify these types of reports; is that right?

A. I believe so, yes.
Q. Okay. So you learned at that point that they typically do not use reducing SDS-PAGE, but instead use a different method; is that fair?
A. I don't -- I don't know what portion you're considering here, they typically use versus -- what do you mean they typically use?
Q. Well, let's take a look at what they say they typically use in accordance with regulatory guidelines.
If we could have RXD 0139, please, Mr. Fisher. Oh, I'm sorry. I'm looking at the wrong number on the document.
RX-184. Here is RX-184 on the first page, and this is from SGS.
Do you see that, Dr. Wilken?
A. I see this document. It says SGS.
Q. Right. And this document is entitled "Aggregation Analysis." Do you see that?
A. I do.
Q. And then it's subtitled, "In Accordance With Regulatory Guidelines." Do you see that?
A. I see that.
Q. And then it has a little description of what it typically does in terms of quantifying aggregation analysis. It states that it's quantitated by appropriate analytical

procedures, for example, size-exclusion chromatography and capillary electrophoresis. Do you see that?

A. Yeah, those are examples here.

Q. Right. Those are examples of what they typically use under regulatory guidelines, right?

A. Yes.

Q. And then, in fact, if we go to page 2, one of the bullets talks to using size-exclusion chromatography. That's SEC, right?

A. Yes. So SEC with laser light scattering here.

Q. Right. And the combination of UV refractive index used allows a qualitative and quantitative assessment of aggregates, correct?

A. That's what it says here.

Q. Okay. And there's no mention of SDS-PAGE used here, right?

A. Not in this sentence you're showing me here.

Q. Or anywhere in this document, is there, doctor?

A. I am just seeing this again, so I don't know. I saw the passages again that you have shown.

Q. Okay. So do you know who, in fact, instructed SGS to use reducing SDS-PAGE instead of one of their preferred techniques?

A. No. We evaluated it according to how, you know, we had seen SDS-PAGE used. We saw it used in the patent.

It's a method that can be used. It's a simple method. It's robust.

Q. And was SGS instructed to use SEC-HPLC as well?

A. I don't -- I believe we have SDS data, not SEC data here.

Q. And this was SDS-PAGE that was used with reducing conditions, correct?

A. This particular study. We also looked at other data as well.

Q. You didn't rely on this data earlier today, correct?

A. No. It was considered. It's been considered overall.

Q. In fact, the data, the purity results of the recombinant human serum albumin samples that were produced to Ventria and tested by SGS in terms of the cell culture product all came back as more than 2 percent aggregated albumin, correct?

A. Could we look at the results here directly just to verify?

Q. Sure. The purity results, table 1. Did you want to see more?

A. The percentage -- the purity is different than the aggregate, so that's what I'm alluding to.

Q. Okay. Let's go to page 7 of 8. Is this the data

that you're looking for, doctor?

A. Yes.

Q. Okay.

A. Thank you.

Q. And with respect to the powder cell culture products, HGEN's products that were tested after shipment to the United States and importation, they all came back as higher than -- greater than 2 percent aggregated albumin, true?

A. It looks like -- I guess we have the last sample there. That might be the clinical grade, the RPX 001. I think that's clinical grade.

Q. So that's a yes, doctor?

A. Yes, it appears that these -- yeah, and so these are inconsistent with all the other data that we've had -- looked at earlier, so when you consider all of the data in context, yes, we have the study that appears to be different from all the data produced by Healthgen and provided to the customers. That differs from what we see here.

Q. Doctor, it was a very simple question, and you can elaborate as much as you want with your counsel.

My question is very simply put. All the data that SGS produced based on the sample that Ventria gave them of Healthgen's product that was shipped from China and imported into the United States was greater than 2 percent

aggregated albumin, true?

A. For the top three samples, right? The bottom sample, not the case, right?

Q. The bottom sample is the liquid, right?

A. I believe so. I'm just doing it by memory. These aren't labeled. I'm not remembering the label. I assume the C means clinical grade in the samples there, right?

Q. You presented on this exact same data with respect to the May test, right?

A. Yeah. I just want to make sure the numbers are the correct representations. It's a little bit different than the M and the C that we saw before, so I just want to make sure I'm correct here.

So, yes, this appears to be different and an outlier from all the data provided prior by the company and in the Certificate of Analysis.

Q. Dr. Wilken, you didn't talk about this data earlier today, did you.

A. No, I did not. It appears to be an outlier to that data.

Q. Thank you.

A. Okay.

Q. Didn't think it was important to talk about this data?

A. Not in the context -- I mean, it's a piece of the information, right, but you have to look overall at all the data provided and make a judgment call based on how much you have, right. You have one data that doesn't align with the others, so you have to make a decision.

Q. So you showed us the data that was less than 2 percent and didn't show us the data that was greater than 2 percent; is that what I'm hearing?

A. We have many pieces of evidence including that from Healthgen directly that shows otherwise.

Q. Doctor, a simple yes or no question.

A. This wasn't presented earlier, if that's what you're asking, yeah.

Q. Okay. If I could have Dr. Wilken's slide from earlier, I think, because it's a representative sample, CDX-001, slide 28.

Do you remember this slide, Dr. Wilken, that you presented on earlier today?

A. Yes, mm-hmm.

Q. Okay. And these are Ventria's Certificates of Analysis; is that right?

A. It appears to be so, yes.

JUDGE MCNAMARA: Question. We are now on the Ventria -- are we on the Ventria confidential business information?

MS. HOEKEL: We are, Your Honor.

MR. SHAFFER: We are.

JUDGE MCNAMARA: Could you make sure, Mr. Shaffer, just confirm for me that no one is on.

MR. SHAFFER: I can confirm.

(Whereupon, the trial proceeded in confidential session.)

C O N T E N T S

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EXHIBIT LISTS FOR RECEIPT INTO EVIDENCE:

Patent-in-suit and File History

JX-0001

JX-0002

Deposition Designations

CX-1080C

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RX-0004C

RX-0007C
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JX-0123C
JX-0122C
JX-0030
RX-0082C

C E R T I F I C A T E

TITLE: CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("RHSA") AND PRODUCTS CONTAINING SAME

INVESTIGATION NO.: 337-TA-1238

HEARING DATE: NOVEMBER 5, 2021

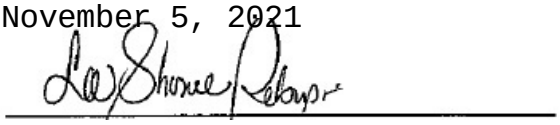
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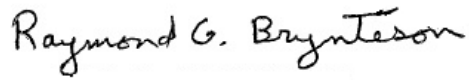
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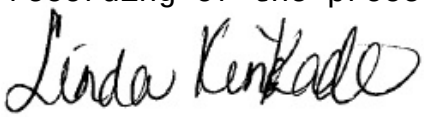
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UNITED STATES
INTERNATIONAL TRADE COMMISSION

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In the Matter of Investigation No.

CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME 337-TA-1238

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OPEN SESSIONS

Pages: 519 through 831 (with excerpts)

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UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

Before the Honorable MaryJoan McNamara

Administrative Law Judge

In the Matter of | Investigation No.

CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME | 337-TA-1238

EVIDENTIARY HEARING

Monday, November 8, 2021

Volume III

The parties met via remote videoconferencing pursuant to notice of the Administrative Law Judge at 9:30 a.m. EDT.

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*** Index appears at end of transcript ***

P R O C E E D I N G S

(In session at 9:30 a.m.)

JUDGE MCNAMARA: Mr. Shaffer, I think --

Well, Dr. Wilken, you're still under oath.

LISA WILKEN, Ph.D.,

having been previously duly sworn and/or affirmed on her oath, was thereafter examined and testified further as follows:

JUDGE MCNAMARA: Mr. Shaffer, I think you were continuing with your cross.

MR. SHAFFER: Yes. Thank you, Your Honor.

If we could start on Healthgen's confidential record, please.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MR. SHAFFER:

Q. Dr. Wilken, you understand during the course of this litigation that Ventria obtained samples from Healthgen on two of -- on the two accused products, right?

A. That is my understanding.

Q. Okay. And these samples had been stored, right?

A. Yeah, I assume so. I don't know the details exactly of the days manufactured and that type of information, but, yes, they had to have been at some point.

Q. Okay. And they were then shipped overseas for testing, right?

A. Yes.

Q. And because of these conditions, as well as possible other environmental conditions, the percent of aggregated albumin would likely go up. That's fair, right, doctor?

A. I don't think necessarily we should assume that. It's well-known how to control and manage these quality parameters, and things are shipped and stored and -- every day, right. We rely on those procedures to do so, and it's understood how to maintain those conditions to keep the product suitable.

Q. Okay. But you also understand that shipping and

storage, as we talked to on Friday, can induce aggregation, fair?

A. It potentially can, but I think it's well understood. It's not a new process or a new phenomenon that someone wouldn't understand or know how to stabilize the product.

Q. Thank you, doctor. And as you told us Friday, once these products were received by Ventria, they were given to and tested by an independent lab?

A. Yes.

Q. And you understand from your review of materials in this case that the clinical grade product that SGS tested was the exact same batch of the clinical grade product that we just looked at in JX-32C, right?

A. That that Certificate of Analysis was for that particular one? I didn't know if that was the particular sample examined.

Q. Okay. So you didn't know that the same batch that you relied on in 32C was the same batch of product that was later tested by SGS? Is that fair?

A. I don't -- I don't think I used that -- I would have to look at the lot number just to assert that, yeah. Just would want to do a check.

Q. Okay. Did SGS specifically quantify the percent of aggregated albumin using SEC-HPLC?

A. No.

Q. Okay. If they had done that, though, that would have been an apples-to-apples comparison based on the SEC-HPLC data that we just looked at in JX-32C, right?

A. I don't think it's necessarily. We would have to ensure that they are using the exact same column and the conditions. So it depends, right. You have to have -- you buy an SEC column that's suitable for a particular molecular weight range, so it potentially could be, but you would need to assure that they are consistent.

Q. But SGS was instructed by Ventria to use reducing SDS-PAGE to calculate aggregated albumin, right?

A. Yes.

Q. Okay. If we could turn to Dr. Wilken's slide 49, please. This represents testing done by SGS in May of 2020. And it's JX-129 for the record.

And here on your slide, doctor, you mention that reducing SDS-PAGE was used, but you don't mention the reducing agent, right?

A. Not listed here.

Q. Do you know which reducing agent SGS used for the testing performed in JX-29?

A. I think in one case they used TCEP and another -- I think one case they had maybe DTT and one TCEP.

Q. Okay. So in this test they used TCEP, right?

A. I believe so, yeah. I know they did on one of them at least, yeah.

Q. And you understand TCEP to be a harsher detergent or reducing agent with more bond-breaking capability than DTT, right?

A. I think the issue for that particular -- it's a newer reducing agent. So I don't think it was just substituted to say, hey, it's harsher so we're going to use this, no. I think one advantage of that particular reducing agent is that it can be done at a lower temperature.

Q. Okay. Doctor, my question was a simple one.

Is it harsher than DTT in terms of bond-breaking ability or no?

A. I'm unsure how they would line up face to face, but I don't think the issue there would be that one is harsher and it's particularly used for this purpose. It is a newer reducing agent, and so --

Q. I understand.

A. Right. So people use that particular reducing agent. It's not that it's better necessarily. One advantage is that the temperature can be at a lower temperature.

Q. And the percent of aggregated albumin for this test came back at .64 percent, right?

A. Yes.

Q. And that's lower than the 1.1 percent we saw in JX-32, right?
A. Yes.
Q. Okay. And SGS did some more testing a month later on the same sample. I think you alluded to that, right?
A. I think we had additional set of data there.
Q. Okay. If we could pull up CX-904 at page 1.
A. I think the dimer was .8 percent there, right? Yeah.
Q. Doctor, we'll get there.
This is the testing that was done a month later.
A. Okay.
Q. In June of 2020, right?
A. Yes.
Q. And it was done on the same sample, right?
A. I believe so.
Q. You didn't discuss this testing in your direct testimony, right?
A. I don't believe --
Q. Okay. The result --
A. I'll look at it. If we can look at it, I will tell you what we've looked at.
Q. The result of the aggregated albumin in this test of the same liquid sample was different, right?

If we could turn to page 7 of 8 of Exhibit 904, please -- CX-904. And at the bottom right, Mr. Fisher, if we could highlight that column for the liquid product.

Doctor, this is almost a threefold increase in the percentage of aggregated albumin over what we saw for the prior test done a month earlier, right?

A. .6 to 1.2, so twofold.

Q. What about .56 of high molecular weight impurities? You're not counting that?

A. I'm not counting that. If we do, we're still under -- still below the 2 percent. If we just want to be conservative and include both, we could.

Q. Okay. And it's just below 2 percent at 1.8 percent, right?

A. If you -- if you were to use both of those.

Q. Okay. And if the two SGS tests were reliably interchangeable, they should have given the same percentage of aggregated albumin, right?

A. You're never going to get exactly the same. That's the inherent two methods. You're going to have variability in everything you measure.

Q. Okay. And you understand that with the tests run in CX-904 they used DTT and not TCEP, right?

A. Yes.

Q. So they tested -- they tested the same sample,

but they used a different reducing agent, right?

A. I believe so. I'm not remembering which one was which, but -- which both are acceptable reducing agents. It's not that one is optimal and one is going to give you one result and --

Q. I understand, doctor. You can enlarge with your counsel if you want to explain that.

Given the disparity in these results, SGS did not use SEC-HPLC to quantify the aggregated albumin, though, did it?

A. They did not use SEC. They used SDS-PAGE, which is an acceptable method to evaluate aggregate analysis. You have --

Q. And -- you can expand upon your counsel -- with your counsel, doctor.

And SGS did not conduct SEC-HPLC testing based on Ventria's instruction; is that correct?

A. I'm not sure whose instruction. We asked for this particular result here.

Q. Using SDS-PAGE and not SEC-HPLC, right?

A. Yes.

Q. Doctor, you would agree, though, as a scientist, comparing the same sample at two different times based on a possibility, as you mentioned in aggregation, it would be best the use the same battery of tests, right?

A. Between the two SDS data, is that what you're saying, for the two different evaluations --

Q. SEC-HPLC and SDS, right? That was the battery of tests?

A. They is an acceptable methods. I mean, there's advantages and disadvantages for each.

Q. Okay. Doctor --

(Clarification by reporter.)

Q. If we could have Respondents opening slide 25, please.

Doctor, let's turn briefly to Healthgen's independent testing on the DI products.

To be clear, doctor, you did not address during your testimony the results generated for Cellastim and Exbumin using SEC-HPLC, did you?

A. I did not. They --

Q. Okay. And --

JUDGE MCNAMARA: All right, folks. Please don't talk over each other. Mr. Shaffer, please wait until Dr. Wilken is finished. And I could not hear her response.

MR. SHAFFER: I'll ask the question again, Your Honor. I'm sorry.

Q. To be clear, doctor, you did not address during your direct testimony the results generated for Cellastim and Exbumin using SEC-HPLC; is that correct?

A. I did not for these -- those results reported, there were no standards reported for identification of the particular dimers. So we have peaks, yeah.

Q. And in that SEC-HPLC data shown here on the left, doctor, every measurement of Cellastim and Exbumin was above 2 percent aggregated albumin; is that right? Can you fairly answer that yes or no?

A. I would not say that -- we would have to -- that's making an assumption. That's making an assumption that every -- any peak that they saw was aggregated albumin, which we don't know because we don't have a particular retention time to link the molecular weight to those results.

Q. Okay.

A. Furthermore --

Q. But --

A. Furthermore, you are -- the other issue is, as we know, albumin is binding molecules. That's the function of it. We know it's carrying other molecules with it. And this particular method would not allow us to discern those bound molecules.

Q. Are you finished, doctor?

A. Yes.

Q. Okay. But you did discuss the lab's testing on Exbumin and Cellastim using SDS-PAGE, correct?

A. Yes.
Q. Okay. And if we could have RDX-4C.1, please, Mr. Fisher.
Doctor, this reproduces two of your slides on direct, slides 34 and 35, which are on the right.
Do you recognize those?
A. Yes.
Q. Okay. And for this data, doctor, to be clear, you struck through these rows of -- some rows of aggregated albumin shown here, right?
A. I didn't strike through aggregated albumin.
Q. You struck through some columns of albumin; is that fair?
A. We can't -- we can't identify that that's albumin at that point or aggregated --
Q. Doctor --
A. Yes.
Q. Did you strike through some data here?
A. There's data, yes, so we're trying to identify the band that's associated with the aggregated albumin.
Q. And it was you who struck through this data? It wasn't the independent lab that did that, right?
A. No.
Q. No, the lab did it? Or you did it?
A. The lab did not do that, no. This is just for

further demonstration. We want to identify the bands associated with the dimer formation.

Q. Okay. And for the SEC-HPLC data produced by Healthgen's third-party lab, you couldn't strike through enough of the data to even get below 2 percent; is that fair?

A. Well, I would say that's not a fair assessment there. The intention here is not to do that. What we want to do is identify the bands that are associated with the aggregate formation.

Q. Okay.

A. That would be the way to evaluate or measure the amount of aggregate in our sample.

Q. Okay. And we'll get there, doctor.

The slide in the upper left-hand corner of this demonstrative is your slide 32.

Now, to be clear, doctor, you struck through rows of albumin here, too, as well, right?

A. No, I'm not saying I struck through rows of albumin.

Q. You struck through high molecular weight impurities, we're talking about albumin here, or no?

A. Molecular weight impurities can also be rice impurities. They can be other things that are not quantified as albumin dimers. So gel does not assess and

identify that this particular band is albumin.

Q. If we could have Dr. Wilken's direct slide 21.

Let's talk a little bit more about this, doctor.

It's your understanding that aggregated albumin is formed from fully functional albumin monomers; is that right?

A. So albumin is defined -- first, there's kind of two parts to this. One is what albumin -- albumin that is expressed, right. And then the second part of that would be the albumin through the processing side. So in terms portfolio what's expressed, I would say we certainly have fully formed albumin.

Q. And that's what you say here on your slide, construction of recombinant mammalian albumin means aggregated albumin is formed from fully functioning albumin monomers? That's what you say, correct?

A. So --

Q. Doctor, I think that's a yes or no answer.

Is that what you say on your slide? Construction of recombinant mammalian albumin means aggregated albumin is formed from fully functional albumin monomers, right? That's your opinion.

A. What my opinion is, is that, in order for that definition to be met of recombinant albumin, we can't just chop off an entire section of the albumin and say this is

albumin, right.

Q. Okay.

A. That's what I'm meaning here.

Q. Okay. So it's your opinion that only a functional albumin monomer could come together to form a dimer, for example, right?

A. I don't think it necessarily has to be when it's aggregated it's fully functional. What I'm saying is that one --

Q. That was -- that wasn't my question, doctor. Let me ask the question again.

So it's your opinion that only a functional albumin monomer could come together to form a dimer, in your opinion, right?

A. Not necessarily. I don't -- I don't think that's necessarily the case. What I do think is, one, we're forming full-length albumin here. We're not forming -- I think it needs to be almost completely a full length, because if you even take off, let's say -- in order to count what you're saying here is some of those other bands, we're saying that would have to be a fragment.

First, taking that off is not going to function as an albumin if that is what we're trying to define as an albumin. So we can't just remove an entire domain and say initially this is fully functional.

On the second part, we'll have to say, okay, is it -- is it realistic or possible, right, or realistic that we would have fragment formation throughout the processing here.

And I would say it's not likely. Rice is one of the most stable systems that there is.

Q. Doctor, you can -- you can enlarge with your counsel if you want to further explain. My question -- that wasn't my question.

Just to be clear, it's your opinion that aggregated albumins cannot be formed from fragment, right?

A. I don't think it's likely that we have fragments. First, as I mentioned, the first limitation up front, which is the expression of that, which would require that we're producing full-length albumin, if not, you know, 100 percent full length, and then, two, is it likely throughout the course of this processing that we're forming any fragmented albumin, and it's not likely.

This is one of the most -- you know, when you think about fragment formation, it has to be derived from something, right. It's not from the expression, yeah. So it's not likely.

Q. So, doctor, is it your opinion that albumin is not a fully functional albumin monomer if it doesn't have -- let me step back.

So, to be clear, so in your opinion the aggregated albumins cannot be formed from fragments, is that your opinion?

A. I don't think it's likely that we would have any fragments, because of both of those limitations.

Q. Okay. Understood. So is it your opinion that if the albumin is not a fully functional albumin monomer that it does not have beneficial biological activity?

A. It could have some. It does not -- it is certainly not going to have the activity of the native mammalian albumin.

Q. So in your opinion only the whole albumin molecule can retain the same biological activity as the native mammalian albumin; is that fair?

A. It would certainly have to be fairly close. I would say, if we're trying to say in those lower molecular weight that would be required to have those upper bands, we would be having to remove a significant portion. So even a 10 kilodalton change would be 80 -- approximately 80 amino acid differences.

Q. Okay. So, doctor, under that, under that, albumin fragments cannot retain the intended biological activity, right?

A. That would not meet -- up front, the first part of the question, which is, yeah, is it going to retain a

therapeutic beneficial activity of native, and I would say, at that point, no.

Q. Okay. But you do understand, doctor, that albumin fragments, no matter how much they have been fragmented, also have desirable functional properties, right?

A. It depends. We'd have to evaluate. I would say it's not -- it's certainly not going to maintain or retain that activity of the native mammalian albumin, because it's incredibly important, particularly for albumin. I think the uniqueness of it is that it has sites throughout the entire structure. It's not like something like an antibody that has one particular location and we could have a side chain and it would still function.

Q. Okay, doctor.

A. Very different, yeah.

Q. You do understand that albumin fragments of recombinant albumin may also have desirable functional properties that can be used in cell culture, though, right?

A. It depends. It may. It's not going to be native mammalian, that's for sure.

Q. Mr. Fisher, if we could please have RDX-4C, slide 3.

Dr. Wilken, this is an excerpt from the '951 patent next to your slide 19.

And you understand that the patent teaches a person skilled in the art that fragments of native versus synthetic albumin sequences may also have the desirable functional properties of the peptide from which they are derived here, that's albumin, and may be used in any of the methods of the invention, here that would be cell cultures, right? You understand that.

A. It may. It may. I don't think it is likely, particularly if it's missing a section, as would be required for that particular quantification.

Q. So it may, doctor? That's your testimony?

A. I would say, since some of the binding functions are very close to the terminus within that molecule, I would think, to retain the native, I'm not saying -- it could potentially have some activity. I don't think it's going to retain the native activity as we anticipated.

Q. If we could please have Dr. Wilken's slide 21.

Here you have the Court's construction and some of the support for that. I do want to highlight what you've highlighted in the Court's construction.

And the Court's very definition of the claim term "recombinant mammalian albumin" considers that albumin fragments can indeed retain the biological activity of native mammalian albumin, true?

A. Could you please repeat? I want to make sure I

caught every --

Q. Sure. The Court's very definition of the claim term recombinant mammalian albumin considers that albumin fragments can, in fact, retain the biological activity of the native mammalian albumin, right?

A. It's just saying that provided -- it would be included provided it does maintain the activity of the native mammalian albumin.

Q. And you highlighted that here, right?

A. Yeah. Yes.

Q. Okay. So even so, doctor, wherever you strike out the data that we've seen in your direct testimony, you assume that because the albumin is not formed from a fully functional monomer, that it doesn't have any biological activity, right?

A. It doesn't retain that of the native mammalian albumin.

Q. Okay.

A. And, two, it's not likely to have formed those particular fragments based on experience with rice showing that -- that's typically not seen or observed in these particular systems.

Q. Okay. If we could have your slide 18.

Wherever you strike out that data on your slides, you've placed this cartoon of your train cars next to it; is

that fair, doctor?

A. There's a -- yeah, a demonstrative here regarding that.

Q. The demonstrative of your train cars, right? And you cite in the corner to two peer-reviewed articles that I think you mentioned very briefly in your direct, CX-900 and CX-902.

These train cars don't appear in those articles, do they?

A. No. It's an example.

Q. Doctor, with respect to the data that you struck out, you don't provide any evidence one way or the other of whether the high molecular weight impurities or albumins or fragments, whatever you want to call them, have biological activity one way or the other, right?

A. That particular method would not assess whether it's fully functional or not fully functional.

Q. And you don't point to anything else to show whether or not there's biological activity associated with that, right?

A. I don't think -- what we're assessing here is not that particular -- that's not what we're measuring here.

Q. You cross out the data and you assume that it doesn't have any biological activity, fair?

A. It's not likely to be an albumin aggregate. It

doesn't align with that definition of albumin aggregate.

Q. That's your opinion, right, doctor?

A. There's no --

Q. Doctor, that's your opinion? Can you fairly answer that yes or no?

A. That -- we're just assuming that that's the case?

Q. Okay. If we could turn to Healthgen's cell culture products for a moment.

Doctor, SGS also tested the cell culture products under reducing SDS-PAGE.

JUDGE MCNAMARA: Mr. Shaffer, we've been on the public record, I think.

MR. SHAFFER: Thank you, Your Honor. If we can go back to Wuhan Healthgen confidential information, please.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

JUDGE MCNAMARA: From Healthgen?

MR. KUDRAVETZ: Good morning, Your Honor. This is Michael Kudravetz on behalf of Respondent.

MR. JACKSON: Your Honor, could we have the witness test his microphone quickly?

JUDGE MCNAMARA: Sure. Good morning.

THE WITNESS: Good morning.

MARCUS HOFER-CURL,

having been first duly sworn and/or affirmed on his oath, was thereafter examined and testified as follows:

JUDGE MCNAMARA: Please state your full name.

THE WITNESS: Marcus Hofer-Curl.

JUDGE MCNAMARA: Go ahead, Mr. Jackson.

MR. JACKSON: Thank you, Your Honor.

DIRECT EXAMINATION

BY MR. JACKSON:

Q. Good morning, Mr. Curl.

A. Good morning.

Q. You just did it, but could you please state your full name again?

A. Marcus Hofer-Curl.

Q. Where do you currently work?

A. I work at InVitria, which is a division of Ventria Bioscience.
Q. For purposes of your testimony, if we use Ventria and InVitria interchangeably, is that okay?
A. Yes, that's fine.
Q. Great. What's your title at the company?
A. I am the director of product applications.
Q. How long have you been at Ventria?
A. Just a little over three and a half years now.
Q. And do you have a college degree?
A. Yes, I do.
Q. Where did you study?
A. I studied at Pitzer College, one of the Claremont Colleges in California.
Q. And what was your degree in from Pitzer?
A. It was in biology.
Q. What motivated you -- well, before we get there, when you were at Pitzer, did you have any type of scholarship?
A. Yes, I did.
Q. Can you explain what that was?
A. I had need-based as well as academic scholarship.
Q. Was the need-based and academic scholarship equivalent to a full ride at Pitzer?
A. Yes, it was.

Q. What motivated you to join a company like Ventria?

A. It was primarily my mother. She spent nearly a decade in the Peace Corps and really devoted her life to addressing inequity in education and access to education. And so where she raised me in rural New Mexico, she ran the GED program, English as a Second Language program, and Adult Basic Education. And while I was not as interested in education as she was and was much more interested in the sciences, that goal to address kind of inequities in health care was really what I went into Pitzer, as kind of my overarching foundation of what I wanted to accomplish was to address those.

During my time at Pitzer I had the opportunity to start working with some of these plant-based protein expression systems, and that's really where I fell in love with the technology.

In addition, I had the opportunity to do home-stays and study health care in Central America, and started to find a common theme where a lot of the really exciting protein-based technologies and therapeutics being developed in the United States would never really be accessible to some of these different areas.

And so kind of these two experiences really led me to, once I got prepared to graduate, to look for who is

working with these plant-based expression systems, who is actually really helping commercialize these and make these accessible to people. Because, again, you're applying, you know, industrial agriculture to make therapeutics, and you're making more than any other competing technology.

And so that's where I stumbled on Ventria Bioscience. And I applied for a role there. And that's where I am now.

Q. Are you passionate about what you do?

A. Yes, certainly.

Q. And are you passionate about the opportunities that Ventria's technology can do to better the world?

A. Yes.

Q. Does Ventria have what you would call sort of a startup culture?

A. Yes, it certainly does.

Q. And does that mean that expenses are closely watched?

A. Yes.

Q. Would you say there is a focus on reinvesting in Ventria's technology?

A. Yes, there is. InVitria, again, it's a division of Ventria Bioscience, but they both seem very closely connected to where a lot of the success of InVitria in terms of our applications of our products in different

manufacturing processes directly relates to the endeavors of Ventria as all of our revenues are reinvested. And so it's working on the therapeutic pipeline that is part of Ventria, new product development for InVitria, as well as increasing the number of scientists we have showing the different applications that our products can be used in.

Q. Mr. Curl, what did you say your title is at Ventria?

A. It's director of product applications.

Q. Can you tell us a little bit about the product applications team?

A. Yeah. So we're essentially the customer-facing arm of InVitria. Our goal is really to help introduce our technology to the industry as well as, once customers are testing our products, help them be successful from a technical standpoint as well. So a ton of our work is presenting data, explaining the different value propositions that might arise from using a technology like InVitria's, and then if we're successful and they test the product, it's making sure that they have the data best practices, as well as access to our scientific team, to help them be as successful as possible.

Q. How many people are on the product applications team?

A. There are six.

Q. About which portion of this team's work relates to Ventria's rHSA technology?

A. The gross majority is either directly the recombinant human serum albumin products or solutions in media containing those.

Q. Does one need to have a technical understanding of Ventria's rHSA in order to be effective on this team?

A. We found it's the most effective way to help customers adopt our technology. We describe it as a more consultative approach to, you know, helping them be successful and realize a lot of the value we're trying to provide the manufacturing industry.

So, again, gene therapy, cell therapy, vaccine manufacturers, we're working with the scientists and the technical team from a consultative standpoint, trying to be, you know, subject matter expert in things like chemically defined media in the application of recombinant human serum albumin in different contexts.

And, again, having that technical background to explain the data that we've generated as well as, you know, have adequate responses to concerns they have and challenges they have for the data is how they found ourselves to be most successful in those relationships.

Q. So is scientific training a key part of being part of product applications?

A. Yes. Our training is about two years long, depending on the individual. It involves a lot of studying InVitria's technology in terms of how our products perform and what context they are used, understanding the customer technology, so becoming familiar with gene therapy manufacturing processes or cell therapy manufacturing processes, as well as a lot of hands-on work where you're actually in the lab working with the team to understand how the products are prepared, as simple as that, to doing cell culture and different assays and things like that.

MR. JACKSON: Thank you.

Your Honor, at this time we'll go on the confidential record, but it will just be Ventria CBI we'll begetting into.

JUDGE MCNAMARA: Okay.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

MR. JACKSON: Thank you.

Q. Mr. Curl, in your role do you hear from customers or those in the industry about what's happening in a market for rHSA?

A. Yes, we do.

Q. Do you ever hear of customers being confused about where rice-derived rHSA is originating?

A. Yes.

Q. If we could pull up CX-0554.

As that's coming up, Mr. Curl, have you heard of Healthgen, the Respondent in this case?

A. Yes, I have.

Q. And we can refer to them as Healthgen? Or have you heard any other names affiliated with this company?

A. Yes, I've heard a few different names.

Q. And have you seen this document here on the screen?

A. Yes, I have.

Q. What does this appear to be?

A. This looks to be like a version of the Oryzogen website.

Q. So does Healthgen sometimes operate as Oryzogen?

A. Yes.

Q. Does every Healthgen product always say Wuhan Healthgen Biotechnology Corp. in your experience?
A. No. It often does not.
Q. If we could go to the page ending 0013 of this slide.
Have you seen this website before, Mr. Curl?
A. Yes, I have.
Q. What does this appear to be showing?
A. This looks like the distributors list of the Oryzogen website, or a version of that.
Q. If we could just go through the North American list, do you see Aspira Scientific?
A. Yes, I do.
Q. Do you know them to have distributed Healthgen's rHSA?
A. Yes, they have.
Q. Do you see US Biological?
A. Yes, I do.
Q. Are they known to have distributed Wuhan Healthgen's rHSA?
A. Yes.
Q. Do you see ScienCell Research Laboratories?
A. Yes, I do.
Q. Are they known to have distributed Healthgen's rHSA?

A. Yes.

Q. Have you noticed any changes on ScienCell's website in recent months?

A. Yes. They recently changed the origin in the description of the material, the recombinant human serum albumin derived from rice, that product page, to list the origin as China and quality released in the United States.

Q. What does quality released in the United States mean?

A. To me it was a surprising phrasing. I've never seen that before. It implies that China is manufacturing the product and then ScienCell is receiving and then quality testing the product --

MR. KUDRAVETZ: Objection, Your Honor.

THE WITNESS: -- which is very rare in my experience.

JUDGE MCNAMARA: I'm sorry. Hold on just a minute. We have an objection.

What's the basis of your objection?

MR. KUDRAVETZ: Objection, Your Honor. This is speculation. The witness said he had never seen that before, and he is stating an opinion.

JUDGE MCNAMARA: No, I don't think he is giving an opinion. I think he is giving his understanding of what he is saying. Whether he is accurate or not may be a

different question.

MR. KUDRAVETZ: Thank you, Your Honor.

JUDGE MCNAMARA: That's what I heard.

Go ahead, Mr. Jackson.

MR. JACKSON: Thank you, Your Honor.

Q. So just to conclude that line of questioning, so has ScienCell made exchanges about the origin of the rHSA they sell?

A. Yes. They added more details in terms of China being the country of manufacture but the United States being the country where it's quality released. However, if you look at the picture of the product that they have on the website, the label lists Carlsbad, California as the address specifically on the label.

So, again, there's some confusion. In my experience, a unique way to describe how a product is supplied and then quality is guaranteed.

JUDGE MCNAMARA: Pardon me just a moment.

Over what period of time did you see this change, Mr. Curl? That wasn't clear to me, in any event.

THE WITNESS: Yeah. I believe I noticed this a few months ago, and that's when I first noticed the change.

JUDGE MCNAMARA: And you preserved copies of the documents that show the changes, what the original website was versus what the new website says?

THE WITNESS: I know I have -- I took some screenshots of what the new website looks like.

JUDGE MCNAMARA: But you don't have any screenshots of the old website?

THE WITNESS: I don't know if I do.

JUDGE MCNAMARA: You might want to check for that.

THE WITNESS: Understood.

JUDGE MCNAMARA: Thank you.

MR. JACKSON: Your Honor, I know you weren't asking me, but I believe screenshots of the old website were exhibits to our complaint in this investigation.

JUDGE MCNAMARA: Okay. Thank you. I needed to know that. Thank you.

MR. JACKSON: You bet.

Q. So are you aware of eEnzyme being a distributor of Wuhan Healthgen's rHSA?

A. Yes, I am.

Q. Thank you. Has Healthgen's place in the market caused problems for Ventria?

A. Yes.

Q. What may happen after Ventria has put in the work to get a company to understand and adopt the technology, as you discussed earlier, and then when Healthgen comes in to play at the procurement stage?

A. Yeah. So we, again, often are working with the R&D teams, the process development manufacturing sciences teams to help, one, you know, create the case for testing our product in the first place, as well as be successful through testing, and then thereafter.

When we're successful and we're, you know, included in a manufacturing process and that process is scaling up for, you know, clinical manufacturing or commercial scale manufacturing, a lot of the purchasing surrounding the product will transition from those technical scientists to a procurement or a supply chain group, and that's usually where we find that a lot of the confusion starts surrounding source and manufacturing.

Q. Do you hear in the industry that Healthgen's rHSA is equal to Ventria's?

A. Yes.

Q. Does that include in terms of purity?

A. Yes.

MR. JACKSON: Your Honor, I think at this point we'll need to return to the confidential record, but it will just be Ventria's CBI.

JUDGE MCNAMARA: Okay.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

DIRECT EXAMINATION

BY MR. JACKSON:

Q. Can you state your name again, sir?

A. My name is Ryan LaMotta.

Q. Where do you live?

A. I live in the Houston, Texas area.

Q. And I know your work in this case addresses a couple of different areas, but for purposes of your testimony now, you're going to address opinions and analysis regarding economic domestic industry, remedy and bond; is that correct?

A. That's my understanding.

Q. Have you prepared a slide deck to assist us with your testimony?

A. Yes, I did.

Q. All right. So if we could look at slide 3, please.

Does this provide a summary of your qualifications?

A. Yes. This gives a little background on my experience and credentials and qualifications.

Q. It says you're director of ASQ Consulting.

Can you tell us a little bit about what you do at

ASQ?

A. Yeah. So we are generally a financial and economic consulting firm. So we work in a range of areas from patent disputes to general consulting projects. But generally my role involves financial and economic analyses, providing guidance to clients, sometimes testifying in different disputes.

Q. Is your work at ASQ relevant to your analyses in this investigation?

A. Yes. So the type of work I do, and have done for years there, is similar to the type of work I've done as part of this investigation.

Q. It says here you previously worked at Grant Thornton and Duff & Phelps.

Can you talk a little bit about your those firms and your work there?

A. Sure. I started my career at Grant Thornton, and that's a public accounting firm, and I worked in the internal audit group there. And so we did, you know, outsourced internal audit functions for companies. We would analyze their financial controls, look at their accounting records, see how their business was put together, provide opinions and guidance to those clients in that context.

I later worked at Duff & Phelps. Duff & Phelps, when I was there, was the largest evaluation firm in the

world. I did work there similar to what I'm doing now, dispute consulting, providing guidance on economic issues related to patent litigation, other types of disputes, business issues the companies might be facing.

Q. So, in general, you work on accounting and financial analyses-type issues?

A. Yes. Economic issues, business issues, things you mentioned, that's correct.

Q. Can we briefly touch upon your MBA from Baylor University?

A. Yes. Okay. So I got my undergraduate and my MBA from Baylor in Waco, Texas. And specific to your question about the MBA, that's a finance heavy, kind of, business strategy type of degree.

Q. Your Honor, at this time Ventria would respectfully tender Mr. LaMotta as an economic expert for purposes of domestic industry, remedy, bond, and commercial success?

JUDGE MCNAMARA: Ms. Niemeyer, I gather there has been no objection to Mr. LaMotta's testifying as an expert for the topics designated?

MS. NIEMEYER: We do not object, Your Honor.

JUDGE MCNAMARA: All right. He is so accepted, then.

MR. JACKSON: Thank you, Your Honor.

Q. Moving to slide 4, Mr. LaMotta, have you reached certain opinions regarding domestic industry in this investigation?

A. Yes, I have.

Q. Can you talk about some of the things that you studied to arrive at those opinions?

A. Sure. As part of my work in this case, starting at the top left, I conducted site visits to all of Ventria's facilities, in-person site visits, to investigate those facilities and the people and the plant and equipment and research materials that were there.

In connection with that I conducted interviews of Ventria personnel. I also conducted interviews of Dr. Wilken. I did a rather in-depth study of the sales and accounting records from both parties as well as other documents in the document production. I've been here at the hearing and listened to the testimony that's come insofar.

JUDGE MCNAMARA: Pardon me just a moment, Mr. LaMotta. You may want to slow down just a little bit.

THE WITNESS: Wit yes, ma'am. That is a common critique of mine. I will do my best.

JUDGE MCNAMARA: Thank you.

MR. JACKSON: Thank you, Your Honor.

Q. So are these the types of information that would be consistent with your work and study in other matters?

A. Yes. Generally the same.

Q. Moving to slide 5, so, based on that review of the record that we just went over, what did you find the evidence demonstrates in this case?

A. Yes. So as it relates to my work on the domestic industry inquiry, it's my opinion that Ventria's domestic investments in DI products are consistent with the Commission's requirement to satisfy the economic prong of domestic industry.

Q. Here on slide 5, is this a demonstrative excerpt from your report in this investigation?

A. That's correct.

Q. Did you analyze all three of what we call subsections (a), (b), and (c)?

A. Yes, that's correct.

Q. And what did you reach a conclusion about regarding Ventria's qualifying investments under each of those three subsections?

A. So my analysis reveals that Ventria's domestic investments under each of the subsections are significant and substantial within the meaning of Section 337 and to Ventria and its business.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

By MS. GIANNELLI:

Q. Dr. DeFilippi, I would like you to summarize your conclusions regarding invalidity before we dive in deeper.

Did you identify any prior art that anticipated claim 1 of the '951 patent?

A. Yes, I did.

Q. And how many anticipatory references will you be discussing?

A. Independently, two.

Q. What is your understanding of anticipation?

A. Anticipation would be all the elements that you're addressing have to be in that single reference.

Q. And which claims are anticipated by Van Urk?

A. Van Urk anticipates claims 1, 11, and 12. I got it.

Q. And which claims are anticipated by Berezenko?

A. That would be claims 1 and 11 are anticipated by Berezenko.

Q. What's the next ground of invalidity that you will address?

A. That would be obviousness.

Q. And what's the first ground of obviousness that you'll address?

A. The first ground is claim 13, and that would have been obvious based on Van Urk and Huang and/or Deeter, and claims 12 and 13 would have been obvious based on Berezenko and Huang and/or Deeter.

Q. What is the final ground of invalidity that you will discuss?

A. That will be claims 1 and 11 through 13, and they would have been obvious based on the combination of Deeter and Van Urk or Berezenko.

Q. Before we turn to that, if we could have slide 5, please. I'd like to introduce you more fully to the Court.

Dr. DeFilippi, can you describe your educational background?

A. Education, it's not up there, but I have an undergraduate degree in -- with honors -- it's a B.A. from Queens College of the City University of New York. Then I went on to the University of Michigan, where I achieved a Ph.D. in biological chemistry, and that department is in the medical school at the university. And then I stayed on for a few months to do a postdoc at the University of Michigan, and then I went on for another two years as a postdoctoral associate, and I taught biochemistry, as well, at the university -- at Cornell University in Ithaca, New York.

Q. What is your current employment?

A. Well, I'm self-employed, but I have my own firm,

Louis DeFilippi LLC.

Q. When did you start your own consulting firm?

A. That was in 1999.

Q. As a consultant, have you assisted companies with the production and purification of recombinant proteins?

A. Yes, I have.

Q. Please name a few of the companies that have sought your expertise as a consultant.

A. They would be Thermo Gen, Medi Cam, and Decode Genetics. And then while I was at those firms, I assisted in bringing projects from -- those are smaller firms -- I assisted in bringing projects for larger firms, and that would include Abbott Laboratories, Iliad, Degussa, and Gore, the company that makes Gore-Tex.

Q. Dr. DeFilippi, about how many proteins have you worked on over the past 20 years?

A. Somewhere in the neighborhood of 25 or more or less.

Q. Of those, what portion were recombinant proteins?

A. I would say approximately one third to one half, probably closer to one third.

Q. Have you worked on proteins from different expression systems?

A. Yes, I have.

Q. Please identify some of those different

expression systems.

A. E. coli, perhaps the most. Pichia would be another one. This is working in the lab with technicians. And then on a consulting basis, things like CHO, Chinese Hamster Ovary cells, which would be mammalian, of course.

JUDGE MCNAMARA: Pardon me. I missed -- I'm sorry, Dr. Giannelli. I missed -- after the E. coli, what was the next expression system that you referenced?

THE WITNESS: It's Pichia. And I may be able to spell it. P-i-c-h-i-a. It would be Pichia Pastoris, P-a-s-t-o-r-i-s. And that is in the yeast family.

JUDGE MCNAMARA: Yep. Thank you.

THE WITNESS: You're welcome.

JUDGE MCNAMARA: The next one was CHO?

THE WITNESS: Yes, CHO. That's Chinese Hamster Ovary cells, which, of course, as you might expect, is a mammalian host.

JUDGE MCNAMARA: Thank you.

Q. Dr. DeFilippi, please describe your expertise with protein purification briefly.

A. Briefly. I could go on forever, as you might suspect.

I've performed many different purifications, ion exchange, chromatography perhaps the most, also participation-type reactions, such as using organic solvents

or salts, like ammonium sulfate, all for purification of proteins. And then there was overlap with polyacrylamide gel electrophoresis for both purification and other items, yes.

Q. Can you please elaborate on the types of chromatography that you've used to purify proteins?

A. Yes. That will include what's termed -- sorry, a lot of abbreviations -- DEAE cellulose, DEAE Sephadex, S-e-p-h-a-d-e-x, CM Sephadex, also size exclusion chromatography, which is also known as gel permeation recombinant albumin, and that is based on size basically.

Q. Is that -- that last technique that you referred to, is that a technique for purification or characterization?

A. Yes to both. You can both -- I used it for both, and others can too. And you can use it as a chromatography column or in a smaller form as an HPLC, high pressure liquid chromatography. I'm not sure if someone mentioned that's it. Or it's also high-performance liquid chromatography, the latter for the marketing people.

Q. Please briefly describe your expertise with protein characterization.

A. Protein characterization, I've done rather extensive amount of spectrophotometry. What does that mean? You use a light to do your analyses. Also binding to dyes

and ligands. Dyes would be, for example, to measure the amount, that's the co-Massey blue that's been mentioned earlier. And a whole variety of ligands.

Q. Are you familiar with polyacrylamide gel electrophoresis, commonly abbreviated PAGE?

A. Yes, I am. I've done a lot of gels. We call them gels.

Q. What type of PAGE have you run?

A. I have run what I call the standard. There are a number of different names for it. But the standard PAGE approach, PAGE with SDS, PAGE -- which is a surfactant, PAGE with SDS plus reducing agents, amongst others.

Q. Are you familiar with techniques for quantifying protein species of different sizes?

A. Yes, I am.

Q. Please provide a few examples of the techniques you're familiar with for quantifying proteins of different sizes.

A. These are somewhat complementary, but if you want to obtain the most unaltered numbers, you would use the size exclusion chromatography. That is the most mild technique. One can also -- and you have to be very careful when you do this so you interpret the data correctly. You can also use SDS-reducing-PAGE, but you have to understand there that, under those conditions, you're driving the aggregates down

to monomers. You will lose a certain amount of information.

So I would look at those two methods as complimentary with the ones that give you the most accurate numbers of the material as it is unaltered being the size exclusion.

Q. Have you conducted research on albumin?

A. Yes, I have.

Q. Please describe your research with albumin.

A. Yes. I was in the lab of Dr. Margaret Hunter at the University of Michigan. She was ex of Harvard. And there I studied the binding of one particular ligand, fatty acids, to the albumin molecule.

Q. And, Dr. DeFilippi, do you have any experience with cell culture media?

A. Yes. A whole variety, as I already mentioned, we did it with these Chinese Hamster Ovary cells, which would be for mammalian, and also for yeast, and also for other organisms, bacteria. So a very extensive number, but I think this we're talking about mostly is the mammalian.

Q. Now have you conducted any hands-on research with recombinant proteins produced in transgenic plants?

A. Produced in transgenic plants, no.

Q. Are you familiar with the scientific literature regarding recombinant proteins produced in transgenic plants?

A. Yes, I am.
Q. Are you a member of any scientific organization?
A. Yes, I am.
Q. What organization?
A. That would be the American Chemical Society.
Q. And have you held any positions at the American chemical society?
A. Yes, I have.
Q. And what positions have you held?
A. I was a director of the Chicago section for two elected terms, one two-year term and one one-year term.
Q. And what was the time frame of those elected positions?
A. That was a few years ago, maybe four or five years ago.
And I wanted to add, I was also the chairman of the senior chemists committee until 2020. And that was, again, for about three years. Excuse me.
Q. Dr. DeFilippi, have you presented your work at scientific conferences?
A. Yes, I have.
Q. Did you ever make any scientific presentations that includes discussion of the production of recombinant proteins produced in transgenic plants?
A. Yes, I have.

Q. What types of transgenic plants have you discussed in presentations at scientific conferences?

A. There were two, tobacco and rice.

Q. What was the time frame of those presentations?

A. That was 2004, 2008.

Q. What was the name of that conference?

A. Well, this is the Gordon Research Conference. You can't just go and present. Of course you have to get -- you have to submit your materials and it has to be approved by other scientists well known in the field.

Q. Back in that time frame, were you monitoring developments on the use of transgenic plants to produce recombinant proteins in the scientific literature?

A. Yes, I was.

Q. As a consultant, were you permitted to publish all the research you were involved in?

A. No. Unfortunately, whatever work you participated with was -- this was company secrets. They did not -- this was all cutting edge, so they did not want that information to be presented publicly.

Q. Let's look at your CV.

If we could please pull up Exhibit RX-305, and if we can zoom in on the top portion of RX-305.

Dr. DeFilippi, what is this document?

A. This is my CV.

Q. Does your CV provide additional information about your qualifications?

A. Yes, it does.

MS. GIANNELLI: Your Honor, we proffer Dr. DeFilippi as an expert on biochemistry, protein characterization, and purification, including recombinant protein characterization and purification.

JUDGE MCNAMARA: What agreement, Mr. Heneghan, do you have with respect to Dr. DeFilippi?

MR. HENEGHAN: Your Honor, we have no objection to that proffer and that specific scope.

JUDGE MCNAMARA: Okay. So then he is accepted for that scope as expressed.

Q. I'd like to turn -- before discussing the ground for invalidity, I'd like to ask you about what was known in the prior art prior to the '951 patent.

And if we see -- on slide 6 of RDX-1C, have you prepared demonstratives summarizing the state of the art prior to February 18, 2010?

A. Yes, I have.

Q. Why did you use that date?

A. That was the -- or is the date of submission of the patent we're discussing, the '951 patent.

Q. Now would any of the pertinent teachings of the prior art change if we considered only the art available as

of the earliest application on the face of the '951 patent, which was filed on February 20th, 2009?

A. No.

Q. If we could go to slide 7, please, and look at the definitions of a person of ordinary skill in the art.

Dr. DeFilippi, on the left, what definition did you propose for a person of ordinary skill in the art, abbreviated here as POSA?

A. Would you like me to read it?

Q. Please do.

A. Okay. Here a POSA working in the field of the '951 patent would possess a Ph.D. in chemistry, biochemistry, or chemical engineering, with at least two years of experience involving production and/or purification of proteins such as recombinant HSA, and/or experience with compositions suitable for use in cell culture media.

Q. Thank you.

Did Dr. Wilken propose a similar definition for a person of ordinary skill in the art?

A. Yes, Dr. Wilken did.

Q. And what your analysis change depending on which definition you applied?

A. No, it would not.

Q. Let's discuss what was known prior to the '951 patent.

First, prior to the '951 patent, was recombinant human serum albumin from a transgenic plant commercially available?

A. Yes, it was.

MS. GIANNELLI: We'll need to briefly go on the Ventria confidential record.

JUDGE MCNAMARA: Okay.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. GIANNELLI:

Q. Dr. DeFilippi, back in 2007 was it known that recombinant albumin produced in transgenic rice could be used in cell culture media?

A. Yes, it was.

Q. Can you provide an example of what was known?

A. Yes. The example is in front of you where, if you look at the second line, it says, Ventria 2007 announces Cellastim outperforms plasma-derived HSA in cell culture media.

And then if you look below that there are a number of graphs, which show comparisons of these various HSA preparations. For example, if you look at the right side where it says improves cell growth, you can see -- I guess that's red -- you have the plasma, that's what the P represents, plasma, PHSA, versus Cellastim, which is the next one over, second from the right.

And then, finally, all the way to the right, that's fetal bovine serum, FBS. That's a 10 percent solution. And that had been what was normally used as a supplement in cell growth where albumin was proposed as a replacement.

Q. Okay. And, Mr. Fisher, if we could blow up the

graph on the left for a moment.

How did Ventria characterize the activity of Cellastim compared to plasma human albumin back in 2007?

A. Well, without running controls, as an example, what ligands might or might not be present, they presented the conclusion that Cellastim outperforms competitors' plasma-derived HSA. Again, this is from blood plasma.

And I'm going to have to take a little water, because my voice is just starting to fade. Excuse me for a few seconds.

You can ask the next question.

Q. If we can move to slide 10, please, Mr. Fisher.

Dr. DeFilippi, here you have a depiction of albumin on the left.

Can you please describe the general structure of albumin or recombinant albumin?

A. Yes. This, as you just stated, is a structure of albumin. I'll walk you through it and then perhaps back up and explain a few things.

Albumin -- these little curly type parts and other type parts on the left represent the polypeptide chain of albumin. It's -- I forgot what the exact number is, maybe 550 or so amino acids that are linked together that make the protein and that protein is a polypeptide. Poly meaning many, of course.

Okay. So there are three major domains: I, II, and III. You see it going maybe from 2:00 to 4:00 to 9:00, or something like that, as you go around it.

And then each of those domains has a subdomain with the capital letters A or B, and these represent the actual evolution of albumin, which started out as a single globular protein, and through mutation was doubled up at the genetic level, which ended up making the protein of two polypeptides linked together. And this continued further, so you have a total of 2, 4, 6 reproductions of the original singular globular protein. But now, as they further evolve, there were further mutations, so that the various functions of each of these domains had been somewhat altered as well. Pretty interesting stuff, I think.

All right. Did I address that sufficiently?

Q. Given the evolutionary history and the way the six different domains evolved by coming together, do those different domains have some duplication or overlap in the type of activity they provide?

A. Yes. There are some duplication and some differences, and that's explained on the right side of this page. Can you just blow up that right part there with the title? There we go.

Again, I'll have to work around with the clock. At 12 noon, you have FA 1. That means fatty acids. That is

where a fatty acid will bind to the albumin molecule.

Before I walk around it, right below that there's that little red thing that looks like a little bit of a fence. That's a heme, h-e-m-e. That's a heme, and that is what would be released from hemoglobin when the hemoglobin is degraded.

So that already tells you, with just those two parts, that the albumin binds fatty acids. But also under problematical or pathogenic conditions, it will sop up heme that's released into the blood and sequester it, because it could have potential toxicity.

So if you walk around just looking at the FA 1s, you can go clockwise around FA 2. Of course FA 7, heaven forbid it would be in the same numbers of course, but you can see there are a total of seven different sites where fatty acids bind.

We addressed the heme. And there are some other sites here that bind molecules that are just there. It's like adventitious binding of such molecules as ibuprofen.

I'll be quiet now or I could go on for another hour.

Q. Let's back up for a moment. Perhaps with reference to the figure, can you explain how albumin functions in cell culture media to promote cell growth?

A. Yes. Albumin binds these ligands and also, I'll

mention, metals, just the word metals, various metals, and can act as a storehouse to deliver these nutrients to the cell.

Q. Now does the structure of recombinant human albumin differ from native human albumin?

A. No, it is identical.

Q. Does the structure of recombinant human albumin differ depending on the transgenic production system?

A. No. The protein does not know its genealogy. When it's made, it folds and you get the same structure, the same protein structure.

Q. So how would the size compare for different recombinant human albumins produced in different transgenic systems?

A. Of the albumin itself, it should be the same in all these systems, identical in all these systems.

Q. And how about the isoelectric point, how would the isoelectric point of recombinant human albumin compare if it was produced in different systems?

A. It would be identical in all these systems. And later, if you want, I can explain what that is.

Q. Please do explain what you mean by "isoelectric point."

A. Isoelectric point is the point in the electric field where the molecule does not move one way or the other

because it has a neutral charge at a particular pH.

Q. Okay.

A. And that pH is the isoelectric point.

Q. Dr. Wilken argued that aggregated albumin must be comprised of albumin species retaining the full activity of native albumin.

Do you agree with that?

A. I do not agree with that.

Q. Did Dr. Wilken provide any data showing the level of activity of any albumin fragment prior to or after aggregation?

A. Not that I've seen.

Q. Now setting aside whether or not activity is required under the adopted construction for aggregated albumin, would albumin fragments in fact retain activity?

A. Yes. They would. And, in effect, that's based upon what we said, the evolution of the protein. You can cleave albumin to certain smaller fragments, and they will retain usually a portion of the activity, not always, but usually, and sometimes even have a greater affinity for the ligands. So the bottom line is you're not deactivating the albumin by generating fragments. That would be too much of a generalization. Excuse me.

Q. With reference again to the figure on the right of slide 10 of RDX-1C, if you were to cleave to form two

fragments, in general, how would that impact activity?

A. Well, for example, you could cleave -- you can see it's a heart shape. And down where you can see FA 6 where the fatty acid number 6 binds, that's going to be -- as I put my hands up, the poor court reporter is going to have trouble here -- where my wrists are touching, if you cleaved at that point, it might indeed remove the activity or greatly reduce the activity at that point. But the more distal, the more distant, the more distal binding sites are -- and this has been shown -- would have much less of an effect on their ligand binding properties.

Q. Dr. DeFilippi, earlier you mentioned that the structure of recombinant human albumin wouldn't differ depending on the transgenic production system.

But just to make sure everyone is on the same page, can you explain what we mean by the term "transgenic production system"?

A. Yes. You have produced in a particular organism -- we would always call these producer strains. You have your producer strain that you developed that the molecular biologists and biochemists working together help develop, and that organism, that producer strain, will be producing through the standard genetics and protein synthesis machinery the protein of interest.

Q. And can you provide some specific examples of

types of production systems for albumin?

A. Well, rice and yeast would be two.

Am I answering your question correctly? All right.

Q. Yes. Thank you.

Now if we move to slide 11, Dr. DeFilippi, how do the biochemical properties of prior art recombinant human albumin compare to the biochemical properties of the recombinant albumin of the '951 patent?

A. What you see here, this is -- this slide is showing the comparison for Cellastim from 2007 and the -- which is the recombinant HSA, and the '951 patent on the right highlighted in yellow, as you can see, and they are absolutely identical. I'll just give a single example.

If you go down a couple of lines on the left where it says N-terminal sequence, you look to the highlighted area, it's DAHKSE. That's the names of the amino acids in sequence, and that's absolutely identical to what you have on the right side, which is the '951 patent. And then if you work your way down, all these values are the same.

MS. GIANNELLI: We need to go on the Ventria confidential record briefly, and I can confirm that there are no participants from the Healthgen side.

JUDGE MCNAMARA: Okay. Thank you.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. GIANNELLI:

Q. Dr. DeFilippi, prior to the '951 patent, was the FDA concerned about endotoxins?

A. Yes. They understood it as an undesirable contaminant.

I notice every time I raise my voice you get the echo, so I'm trying to control the volume. Sorry about that.

And so the answer is, yes, it was undesirable because it was known to be toxic to cells, and, therefore, you'd want to control the level in any products that would be exposed to cells.

Q. Okay. And so were endotoxins a concern in cell culture media in particular?

A. Yes. Exactly right. Because these endotoxins, basically, are ubiquitous. It takes a fair amount of work to control the levels. And indeed the FDA recognized you had to control the levels below a certain -- as they say at the bottom, establish an appropriate acceptance limit. You have to be at or below that acceptance limit.

Q. For completeness, can we please pull up RX-18?

Dr. DeFilippi, is this the FDA guidance that you referenced in the demonstrative we were just looking at?

A. Yes. This is from September 2004, and indeed that's the reference.

Q. Thank you. I was going to have him zoom in, but you can read it from there. That's great.

A. No. I took my krill oil this morning, which has aided my eyesight.

Q. Prior to the '951 patent, Dr. DeFilippi, had scientists in the field figured out how to obtain recombinant human albumin without endotoxin?

A. Yes, they did.

Q. If we could please move to slide 14 of RDX-1C.

Were there any commercial recombinant human albumins that were endotoxin-free?

A. Yes. Yes, there were.

Q. And what product have you included on slide 14?

A. This is a product known as Recombumin, and it's a recombinant human albumin. As is stated here from the European Medicines Agency, they stated that the preparation is sterile, which is okay, but ò the important part is that it is endotoxin-free.

Q. Dr. DeFilippi, what is the date of this document?

A. If you look at the right towards the middle, far right, this comes from 2006.

Q. Mr. Fisher, can you please pull up RX-45.

Dr. DeFilippi, is this the document that we were

just discussing in demonstrative slide 14?

A. Yes, it is.

Q. Mr. Fisher, if you could please highlight the sentence starting with "The rHSA approved for use."

Dr. DeFilippi, could you please read that statement into the record?

A. Yes, I can. ò it says, The rHA -- they say rHA. It's the same exact thing as recombinant human serum albumin; it's just a different abbreviation. The rHSA approved for use in the manufacture of M-M-R VAXPRO -- that's involved in vaccines -- is Recombumin, a proprietary product manufactured by Delta Biotechnology Limited, UK, produced without the use of animal-derived materials.

Q. If we look at the first line under the introduction, is the M-M-R VAXPRO a vaccine?

A. Yes, it is (see exhibit). It's measles, mumps, rubella.

Q. During opening statements counsel for Ventria said that Ventria's Exbumin product was the first recombinant human albumin approved for use in a vaccine.

Do you recall that?

A. I do recall that.

Q. Was Recombumin, in fact, approved for use in the new MMR vaccine as of the date of this document, which is 2006?

A. Yes, it was.

Q. Turning to the next aspect of what was known prior to the '951 patent, had scientists figured out how to obtain recombinant human albumin with less than 2 percent aggregated albumin?

A. I'm sorry. Repeat, please.

Q. Prior to the '951 patent, had scientists figured out how to obtain recombinant human albumin with less than 2 percent aggregated albumin?

A. Yes.

Q. If we could go to RDX-1C, slide 15.

Dr. DeFilippi, what is the product you have shown here?

A. This is a recombinant serum albumin produced by a company known as New Century Pharmaceuticals, Inc. And this, as you see here, is their 2005 catalog.

Q. What is the reported level of monomeric albumin in this recombinant human albumin product?

A. The level is greater than 99 percent monomer content.

Q. And what does that indicate about the level of aggregated albumin in this product?

A. The amount of aggregated albumin has to be less than 1 percent.

Q. Does this 2005 catalog also say anything about

the level of endotoxin in this recombinant human albumin?

A. Yes. They use the term "low endotoxin."

Q. What's the first marketed use of this recombinant human -- recombinant human albumin?

A. This, as you can see, in the blowup just below the purity blowup, it says product applications, cell culture.

Q. Mr. Fisher, please pull up RX-30.

Dr. DeFilippi, can you identify this document, please?

A. Yes. This is the same as we had just a moment ago. This is the 2005 catalog from New Century Pharmaceuticals, Inc.

Q. If we could please go to slide 16.

Dr. DeFilippi, can you please summarize the key features of what was known in the art prior to the '951 patent?

A. Yes. What was known, going from top to bottom here, is that the rHSA produced in a transgenic plant and used in cell culture, that was known.

Also known was the rHSA produced in transgenic rice; in other words, they knew that technology, how to do it. They knew how to prepare an endotoxin-free rHSA. And also known was that one could produce rHSA with less than 2 percent aggregated albumin.

Q. Please advance to slide 17.

Before we turn to the grounds of invalidity you have identified, do you recall that the judge here has interpreted certain claim terms?

A. Yes. I do recall that Her Honor has done so, yes.

Q. Did you review the adopted constructions?

A. Yes, I did.

Q. How do the adopted constructions compare to those that you proposed during claim construction proceedings?

A. Say that again, please.

Q. How do the adopted constructions compare to the -- to the proposed constructions that you suggested during claim construction proceedings?

A. They are the same.

Q. Did you apply the adopted constructions in all of your analyses for this case?

A. Yes, I did.

Q. I'd like to turn to the first ground of invalidity.

Dr. DeFilippi, remind us, what is the first ground of invalidity that you'll discuss here?

A. We're talking about anticipation, and here we have that claims 1 and 11 are anticipated by both Van Urk and separately Berezenko.

Q. Let's look at the first anticipatory reference on slide 19 identified here as Van Urk WO 00/44772.

Dr. DeFilippi, what is the priority date on Van Urk?

A. The priority date is the 30th of January, 1999.

Q. Now on a high level, what did Van Urk disclose?

A. You can see that's highlighted under the abstract, about dead center in the slide, and that says, a process is provided for the preparation of a highly pure albumin solution.

Q. Now was Van Urk considered by the U.S. Patent Office when they were deciding whether to issue the '951 patent?

A. It was not considered.

Q. Move to slide 20. Let's look at the second anticipatory reference U.S. Patent No. 6,034,221 to Berezenko.

Dr. DeFilippi, what is the date on -- of Berezenko's patent?

A. That would be the 7th of March, 2000.

Q. And you have shown here two claims of Berezenko's patent.

Can you please summarize the pertinent features of Berezenko's invention as claimed?

A. Yes. You can see highlighted with claim 1, the

claim in Berezenko is a highly purified albumin, which is at least 99.5 percent monomeric. And then if you jump down to claim 21 at the bottom of the slide, again, they are referring to albumin, the albumin containing formulation, and they are saying that it is nonpyrogenic. And, as you recall, the limits would be the same. So it's a nonpyrogenic solution. I'm walking in circles. I'm sorry. Yes.

Q. That's fine, Dr. DeFilippi. Thank you.

Let's break that down a bit. When the claim refers to at least 99.5 percent monomeric, what would that mean about the level of aggregated albumin in Berezenko's highly purified albumin?

A. That would make it less than 0.5 monomeric.

Q. Less than 0.5 monomeric, Dr. DeFilippi?

A. Sorry. I misspoke. Less than 0.5 percent polymeric or aggregate.

Q. Just to make sure we have a clear record, in claim 1 of Berezenko, what would be the maximum level of aggregated albumin permitted by the claim?

A. That would be 0.5 percent.

Q. Now you've mentioned the term nonpyrogenic a couple of times.

What claim term does the term nonpyrogenic relate to?

A. This is the inTara toxin.
Q. How does the term nonpyrogenic relate to the level of endotoxin?
A. Endotoxin I meant. Sorry. Yes. The endotoxin is in the pyrogenic chemical family. So the endotoxin level, here they are saying nonpyrogenic, therefore, at this point in time, these levels would be below 0 .01 percent. That's the kind of analysis that would give you a nonpyrogenic value.
Q. Okay.
A. For the endotoxin I'm speaking of, yeah.
Q. Just to make sure we're clear, if a product is nonpyrogenic, what does that say about the level of endotoxins present?
A. That it would not be present in a detectable quantity.
Q. Now was Berezenko considered by the Patent Office when they were deciding whether or not to issue the '951 patent?
A. It was only partially considered.
MR. HENEGHAN: Objection, Your Honor. If I could address that. It's also covered by this editorial comment in the slide here. I think it's speculation for Dr. DeFilippi to say what particular in the Berezenko reference the Patent Office considered, and also is

bordering on a legal opinion. So we object to him talking about which parts of Berezenko were considered or not considered by the Patent Office.

JUDGE MCNAMARA: So would you care to address that, Dr. Giannelli?

MS. GIANNELLI: I may be able to fix it by just rephrasing.

JUDGE MCNAMARA: Okay. And also --

MR. HENEGHAN: If I could just --

JUDGE MCNAMARA: Go ahead.

MR. HENEGHAN: I wasn't really objecting to the question. I was objecting to the answer, because the question really didn't raise it, but Dr. DeFilippi sort of volunteered it.

JUDGE MCNAMARA: Okay. Are you moving to -- are you asking that I strike part of Dr. DeFilippi's answer? What are you asking for, Mr. Heneghan?

MR. HENEGHAN: I'm sorry, Judge. I should have phrased it that way. I'm asking that his answer in relation to what the Patent Office did or did not consider be stricken as speculative.

JUDGE MCNAMARA: With respect at least to Berezenko?

MR. HENEGHAN: Yes. We know that the Patent Office had Berezenko before it and considered it, but we

can't say exactly which parts of it the Examiner thought about or didn't think about.

JUDGE MCNAMARA: Well, I don't think that's what was being asked, especially if there's prosecution history.

MR. HENEGHAN: I agree with you. It is what Dr. DeFilippi volunteered in his answer, so I think that should be stricken.

JUDGE MCNAMARA: Dr. Giannelli, why don't you get us out of this and move this off of a legal opinion to what was observed to have been considered as part of the prosecution history so that I don't have a half legal opinion there.

MS. GIANNELLI: I think I can fix this by rephrasing.

JUDGE MCNAMARA: I think you can. Thank you.

Mr. Heneghan, can you be sure to identity yourself when you jump in?

MR. HENEGHAN: Of course. I'm sorry.

JUDGE MCNAMARA: That's all right. Thank you.

MS. GIANNELLI: This is, again, Max Giannelli.

Q. Dr. DeFilippi, did the Patent Office cite all the pertinent disclosures in Berezenko when they were examining the '951 patent to decide whether or not to issue it?

A. No.

Q. For completeness, I don't believe this has been

moved into the record yet. Mr. Fisher, could we pull up JX-27.

MR. HENEGHAN: Judge, this is Mr. Heneghan again. Just in the sake -- for the sake of efficiency, we would be happy to stipulate that if an exhibit is referred to on a demonstrative slide, it can be admitted into evidence. It doesn't have to be called up separately and identified over again.

JUDGE MCNAMARA: I really -- I'm sorry, I didn't mean to interrupt you. You paused. I thought you were done. I wasn't sure.

MR. HENEGHAN: I was.

JUDGE MCNAMARA: No, I think that's terrific. I'm assuming that you've already worked out beforehand the exhibits, so if there was an objection I would have known about it.

MR. HENEGHAN: Absolutely, Judge. Yeah.

JUDGE MCNAMARA: Okay. Thank you, Mr. Heneghan.

MS. GIANNELLI: Yes. Thank you. I appreciate that.

Q. So I would like to start walking through the claim elements of claims 1 and 11 of the '951 patent, starting on slide 21. Let's look at the first claim limitation, and if we could advance to slide 22.

Dr. DeFilippi, what is the first limitation of

claim 1?

A. That reads a cell culture media supplement or complete media composition for improving the growth of a cell in cell culture comprising.

Q. Do we need to concern ourselves with the bracketed and italicized language?

A. No, we do not. Do you want me to read that section that we don't have to consider, or read it as is?

Q. I just wanted to clarify why it was bracketed and italicized.

Dr. DeFilippi, is it your understanding under the adopted construction that the bracketed and italicized portion is not limiting?

A. That's true, yes.

MR. HENEGHAN: Judge, this is Tom Heneghan. We're happy to stipulate that that's the case from the claim construction as well, if that makes it more clear.

JUDGE MCNAMARA: Thank you very much. I appreciate that, Mr. Heneghan. Yep.

Go ahead, Dr. Giannelli.

Q. Dr. DeFilippi, what does Van Urk say concerning a cell culture media supplement or complete media composition?

A. It's introduced on the right highlighted areas mostly where it is stated in Van Urk, the albumin of the present invention may -- this is a typo -- may fulfill

various roles. And then it goes on to say, by way of example, it may be used -- again jumping down to the third line from the bottom -- may be used in cell culture.

Q. When Van Urk refers to albumin, as in the passage that you just referred to, what does he mean by albumin?

A. He is referring to it generically where he states, in this specification the term albumin refers generically to HSA and/or rHSA.

Q. How does Van Urk define rHSA?

A. That's the recombinant human albumin, which is recombinant human serum albumin.

Q. Okay. If we could please move to slide 23 of RDX-1C. We just -- you just explained how Van Urk satisfies this limitation.

What does Van Urk say about a cell culture media supplement?

A. You mean Berezenko, do you?

Q. Yep. Let me ask a new question.

Does Berezenko disclose a cell culture media supplement or complete media composition?

A. Yes, Berezenko does.

Q. And what are the pertinent disclosures of Berezenko?

A. There they state, albumin is also used to supplement media used for growing higher eukaryotic cells.

That means in a cell culture.

Do you want me to continue below, or is there another question?

Q. That's fine. So would a person of ordinary skill in the art understand that Berezenko disclosed a cell culture media supplement under the adopted construction?

A. Yes, they would.

Q. Okay. And when Berezenko refers to the albumin, what does it mean by that?

A. Similarly, it's generic where they state the term albumin refers generically to HSA and/or rHSA. Again, that's recombinant human serum albumin.

Q. Let's look at the next claim term, slide 25, please.

Does Van Urk disclose a recombinant mammalian albumin, Dr. DeFilippi?

A. Yes, Van Urk does.

Q. What are the pertinent disclosures of Van Urk?

A. It's highlighted on the right where he is talking about the present invention, and there talking about the present invention, and they are presenting recombinant human albumin, the rHA produced by transforming or transfecting an organism with a nucleotide coding sequence encoding the amino acid sequence of human serum albumin, including rHA producing transgenic plants.

Q. And --

JUDGE MCNAMARA: Pardon me. Dr. DeFilippi, you're referencing RDX-25, correct? ò

A. I believe that's correct, but I can be corrected if --

JUDGE MCNAMARA: Of your deck?

MS. GIANNELLI: Yes, that's correct, Your Honor.

JUDGE MCNAMARA: Thank you.

Q. Dr. DeFilippi, does this disclosure of Van Urk meet the adopted construction of recombinant mammalian albumin?

A. Yes, it does.

Q. Does this disclosure also meet the added limitation of claim 11, which requires a recombinant human serum albumin?

A. Yes, it does.

Q. If we can please move to RDX slide -- RDX-1C, slide 26. And we just saw how Van Urk discloses a recombinant mammalian albumin.

Does Berezenko also disclose a recombinant mammalian albumin?

A. Yes, Berezenko does.

Q. Please summarize the pertinent disclosures of Berezenko.

A. Most of it is highlighted in yellow where

Berezenko is presenting the process of the present invention and stating that it is particularly applicable to purifying recombinant human albumin (rHA). The albumin produced in accordance with the invention is preferably human albumin.

Do you want me to -- -- the next part is some --

Q. Does Berezenko meet the adopted construction of recombinant mammalian albumin?

A. Yes, Berezenko does.

Q. Okay. And does this disclosure of Berezenko also meet the limitation of claim 11, which recites a recombinant human serum albumin?

A. Yes, it does.

Q. If we could please advance to RDX-1C, slide 28.

Let's look at the next claim limitation, produced in a transgenic plant.

Does Van Urk disclose this limitation under the adopted construction?

A. Yes. Van Urk, again, is highlighted to the right. Again, they are talking about the rHA produced by transforming or transfecting an organism with a nucleotide coding sequence encoding the amino acid sequence of human serum albumin, and this includes rHA producing -- produced using transgenic animals or plants. Plants is the key part here.

Q. And that excerpt is from JX-30 at page 1, lines

3-9, correct, Dr. DeFilippi?

A. That is correct.

Q. Does Van Urk provide any examples of transgenic plants suitable for producing recombinant human serum albumin?

A. Yes, Van Urk does.

Q. And what examples does Van Urk provide?

A. You can see on the bottom highlighted as an alternative, the albumin may be obtained from a transgenic plant, and then gives a number of examples, and, lastly, is corn (maize).

Q. Let's look at the second anticipatory reference on slide 29. We discussed earlier that Berezenko claims highly purified albumin.

Does Berezenko disclose the type of albumin that can be purified by his process?

A. The type of albumin, you can see down about four lines, he specifically states the process is particularly applicable to purifying recombinant human albumin (rHA).

Q. And does Berezenko disclose how that recombinant albumin may be expressed?

A. Yes. He discusses the host, where Berezenko states, DNA encoding albumin may be expressed in a suitable host. And then you go to the bottom where he's saying what the host is. That's the expression system. And Berezenko

continues, many expression systems are known, including, and then skipping down, plant cells.

Q. So, Dr. DeFilippi, does Berezenko disclose produced in a transgenic plant under the adopted construction?

A. Yes, Berezenko does.

JUDGE MCNAMARA: Pardon me. Dr. Giannelli, this is a good stopping point. It's 5:30.

So, Dr. DeFilippi, you're still under oath, and the same caution will apply to you as was applied to the other witnesses. You may not speak with your counsel tonight since you're in the middle of an examination. And I don't know if you had any plans to meet with anybody -- I guess you're the only witness, so who would you be meeting with.

THE WITNESS: I'll make a phone call and find out, right?

JUDGE MCNAMARA: Yeah, right. Okay. So you understand the sequestration rules -- sorry, the sequester rules, which I'm sure Dr. Giannelli has explained to you.

THE WITNESS: I do understand, yes.

JUDGE MCNAMARA: Okay. Very good.

Okay. Then is there any housekeeping business I need to take up tonight before we leave?

MS. GIANNELLI: Not that I'm aware of,

Your Honor.

MR. HENEGHAN: Same here, Judge. This is Tom Heneghan. We don't have anything.

JUDGE MCNAMARA: Okay. Very good. Then we're finished for the evening, and I'll see you tomorrow morning at 9:30. Have a good evening everyone.

(Exhibits, as submitted by counsel and reflected in the attached index, were received into evidence.)

(Whereupon, at 5:32 p.m., the proceedings adjourned, to reconvene the following day, Tuesday, November 9, 2021, at 9:30 a.m.)

C O N T E N T S

INDEX OF WITNESSES

WITNESS	DIRECT	CROSS	RE-DIRECT	RE-CROSS	STAFF
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EXHIBIT LISTS PROVIDED FOR RECEIPT
INTO EVIDENCE:

EXHIBITS ADMITTED PURSUANT TO
COMPLAINANT VENTRIA BIOSCIENCE INC.'S
FURTHER REVISED REQUEST
FOR RECEIPT OF EVIDENCE WITHOUT A SPONSORING WITNESS,
IN RESPONSE TO ORDER NO. 26 [EDIS ID NO. 755826]

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JX-0068C
RX-0261C
LIST OF EXHIBITS USED WITH SCOTT DEETER
CDX-0005
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CX-0516
CX-0519
CX-0533
CX-0579C
CX-0634C
CX-0655C
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JX-0101C
JX-0105C
JX-0114C
JX-0130C
JX-0131C
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RX-0032

C E R T I F I C A T E

TITLE: CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME

INVESTIGATION NO.: 337-TA-1238

HEARING DATE: November 8, 2021

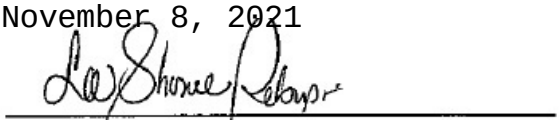
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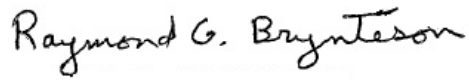
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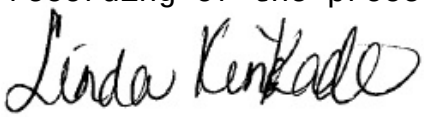
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UNITED STATES
INTERNATIONAL TRADE COMMISSION

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In the Matter of Investigation No.

CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME 337-TA-1238

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OPEN SESSIONS

Pages: 832 through 1146 (with excerpts)

Place: Washington, D.C.

Date: November 9, 2021

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UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

Before the Honorable MaryJoan McNamara

Administrative Law Judge

In the Matter of Investigation No.

CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME 337-TA-1238

EVIDENTIARY HEARING

Tuesday, November 9, 2021

Volume IV

The parties met via remote videoconferencing pursuant to notice of the Administrative Law Judge at 9:30 a.m. EST.

Reported by: Linda S. Kinkade RDR CRR RMR RPR CSR

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*** Index appears at end of transcript ***

P R O C E E D I N G S

(In session at 9:30 a.m.)

JUDGE MCNAMARA: Good morning, everyone. Is everyone ready to get started?

MS. NIEMEYER: Good morning, Your Honor. We just had a couple of short housekeeping matters that we wanted to bring up.

JUDGE MCNAMARA: Sure.

MS. NIEMEYER: Okay. One was --

JUDGE MCNAMARA: By the way, it's Ms. Niemeyer. Ms. Kinkade knows; I know.

MS. NIEMEYER: I apologize, Your Honor. With the video and where I can see myself --

JUDGE MCNAMARA: I know. It's like dialing your own telephone number. You just don't think about it. You don't go around, you know --

MS. NIEMEYER: Exactly. The first item was just -- we noted that the exhibits with respect to Mr. Deeter were listed in the transcript, and we just wanted to confirm that those had been formally entered into the record, the list that the parties agreed upon and emailed to chambers and the court reporter.

JUDGE MCNAMARA: I did not receive them. I think I just -- I may have seen an email coming across from Nicole this morning, but I saw that Ms. Kinkade had received a list

yesterday, but I didn't receive it, or McNamara337 didn't receive it. So Nicole may have just forwarded that to me. I'm not sure. I'll double-check and let you know during the break if that came through for me.

It should be a separate list, and I'm sure that if you agreed upon them, they should be admitted into the record.

So Ms. Kinkade, I know you're there. Can you --

(Clarification by reporter.)

JUDGE MCNAMARA: Whose exhibits are they, Ms. Niemeyer?

MS. NIEMEYER: Everyone's. It's the exhibits of all the parties with respect to Mr. Deeter that have not already been admitted.

JUDGE MCNAMARA: All right. So they are all the Deeter exhibits, but nothing has been agreed upon yet for Dr. Wilken and Dr. DeFilippi.

How about Mr. Curl?

MS. NIEMEYER: So the exhibits with respect to Dr. Wilken, Mr. Curl, and Mr. LaMotta, since they are now off the stand, those are agreed to, and I believe Ms. Shoffstall has popped up on the screen. The parties agree on those. Those can be sent to chambers and the court reporter, if Your Honor could confirm that those would be received into evidence as the agreed-upon list.

JUDGE MCNAMARA: Sure. If you've agreed upon, there's no problem with admitting them.

MS. NIEMEYER: Great. Thank you, Your Honor.

(Exhibits, as submitted by counsel and reflected in the attached index, were received into evidence.)

MS. NIEMEYER: We just wanted to make sure the record was clear. We're now in the second-to-last day of trial, and the parties have been providing time updates. The estimated time that we thought we would have at the beginning is a bit different from where we are now. The estimated remaining time that each party has allocated based on when we started is about 16 and a half hours, which is more time than we think we'll get through today and tomorrow. And the parties are discussing different ways to address this.

One of the things -- one of the proposals was each side tries to cut off two hours of its remaining estimates. That's one estimate. I don't know if it would be possible to go maybe a little bit later or start a little bit earlier.

We just want to make sure that, especially as Respondents, since we have the last two witnesses, that we have an opportunity to present them. We have a strong preference to make sure that they go up now because they are ready, they are prepared, everybody is here, but we really

just want to make sure that everybody has the opportunity to present its evidence and examine that evidence.

So we wanted to raise this issue today before it got later in the case.

JUDGE MCNAMARA: That makes sense. I imagine that you've all talked together about this? Mr. Heneghan?

MR. HENEGHAN: We have, Judge. We haven't quite been able to come up with a common solution, but we have been talking about it. Our primary concern is that we want to conclude the evidence at the end of the day tomorrow. We don't want to suggest that it should be picked up again a week, two weeks or three weeks from now.

The same point that Ms. Niemeyer made, they want to make sure they finish presenting their witnesses, and we also want to make sure we have a full opportunity to cross-examine them, because the last two witnesses are both Healthgen witnesses.

So I'm not sure that focusing on our estimates really makes much sense, because they were just that, estimates. It's really -- both parties have enough time within the allocated time you gave us to get to the end of Wednesday. The question is how we use that time between now and then.

If there's some way to sort of, like Ms. Niemeyer said, start a little bit earlier, go a little past 5:30, if

the Court can accommodate us that way, we're happy to do that. We just thought let's raise it today so that we're not trying to figure it out at noon tomorrow.

JUDGE MCNAMARA: Probably a good idea.

Mr. Guarnieri, have you been a part of these discussions?

MR. GUARNIERI: I have, Your Honor. The parties have run up against the fact that these virtual hearings just don't give us as much time when we're in the courtroom. That's just a reality. The Staff's general view is that we should be able to finish these hearings in five days. It's difficult, but counsel are sophisticated parties. I think we can get it done in five days.

I sort of agree with Mr. Heneghan that the estimates are just estimates. Unfortunately, when the estimates hit the real world, it turned out they were just a little bit too aggressive.

So I think the parties have done a good job. I do agree that maybe the easiest solution is just try to take whatever time is left, based on what we've used so far, which I think is about, as I understand from the parties' estimates, about five hours of record testimony a day, maybe a little bit more than that, try and just divide that up as evenly as possible between the private parties.

The Staff had some time in there. These are all

the witnesses, so I don't imagine I'm going to use any more of Staff. I'm happy to concede that to the private parties at this point. I might have some very, very few questions for Mr. Reed on remedy, but even that is doubtful.

JUDGE MCNAMARA: Okay. So based on the timekeeping I saw, that would be an addition of an hour, roughly, that you would cede, Mr. Guarnieri?

MR. GUARNIERI: Yes, Your Honor, I think that's correct.

JUDGE MCNAMARA: Okay.

MR. HENEGHAN: If I could interject --

JUDGE MCNAMARA: Sure.

MR. HENEGHAN: We agree with what Mr. Guarnieri was saying. Frankly, we would be comfortable with just splitting the time we had or any time in half, and I think it would end up being five hours per party. We've been doing about five to five and a quarter hours of actually on the record time the last three days.

MS. NIEMEYER: I apologize. I do want to note that based on the estimates of where we've gone so far and where we are, the remaining time estimated for Ventria was just under seven hours and the remaining time for Healthgen was about eight hours. I think if we just split it, that does not end up in a 50-50 split of overall time for the parties. I think we would be prejudiced if that were to be

the case.

That's why we had suggested taking two hours off the total. That would kind of get us to where we have a 50-50 split. We do want to make sure that we have an equal opportunity to present our cases.

JUDGE MCNAMARA: Yep.

MR. HENEGHAN: Judge, if I could respond to that?

JUDGE MCNAMARA: Sure, Mr. Heneghan.

MR. HENEGHAN: There hasn't been a 50-50 split as far as the estimated time used. We are under our estimate as a total and they are over their estimate as a total. So talking about them getting more time going forward just doesn't seem fair.

I think the fair allocation, the perfect allocation would be for us to get a little more time, and we're willing to cede that. We're willing to go 50-50.

JUDGE MCNAMARA: Hold on, Ms. Niemeyer. I think the positions are pretty clear.

Here's what we can also do. We can add some time, but I tend to -- I've been watching the time that each party has used, and I think it did run over on Friday for sure, Ms. Niemeyer, at least in terms of what you had anticipated. And I also recognize that these are hard to do.

Let me also just remind you for the future, my

procedural schedules always say if you think you're going to need more time, or less time, let me know and I'll schedule it in. I always build that into my procedural schedules so that you have a couple months before the hearing to sort of let me know if you need more time. So just remember that going forward. Because I can adjust. It just gets harder the closer you get.

I think -- Ms. Kinkade, would you like to participate in this since you are pretty key to it all as well?

THE REPORTER: I'm available, Your Honor, whatever you need.

JUDGE MCNAMARA: What if we tried to go an extra half an hour at the end of the day, if we went until 6:00, and if we lopped off 15 minutes at lunchtime, it's 45 minutes instead of an hour, Ms. Kinkade, how would you be with that?

THE REPORTER: Fine, Your Honor.

JUDGE MCNAMARA: You're really good. You're really kind. I know the issue there.

So let's try that. That gives two hours. Mr. Guarnieri has graciously ceded about an hour. He may have a few questions, but he's pretty brief.

So that would give us an extra three hours. I'm sorry. An extra two -- let me just think. Half an hour

today -- I'm sorry. 15 minutes today, 15 minutes tomorrow, that's a half an hour. Half an hour at the end of the day, an hour and a half, that's two and a half hours that's been added.

MR. HENEGHAN: I think it's an hour and a half, Judge, but we appreciate it regardless.

JUDGE MCNAMARA: Well, Mr. Guarnieri is ceding an hour.

MR. HENEGHAN: That's right. I wasn't counting Mr. Guarnieri's time. Thank you.

JUDGE MCNAMARA: He is ceding an hour, so that's two and a half hours total.

MR. HENEGHAN: Thank you.

JUDGE MCNAMARA: So why don't you make a decision. I'm not going to split it equally, because I think, again, I know estimates are estimates, but, Ms. Niemeyer, you-all did run over some on time, but see how you can make this work.

Mr. Heneghan, if you think you're going to end just a little bit early, I know you'll be gracious enough if you think you'll have that extra time. If you need it, take it. But why don't you work it out at the break, and I won't talk any more so we don't waste any more time.

MS. NIEMEYER: Your Honor, is it possible to start earlier than 9:30 tomorrow?

JUDGE MCNAMARA: Ms. Kinkade?
THE REPORTER: Yes, that's fine.
JUDGE MCNAMARA: I can start at 9:15.
MS. NIEMEYER: That is appreciated, Your Honor.
And I do want to note, sort of putting aside I'm not quite sure how estimates is being used, but Ventria has used about 8 hours 40 minutes and Healthgen has used 7 and a half. So the amount of time that the parties have used to now, Healthgen has used significantly more than -- or an hour and 10 minutes than Healthgen -- oh, sorry -- vice versa. Ventria has used 8 hours and 40 minutes; Healthgen has used 7 hours and 30 minutes.
JUDGE MCNAMARA: You can work this out.
MR. HENEGHAN: We just completed our case-in-chief, not to beat a dead horse.
MS. NIEMEYER: Sure. I just wanted to confirm that the parties are treated equally as far as when we get to the end of the record.
JUDGE MCNAMARA: Oh, don't worry, Ms. Niemeyer. I'm sure you'll make sure we're treated equally.
MS. NIEMEYER: I will do everything I can. And I appreciate that, Your Honor.
I will turn it back over to the witnesses so we don't spend more time on this, if that's all right with Your Honor.

JUDGE MCNAMARA: That would be nice.

MS. NIEMEYER: Thank you very much.

MR. HENEGHAN: Thanks also to Ms. Kinkade for being so generous with her time. She's the one working the hardest of all of us.

JUDGE MCNAMARA: For sure. Absolutely.

Okay. Dr. DeFilippi, good morning.

THE WITNESS: Your Honor.

JUDGE MCNAMARA: Good morning. All right. You are still under oath, so I think Dr. Giannelli can pick up where she left off from yesterday.

LOUIS J. DEFILIPPI, Ph.D.,

having been previously duly sworn and/or affirmed on his oath, was thereafter examined and testified further as follows:

JUDGE MCNAMARA: Good morning, Dr. Giannelli.

MS. GIANNELLI: Good morning. Thank you, Your Honor.

DIRECT EXAMINATION (resumed)

BY MS. GIANNELLI:

Q. This is Max Giannelli on behalf of Healthgen.

Good morning, Dr. DeFilippi.

A. Good morning.

MS. GIANNELLI: We need to start briefly on the Ventria confidential record.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. GIANNELLI:

Q. Dr. DeFilippi, yesterday we were walking through the claim limitations and we had arrived at less than 1 EU of endotoxin per mg albumin.

What does Van Urk say about the endotoxin level in its recombinant albumin?

A. The bottom line is at the bottom of the first paragraph, and that is that no endotoxin was detected.

Q. And would that be below the 1 EU per milligram claimed in the patent?

A. Yes, it would be, because the detection limit at that point in time was 0.001. So a factor of a thousand lower.

Q. Does Van Urk provide any other information on the level of endotoxin in its recombinant albumin?

A. Yes. They also state that the product, as you see on the bottom highlighted, is nonpyrogenic, and that would mean since endotoxins are in the family of pyrogens, again, there would be no endotoxins present.

And I know I mispronounced that badly yesterday.

Q. Thank you, Dr. DeFilippi.

Now looking back at the top quote, in the first line, Van Urk refers to a solution of drug product.

Dr. DeFilippi, what is the drug product in Van Urk?

A. That is the recombinant HSA.

Q. Let's move to slide 32. You just explained how Van Urk satisfies the endotoxin limitation. So let's look at Berezenko.

What does Berezenko say about the endotoxin in its highly purified albumin?

A. There again, highlighted on the right, where Berezenko is presenting albumin, it says that albumin is characterized by extremely low levels of, or being essentially free of, then jumping down, endotoxin, and continuing, by essentially free is meant below detectable levels.

Q. Would a person of ordinary skill in the art have understood that below detectable levels means less than 1 EU endotoxin per mg albumin?

A. Yes. And, as I said previously, that would be actually below 0.001 EU per milligram.

Q. Does Berezenko provide any other information on the level of endotoxin in its recombinant human albumin product?

A. I have to correct myself. I believe it's per milliliter. It's not normalized to milligram. It would be milliliter, the detection level.

Okay. I'm sorry. Repeat your question.

Q. Would a person of ordinary skill in the art have understood that below detectable levels means less than 1 EU of endotoxin per mg of albumin?

A. Yes, they would.

Q. Does Berezenko provide any other information on the level of endotoxin in its recombinant human albumin?

A. Yes. They say the product is sterile and nonpyrogenic. And, as we said before, being nonpyrogenic would also mean that the endotoxin level is extremely low, not enough to give a response.

Q. Slide 34, please. Let's look at the last limitation of claim 1.

Does Van Urk disclose recombinant human albumin with less than 2 percent aggregated albumin?

A. Yes, Van Urk does.

Q. What does Van Urk say about the level of aggregated albumin in its recombinant human albumin?

A. Van Urk states that there may be up to 1 percent dimeric albumin, but no larger polymers or aggregates are detectable.

Q. And how does that compare to the claim limitation of less than 2 percent aggregated albumin?

A. It would satisfy the claim of less than 2 percent aggregated albumin.

Q. If we move to slide 35, Dr. Wilken noted in her testimony previously that Van Urk used reducing SDS-PAGE. And that's summarized in her demonstrative on your slide RDX-135.

Dr. DeFilippi, did Van Urk use reducing SDS-PAGE to quantify aggregated albumin?

A. Not to quantify aggregated albumin, no.

Q. Let's look at the techniques in Van Urk on slide 36, please.

So what techniques did Van Urk disclose that provide information on aggregated albumin?

A. Well, on the left you can see, where it says Van Urk Qualitative Protein Assessment, there Van Urk is using SDS-reducing-PAGE. That's the polyacrylamide gel electrophoresis. And they see a single band, a monomer, they say, which, when treated with a reducing agent, beta mercapto ethanol, migrates as a single band (monomer).

Q. Dr. DeFilippi, what type of information does reducing SDS-PAGE provide?

A. Well, what happens is, whether there are different aggregates or dimers and the like, the SDS-PAGE does not show that. The SDS-PAGE, under reducing conditions, drives any of these dimers and aggregates that are held together by what are called noncovalent bonds, that would be plus minus bonds and the like, as well as the

sulfur disulfide bonds. Those would be reduced. That's a bond-breaking event, so that would break open too. And it would drive all of those to the monomer.

So it's not telling you what's in the product concerning dimers and aggregates, but rather gives you information on the monomer itself.

Q. But is reducing SDS-PAGE a common technique?

A. Yes, it is, very common technique.

Q. And how is it commonly used?

A. To show how pure the enzyme or protein is compared to other species, other kinds of enzymes or proteins, basically based upon size. Again, not aggregates, not dimers, but the monomers. So if you had something -- as an example, if you had lysozyme in there, which is a much smaller enzyme, you would see two different bands, one would be the albumin, one would be the lysozyme. But it doesn't tell you degrees of aggregation or association in the untreated sample. The treating alters the result.

Q. Now there's also nonreducing SDS-PAGE.

How does nonreducing SDS-PAGE compare to reducing SDS-PAGE?

A. Now there you're going to be tending to dissociate, again, to a certain extent any of the dimers or aggregates that are held through what I referred to previously as noncovalent bonds.

As I said, charge, charge -- there are a number of different kinds. Van der Waals, of course, is another. And the surfactant -- the SDS is a surfactant, a detergent -- that will break these noncovalent bonds but not the sulfur sulfur, not the disulfide bonds.

Q. Which is stronger, a noncovalent or covalent bond, in general?

A. Covalent bonds are almost always considered to be the stronger.

Q. What do you call the agents that disrupt aggregates in reducing SDS-PAGE?

A. Well, these happen to be surfactants. They are disruptive agents, denaturing agents. There are a number of ways to describe them.

Q. Let's look at the technique on the right, gel permeation HPLC.

Is there another name for that technique?

A. Yes. Gel permeation is the same as size exclusion. They are basically synonyms, but gel permeation tends to describe how it works a little bit more. And the reason for that is you have a chromatography column, and I'm going to probably repeat myself a little later, but that's filled with these little beads that have pores in them of very, very specific range.

You take a fluid at the top, you percolate it,

literally percolate it down through the column. And that fluid contains the proteins of interest. And as they go down the column, small molecules can enter those little pores so they have more of a zigzag movement downwards.

The larger the protein is, the less of a propensity it has for entering the pores. It is excluded from the pores. That's why it's called gel exclusion chromatography. And those will move down the column with the solvent more quickly.

So you collect fractions, you put little test tubes underneath and collect drops, or you can have it in an HPLC system and look at signals that will indicate where the protein is. They both work. I've done both. And the result will be quantitation of the various sizes.

Q. Okay. Now you've mentioned size exclusion a few times.

Is that -- is there a common abbreviation for size exclusion chromatography?

A. Well, it's --

Q. Let me ask a different question. You've mentioned size exclusion. We've been discussing also SEC-HPLC.

What does the SEC in SEC-HPLC stand for?

A. I just said it the other way around. SEC is size exclusion chromatography. Thank you.

Q. So when you refer to size exclusion chromatography, that's the SEC, correct?

A. Correct, that's the SEC in the size exclusion.

Q. Can gel permeation HPLC be used to quantify aggregated albumin?

A. Yes.

Q. Does gel permeation HPLC change the level of aggregated albumin in a sample artificially?

A. No, it does not.

Q. Now if we move to -- looking at the quote on the bottom, Dr. DeFilippi, what was the total aggregated albumin reported in Van Urk?

A. You can see on the bottom where Van Urk says the same, Total Reported Aggregated Albumin, and Van Urk -- in Van Urk it is stated that there may be up to 1 percent dimeric albumin, but no larger polymers or aggregates are detectable.

Q. If we move to slide 37 of RDX-1C, let's look at our second anticipatory reference.

Does Berezenko also disclose less than 2 percent aggregated albumin?

A. Yes, Berezenko does disclose less than 2 percent aggregated albumin.

Q. Can you please summarize Berezenko's pertinent disclosure here?

A. Yes. Certainly. That's on the right box where it is stated that the albumin of the invention is at least 99.5 percent monomeric, preferably essentially 100 percent monomeric.

So taking the 99.5 value, since that's at least 99.5, the balance of materials, dimers and polymers, aggregates, would be less than 0.5 percent, which, of course, satisfies the less than 2 percent aggregated albumin element of the first claim.

Q. If we move to slide 38, can you please summarize your opinion on claims 1 and 11 of the '951 patent based on Van Urk?

A. Yes. Just in brief, you can see where the checkmarks are. Each individual element of -- did you say just claim 1? I'm sorry.

Q. Claims 1 and 11.

A. Okay. For both 1 and 11, they are all satisfied in Van Urk.

Q. Okay. And can you please summarize your opinions of claims 1 and 11 of the '951 patent based on Berezenko?

A. Yes. Based on Berezenko, once again, all the claims or elements of claims 1 and 11 are satisfied by Berezenko.

Q. If we could have slide 40, please. Let's look at the next claim, claim 12. Now claim 12 depends from claim

1. Dr. DeFilippi, what does claim 12 add?

A. Claim 12 specifically adds that the composition is a transgenic grain. It's following from number 1 (i), that says produced in a transgenic plant, focuses down to transgenic grain.

Q. And what does Van Urk disclose about producing recombinant albumin in a transgenic grain?

A. Van Urk -- in Van Urk it's stated that the albumin may be obtained from a transgenic plant, which, of course, echoes claim 1(i), and then such as tobacco, potato, or corn (maize). Of course, maize or corn is one of the three major grains and would thereby satisfy the element segment in 12, in claim 12, a transgenic grain.

Q. Remind us, Dr. DeFilippi, does the albumin in Van Urk include recombinant human albumin?

A. Yes, it does.

Q. If we can move to slide 41.

What is the next ground of invalidity that you will discuss here today?

A. This is going to be claim 3 -- 13. This is the obviousness, and obviousness based upon Van Urk and Huang -- I'm sure I'm mispronouncing that -- and/or Deeter. And then claims 12 and 13, obvious based on Berezenko and Huang and/or Deeter.

Q. Okay. Let's start with Huang on slide 42, please.

What is the title of Huang?

A. The title is "The Production of Human Serum Albumin by Sugar Starvation Induced Promoter and Rice Cell Culture," paying most attention to the rice cell, of course.

Q. What year was Huang published?

A. Huang was published in 2005, which is about five years prior to the patent in question.

Q. How did Huang express its recombinant human serum albumin?

A. This was expressed in a rice culture. They state that use of rice cell culture was an effective system for the production of product under discussion.

Q. What words does Huang use to describe rice cell culture as a production system for recombinant human albumin?

A. Well, Huang was very positive about it. They said the rice cell culture represents a powerful system. And they got yields up to 76.4 mg per mL -- mg per liter.

Q. And did Huang achieve a good yield of recombinant albumin from rice cell?

A. Yes, that would be considered a very good yield.

Q. And apart from the good yield, did Huang disclose any other advantages?

A. Yes. He clearly states that the rice cell culture system provided or provides a value -- valuable alternative to other approaches, and stated the advantages would be high growth rate and the fact that they -- that rice does not produce any toxic secondary metabolites that are found in some plant cell cultures, such as those derived from tobacco, which is well known.

Q. So if a person of ordinary skill in the art wanted to choose a transgenic plant for the production of recombinant human serum albumin, what plant would they choose after reading Huang?

A. After reading Huang, they clearly would have chosen rice.

Q. Let's look at Deeter on slide 43, please.

Dr. DeFilippi what is the title of Deeter example 3?

A. Example 3 states, Expression of Recombinant Human Serum Albumin in Rice Grain.

Q. Does Deeter disclose the yield of recombinant human serum albumin from transgenic rice?

A. Yes, Deeter does. And the number is up to 8 and a half grams per kilogram of flour.

Q. How would a person of ordinary skill in the art have characterized the yield of recombinant human serum albumin in transgenic rice in Deeter?

A. Again, they would have described it as being very good.

Q. Did Deeter disclose any applications for its recombinant human albumin?

A. Well, they are talking about the use of it in cell culture media as a -- to grow cells in media. It's a cell culture medium component.

Q. According to Deeter, how did its recombinant human serum albumin perform in cell culture media?

A. Well, they compared it to the pHSA. Recall P means from plasma. So that's directly isolated from human blood. And they say the rHSA from rice is functionally equivalent to pHSA. In this particular case they are saying it's about the same, functionally equivalent.

Q. Go to slide 44. Let's look at the combination altogether.

Now if a person of ordinary skill in the art would select the transgenic plant to use in combination with the disclosures of Berezenko or Van Urk, which transgenic plant would they have selected based on Huang and Deeter?

A. Well, it would have been a grain and, more specifically, a transgenic grain.

Q. Is there a particular transgenic grain that Huang and Deeter would have pointed them to?

A. Yes. They would have pointed them to transgenic

rice.

Q. So prior to the '951 patent, if a person of ordinary skill in the art had wanted to select a transgenic plant for selecting recombinant human albumin, which transgenic plant would they have chosen?

A. They would clearly have chosen transgenic rice. They would have chosen the rice grain.

Q. On a high level, why is that?

A. Probably the best reason is the lack of potential toxic substances that many plants do produce, which tobacco is known to produce.

Q. Besides rice, had human serum albumin been commercially produced in any other transgenic plant prior to the '951 patent?

A. No.

Q. So what did you conclude based on the combination of Van Urk or Berezenko and Huang or Deeter?

A. One would have focused on rice as the -- we call those producer strains. You can use other terms. For the strain of creature, it would be a plant, and, more specifically a grain, and, more specifically than that, a transgenic rice. That would be your producer strain.

Q. And so what did you conclude regarding the validity of claim 13 based on this combination?

A. Validity of claim 13 is already a path one would

have chosen, a POSA would have chosen to take. They would have used a transgenic rice cell. It's already satisfied in the literature. Perhaps that's the more correct way to state it.

Q. If we go to --

A. I guess obvious is the correct term. There we go.

Q. Okay. So what did you conclude regarding claim 13 based on this combination shown on this slide?

A. That, in summary, claim 13 would have been obvious based on Van Urk and Huang and/or Deeter.

Q. And then what did you conclude based on claims 12 and 13 based on this combination?

A. Claims 12 and 13 would have been obvious based on Berezenko and Huang and/or Deeter.

Q. And if we could go to slide 45.

Dr. DeFilippi, what is the last ground of invalidity that you'll discuss?

A. I'll be discussing claims 1 and 11 through 13. They would have been obvious based on Deeter and Van Urk and/or Berezenko.

Q. Slide 46, please.

Does Deeter disclose the production of recombinant human serum albumin?

A. Yes, Deeter does.

Q. Remind us, what expression system did Deeter use to produce that albumin?

A. The expression system would be transgenic rice.

Q. Did Deeter disclose the level of endotoxin in its recombinant albumin?

A. They did not disclose the level.

Q. But would that endotoxin have been present and readily detected in Deeter's recombinant albumin?

A. Yes, to both. It would have been present since endotoxin is ubiquitous, and it would have been present and would be detectable.

Q. Would a person of ordinary skill in the art have wanted to improve Deeter's recombinant human albumin?

A. Yes. One would have, yes.

Q. And how would a person of ordinary skill in the art have gone about trying to remove the endotoxin from Deeter's recombinant human albumin?

A. They would look in the published literature, the patent literature, and lo and behold, Van Urk and Berezenko have presented systems that will remove endotoxin from the rHSA.

Q. Let's walk through how the elements would be met by this combination. On slide 47, the first element is a cell culture media supplement or complete media composition.

Does Deeter disclose this element?

A. Yes, Deeter definitely discloses that element.
Q. And what does Deeter say?
A. That's on the right where you see example 8 highlighted. After that, Deeter states, cell culture media supplemented with recombinant human serum albumin, and it says it promotes cell growth. I was going to say, in a system, that would be equivalent to the statement cell culture.
Q. Would a person of ordinary skill in the art have expected Deeter's recombinant human serum albumin to remain a cell culture media supplement after removing endotoxin by the processes of Van Urk or Berezenko?
A. They definitely would.
Q. Why is that?
A. That's because the removal of the endotoxin without altering the albumin would improve the properties of the -- of the products since endotoxin has negative effects on cell growth --
Q. And if we move --
A. Excuse me.
Q. I apologize, Dr. DeFilippi. I may have spoken over you.
What was the last part of your answer?
A. Cell viability. And also removal of endotoxin will improve viability of the cells in the cell culture, to

add a little more to the phrase.

Q. If we go to slide 48, does Van Urk on the left state whether the albumin purified by its processes would be a cell culture media supplement?

A. Yes. Clearly you can see on the left Van Urk -- present in Van Urk it is stated rHSA may be used to supplement media used for growing eukaryotic cells. And, by definition, that's a cell culture, and, therefore, it's a cell culture media.

Q. And does Berezenko state whether the recombinant albumin purified using its processes would be a cell culture media supplement?

A. Yes. Similarly, Berezenko states rHSA may be used to supplement media used for growing higher eukaryotic cells. And higher eukaryotic cells will include things such as mammalian cells in cell culture.

Q. Let's move to the next claim limitation, recombinant mammalian albumin.

Does Deeter disclose a recombinant mammalian albumin?

A. Yes, Deeter does disclose a recombinant mammalian serum albumin.

Q. Okay. And what kind of mammalian albumin does Deeter disclose?

A. Specifically, you can see on the right where it

says example 3, Deeter says expression of recombinant human serum albumin in rice grain. And below that he talks about how much.

Q. How does that compare to the added limitation of claim 11, which recites a recombinant human serum albumin?

A. Yes. This is a recombinant human serum albumin. So it satisfies that claim, claim 11.

Q. If we go to slide 50, how does the recombinant human serum albumin of Deeter compare to the recombinant human serum albumin of the '951 patent?

A. Yes. If you look at the highlighted portion to the right on both boxes, these are identical biochemical values you obtain from various kind of analyses. And I'll just mention one of them, but they are all identical.

Where they say N terminal sequence, you can see the -- impossible to understand -- DAHKSE. Each letter there is an abbreviation for one of the amino acids that is present. So they are there, like, beads on a string, except this is your polypeptide that makes up the protein, and so it's the proper sequence of one of each of these 20 different amino acids that are naturally normally found. So it tells you these sequences are identical. So the N terminal, that's the part that has the nitrogen group on the polypeptide, it says, if you walk your way through that, they are identical on both of the proteins.

And then, similarly, on the way down, PI, for example, is 5.3, et cetera.

Q. Let's look at the next claim limitation, produced in a transgenic plant. Slide 51, please.

Does Deeter disclose recombinant human serum albumin produced in a transgenic plant?

A. Yes, Deeter does.

Q. And what expression system does Deeter use?

A. If you look on the right, that's from Section 16, 0016 in Deeter, where it is stated that another aspect of the invention comprises a method of transforming a rice cell. So the -- that is where the albumin is produced in a rice cell.

Q. Would that fall within claim 12, which recites a transgenic grain?

A. Yes. The rice cell is a transgenic grain cell.

Q. And does Deeter also satisfy the limitation of claim 13, which requires a transgenic grain, that is, transgenic rice?

A. Yes. Again, when you transform, that means it's now -- the product of that is transgenic, and the statement transforming a rice cell by incorporating the DNA, et cetera, that clearly satisfies 13, transgenic rice.

Q. We move to slide 52, and look at the next limitation.

Remind us, does Deeter disclose the level of endotoxin in its recombinant human serum albumin?

A. Deeter itself does not disclose the endotoxin.

Q. Would a person of ordinary skill in the art have been able to readily detect the level of endotoxin in Deeter's recombinant human serum albumin?

A. Yes. At that point in time, analyses were readily available to quantify the amount of endotoxin that was present. So it would be readily measured.

Q. And if Deeter's recombinant human serum albumin had been purified using the guidance of Van Urk, what level of endotoxin would a person of ordinary skill in the art have reasonably expected to achieve?

A. They would reasonably expect to achieve a level where no endotoxin was detected -- and you can see that stated in the middle box on the right -- and that the product would be nonpyrogenic.

Q. Would you still expect to achieve that result if you started with, say, a potentially higher level of endotoxin in Deeter's recombinant human serum albumin?

A. Yes. That would be a capacity issue. You might take either of two approaches, have either a larger column of the chromatography media that removes the endotoxin -- we can get to what that is in a minute -- or you can do a double purification. You can run it through -- run an assay

to confirm or refute that you have reached a low enough level, and, if not, you can repeat on a fresh column the same procedure.

Q. Does Van Urk provide guidance to a person of ordinary skill in the art on how to remove endotoxin from recombinant human serum albumin?

A. Yes.

Q. Now turning to the second reference, if a person of ordinary skill in the art purified Deeter's recombinant human serum albumin using the guidance of Berezenko, what level of endotoxin would a person of ordinary skill in the art have reasonably expected to achieve?

A. Would have expected to achieve a level in the sample, the sample -- where the sample would be essentially free of endotoxin, and that would mean that it's below detectable levels.

Q. And, again, would a person of ordinary skill in the art have understood below detectable levels to be below 1 EU of endotoxin per mg of albumin?

A. Yes, they would.

Q. Does Berezenko provide guidance to a person of ordinary skill in the art on how to remove endotoxins from recombinant human serum albumin?

A. Yes.

Q. Let's look at the last limitation on slide 53,

less than 2 percent aggregated albumin.

Dr. DeFilippi, if a person of ordinary skill in the art purified Deeter's recombinant albumin using the guidance of Van Urk, what level of aggregated albumin would they have reasonably expected to achieve?

A. Yes. Using Van Urk's guidance, they would have expected that there would be less than 1 percent dimeric albumin and no polymers or aggregates that would be detected under those conditions, and, therefore, that would satisfy the less than 2 percent aggregated albumin element of claim 1.

Q. And if a person of ordinary skill in the art purified Deeter's recombinant human serum albumin using the guidance of Berezenko, what level of aggregated albumin would they have reasonably expected to achieve?

A. Again, this is going to be similar, where Berezenko states that there is at least 99.5 percent monomeric and preferably essentially 100 percent monomeric, so that would guide one to see up to 0.5 percent of aggregated dimer. And then he gives you a little more leeway on the bottom where he says there is about 1 percent dimeric albumin, but no larger polymers or aggregates would be detectable.

So, again, even with the higher number, the 1 percent, the Berezenko procedure would give a product that

satisfies this element of claim 1, the 1 (iii), where it is stated that there is less than 2 percent aggregated albumin.

Q. If we go to slide 54, Dr. DeFilippi, can you please summarize your conclusions on claims 1 and 13?

A. Yes. Without going through too much detail, claims 1 and 13 would both be satisfied, as you can see, by Deeter's recombinant HSA, purified by Van Urk or Berezenko.

Q. Thank you, Dr. DeFilippi. I forgot to look at the title of the slide.

Can you summarize your conclusions on claims 1 and 11 through 13 based on this combination?

A. I could certainly do that. The conclusion is the same. 1 and 11 through 13 would have been satisfied by Deeter's rHSA that was purified by Van Urk or Berezenko's procedures.

Q. Now let's move to slide 55.

Dr. Wilken has argued that Van Urk and Berezenko would not be enabled.

Do you recall her arguments?

A. I do recall her arguments.

Q. Now, first, Dr. Wilken argued that Van Urk and Berezenko did not teach a person of ordinary skill in the art how to produce recombinant human serum albumin from a transgenic plant.

Do you recall that aspect of her argument?

A. I do recall that aspect of her argument.
Q. Let's go to slide 56.
Before the '951 patent, would a person of ordinary skill in the art have already known how to produce recombinant human serum albumin from a transgenic plant?
A. Yes. Deeter very clearly states that, how to produce the rHSA from a transgenic plant, and, in specific, rice.
Q. Okay. And what have you summarized here on the left of slide 56?
A. Interestingly, the procedure described by Deeter in 2005 is absolutely identical except for the references mentioned, the figures and the like, to the '951 patent, which is 2010. So from 2005 to 2010 it's the exact identical procedure.
Q. And I take it -- have you highlighted here all the words that are identical in both the disclosure of Deeter in 2005 and the disclosure of the '951 patent in 2010?
A. Yes. And you can take any section you like and do a cross-comparison and you'll see that it's a perfect match.
Q. So would a person of ordinary skill in the art have known how to produce recombinant human serum albumin from transgenic rice based on what was already known without

undue experimentation?

A. Yes, they would.

Q. In the second aspect of Dr. Wilken's tack on Van Urk and Berezenko, she argues that the step of extracting recombinant human serum albumin from a plant would have required extensive experimentation.

Dr. DeFilippi, before the '951 patent, would a person of ordinary skill in the art have known how to extract recombinant human serum albumin from a transgenic plant?

A. Yes, they would.

Q. How much knowledge would a person of ordinary skill in the art have had regarding methods for extracting recombinant proteins from transgenic rice prior to the '951 patent?

A. Preferably a sufficient amount of knowledge.

Q. How would you describe the level of knowledge in the field of extraction of recombinant proteins from transgenic hosts?

A. It's very well known.

Q. Now for transgenic rice in particular, would a person of ordinary skill in the art have known how to extract recombinant human serum albumin?

A. Yes.

Q. And if we go to slide 57, were there reported

methods for extracting recombinant human serum albumin from transgenic rice prior to the '951 patent?

A. Definitely, as you can see with Deeter here, it basically starts with an approach that has been known for a few thousand years, and then matures it down for his particular application.

Q. What are the general steps disclosed in Deeter for extracting recombinant human albumin from transgenic rice?

A. Well, first you dehusk it. As I said, that's been known for a few thousands years. Grind to flour, and that would be the same. And now he adds a little bit additional where you mix, for a period of 30 minutes, with the rHSA extraction buffer, and he lists what the buffer is, and then the following steps he does after that.

Q. Did you listen to the testimony of the inventor on the Deeter patent application, Mr. Scott Deeter, of Ventria?

A. Yes, I did.

Q. Did Mr. Deeter testify about the ease of extracting recombinant proteins from transgenic rice?

A. I believe he did, yes.

Q. Prior to the '951 patent, would a person of ordinary skill in the art have already known how to extract recombinant human serum albumin from transgenic rice without

undue experimentation?

A. Yes.

Q. The third step of Dr. Wilken's attack on Van Urk and Berezenko is that the act of purifying recombinant human serum albumin produced in a transgenic plant would require extensive experimentation.

Do you agree?

A. Extensive experimentation, no, I do not agree.

Q. Okay. And, in fact, in her rebuttal expert report Dr. Wilken said that a person of ordinary skill in the art would not even consider the disclosures of Van Urk or Berezenko when purifying recombinant human albumin produced in transgenic rice.

Do you agree with that aspect of her argument?

A. No, I do not agree with that aspect.

Q. Let's go to slide 58, please.

On the left does Van Urk say whether its process can be used to purify recombinant human serum albumin produced in a transgenic plant?

A. Yes, he is very clear on that. If you look on the left, he is talking about a process for purifying the particular protein we're discussing, of course, the recombinant human albumin, the rHSA. They abbreviate the term slightly shorter, rHA. Same exact protein, however. And then says that they are including rHA produced using

transgenic plants. So that's clearly laid out in that section.

Q. Okay. On the right does Berezenko say whether its process can be used to purify recombinant human albumin produced in a transgenic plant?

A. Yes. The short answer is yes. And then to expand a bit, on the right it is stated the process of the present invention -- again, they are talking about this purification process -- is particularly applicable to purifying recombinant human albumin (rHA). And moving down a little further, DNA encoding albumin may be expressed in a suitable host. And that suitable host, as you jump down further, is described by the expression system where they are saying many expression systems are known, including, and then a number are listed, and it includes plant cells.

Q. Now let's look a little more closely at Van Urk on slide 59.

Does Van Urk provide guidance on appropriate techniques to use to purify recombinant human serum albumin produced in a transgenic plant?

A. Yes, Van Urk does.

Q. What types of steps does Van Urk disclose here?

A. These are chromatography methods and variations on the chromatography, such as what's called cationic exchange. Cationic exchange simply means it's exchanging

positively charged ions and the like. And he lists a number of other systems you need, ultrafiltration and diafiltration and the like.

Q. If we move to slide 60, does Van Urk explain how to use those techniques to purify recombinant human serum albumin produced in a transgenic plant?

A. Yes, Van Urk clearly does. They list all the different steps required, and the various solutions that are employed with these steps, the concentrations in those solutions. So the Van Urk patent -- the Van Urk publication clearly delineates all the steps that are required.

Q. And does Van Urk also explain the preferred order of those purification steps?

A. Yes, Van Urk does.

Q. Does Van Urk disclose the preferred columns to use in each step?

A. Yes, Van Urk does.

Q. And does Van Urk describe the conditions for performing each step?

A. Yes, once again, Van Urk does.

Q. And if you look -- if you read on the right, the heading for table 3 is highlighted.

What is the heading of table 3?

A. That states Chromatography Solutions for the Purification of Albumin.

Q. Can you summarize the type of information that Van Urk disclosed in table 3?

A. Yes. He is telling you the application. For example, he is mentioning the chromatography media, how you deal with the media. Equilibrate it means you get it so it's exactly the way you want it. The constituents are next.

Just as an example, CH3COOH, everybody knows that to be acetic acid. It's neutralized with NaOH. That's sodium hydroxide. He gives the concentrations. Then to the right of that, the pH, which is your level of acidity or basicity, he tells you where to adjust that.

And, as a check, on the right is your conductivity. That just means how easily -- it's an electrical process, and that's basically a check to make sure you made it right. And, just as a short summary, the higher conductivity, in general, the higher the salt concentration.

Q. If we could blow that up again.

If we jump to the column labeled Name, what type of information is identified in this column? For example, what does SP-FF refer to?

A. Yes. That's the Sulphopropyl Fast Flow. Fast Flow is basically a brand name. It tells you that their system works really good. But the SP tells you the chemical

nature of that particular chromatography media.

And perhaps even more important is the DE-FF, which is just below that in the same box. That's the -- the DE is the diethylaminoethyl compound on the surface of these chromatography media. And, again, that describes exactly what you need to know.

Q. Okay. And so --

A. I could go on and on with this. I do that too much. I'm sorry.

Q. Would the abbreviations in this column be associated with specific types of chromatography discussed elsewhere in the text of Van Urk?

A. Exactly correct, yes.

Q. And the SP-FF, I'm not sure I heard the name correctly.

Is that the Sepharose Fast Flow?

A. Well, that's the Sulphopropyl, is what the SP represents. I might be mispronouncing it slightly. It's a sulfur-oxygen negatively charged media.

And when I say media here, it's chromatography media, not to be confused with cell culture media. These darn biochemists can't come up with new names for some reason.

Q. How would you characterize the level of guidance in Van Urk for the purification of recombinant human

albumin?

A. You have all you need to know in excruciating detail.

Q. Does Van Urk provide enough information to guide a person of ordinary skill in the art on how to purify recombinant human albumin produced in a transgenic plant without undue experimentation?

A. Van Urk does, yes.

Q. If we move to the second anticipatory reference, Berezenko, does Berezenko provide guidance on appropriate techniques to use to purify recombinant human serum albumin produced in a transgenic plant?

A. Yes.

Q. What types of techniques does Berezenko disclose?

A. If you want to blow it up a little, but without having -- able to see it, I know what he used. He used the similar media, chromatography media. On the left, number 1, you see S-FF, for example. These are all -- or mostly at the top part is ion exchange, but if you go to number 5, also employs -- no, back to where you were -- right there, 1, 2, 3, 4, 5, on the left. That's gel permeation, which we've discussed a number of times already.

As I said before, you can use it either for purification or for analysis. I've used it for both.

Q. And so, Dr. DeFilippi, does the -- can you read

the title of table 3 of Berezenko into the record?

A. Chromatography Recipes for the Routine Purification of rHA.

Q. In the column identified as Name, are those the different steps of Berezenko's process that are discussed elsewhere in the text of Berezenko?

A. Well, where it says Name, that would be the actual media. I think to the left of that, 1, 2, 3, 4, lines you up with the sequence for the steps.

Q. Thank you for the clarification.

A. You're welcome.

Q. And then does table 3 provide information on how to implement each step of Berezenko's purification process?

A. Yes, it does. Yes, they do. They outline the actual constituent. Those are going to be the salts and the buffers that are present. How much, that's your concentration. GL to the minus 1, that's grams per liter. So you know your concentration. As I said before, you have pH, which indicates levels of acidity or basicity. And the conductivity, which I have also used in the lab also, that double-check to make sure you made it right. It's telling you what the range is.

Q. How would you characterize the level of guidance in Berezenko for the purification of recombinant human serum albumin?

A. How would I describe it? Excruciating detail. He has given you everything you need to know.

Q. So does Berezenko provide enough guidance to teach a person of ordinary skill in the art how to purify recombinant human serum albumin produced in a transgenic plant without undue experimentation?

A. Certainly so, yes.

Q. Turning to endotoxin in particular, Van Urk and Berezenko disclosed specific examples of purifying recombinant human albumin produced in transgenic yeast to remove endotoxin.

Do you recall that disclosure of Van Urk and Berezenko?

A. Yes, I do.

Q. Now does it matter that Van Urk and Berezenko disclose specific examples of purifying recombinant human serum albumin in yeast instead of transgenic rice?

A. No. The protein is identical in all those cases, and, therefore, it's going to behave identically on these various chromatography -- I'm going to use the word resins, that's another term, so we don't mix the media, the chromatography media from chromatography resins.

Q. Would you expect that the same process that removed endotoxins from recombinant human albumin produced in transgenic yeast would also work to remove endotoxin from

recombinant human serum albumin produced in transgenic rice?

A. Yes, it would.

Q. If we could move to slide 62, could you explain why that is?

A. Yes. Well, first, you have to remember endotoxin is a third party. That's produced by a class of microorganisms known as Gram-negative microorganisms. It's part of their cell wall.

So -- sorry.

Q. If I could stop you there just for clarification.

Does that mean that the endotoxin is not produced by the transgenic host, for example? It doesn't come from the rice or the yeast?

A. Yes. And that's my point. The endotoxin is coming from this third-party organism, and, therefore, the host is not the determining factor here. It's the microorganism.

Q. Okay.

A. Yes.

Q. And so if you could just -- I apologize for interrupting your discussion. If you could just, for the Court, explain, in general, what you have shown here on this slide, what type of instrument this is.

A. Yes. This would be -- well, it's not an instrument per se, but it could be. This is a generalized

cartoon, let's say, or flowchart, but we're applying it to separation of endotoxin from albumin. This is your chromatography setup.

On the far left, where you see the body of the column, that's where -- it looks like a fine grain or a fine sand, I should say. It's packed with this fine sand-looking material, but it's a resin. It's got a specific chemical surface. And that is packed in the column on the left, and it's equilibrated. That means it's mixed with a solution of interest, which has already been described. Van Urk lists those solutions you need to use.

So on the top, on the far left where it says "impure solution," you add the compound that's got the mixture of -- sorry -- you add the solution that has the mixture of compounds you want separated.

And then you go to the right to number 2, and you can see where we're mentioning that it's endotoxin and albumin, and the take-home message here is the albumin is moving faster than the endotoxin. That's more clearly shown in number 3, because I'm running fluid down and I'm washing everything that's being applied out of the column, but the endotoxin tends to stick to the chromatography resin. In specific, we're talking about the DEAE, the diethylaminoethyl, as a positive charge, and it grabs the endotoxin, which has a negative charge.

The albumin has less of a propensity to bind to this column under the conditions it's being run, so the albumin is passing through more quickly, that's my right hand here, and the endotoxin is passing down more slowly.

And the end result, as you go to 4 and 5, is that the albumin comes out first with the endotoxin being retarded, held back. And you have a huge amount of endotoxin. This will still get rid of a very high percentage. And then, if you need to, you just collect the albumin, get a fresh column, and start number 1 again.

Q. Thank you, Dr. DeFilippi.

Is the way the albumin flows through this chromatography column going to change depending on whether it was expressed in transgenic rice or transgenic yeast?

A. No, it's not going to change. This is the same albumin from any of these hosts. And, therefore, it's going to be a very -- it's going to function as it passes through the column in a very predictable fashion.

Q. Again, if a process removed endotoxin from recombinant human albumin produced in transgenic yeast would it also work for recombinant human albumin produced in transgenic rice?

A. Yes, it would.

Q. Now is the endotoxin going to interact differently on the column depending on where the albumin

came from?

A. No, because the endotoxin has no association in a chemical or genetic sense with the albumin. It's being produced by the Gram-negative -- the Gram-negative bacteria. E. coli would be one example of Gram-negative microorganism.

Q. And outside of Van Urk and Berezenko, had it been reported that chromatography could remove endotoxin from albumin?

A. Yes.

Q. And if we move to slide 63, a publication by Matejtschuk, which is RX-24, Dr. DeFilippi what is the year that the Matejtschuk publication published?

A. The year it was published was 2000, the year 2000.

Q. And what is being purified in this passage of Matejtschuk?

A. Specifically, the compound of interest is the same. It's albumin.

Q. And what type of impurities are described as being removed?

A. The endotoxins are being removed. And, again, I specifically mentioned the DEAE, the diethylaminoethyl material. In this case he has DEAE Sepharose. You can use DEAE cellulose. There are a number of different kinds. But this is the DEAE Sepharose Fast Flow. Where you see the FF,

that's the Fast Flow Chromatography column. And he is saying the impurities are bound and removed. The albumin is unretained, as I already mentioned previously.

If you go to the bottom, the result of all of this is highlighted where it's stated the concentrations of endotoxin were consistently -- that's a good word to remember -- consistently lowered.

Q. Okay. So Matejtschuk, as you just explained, says that the impurities such as endotoxin were bound, and the albumin is unretained.

And if we'll could go back to slide 62, can you just explain again for the Court what this means in terms of the DEAE chromatography step?

A. Yes. If you just look at the albumin going from steps 1 to 2, this is as the percolation down the column of the solution that contains the albumin and endotoxin progresses, you can see that the albumin is moving down in a more rapid fashion, because it's not retained; whereas the endotoxin, it has a strong interaction, and it might move down slowly, but it is sufficiently slow that it is removed from the albumin.

Q. Okay. And if we go to slide 64, how does the DEAE Sepharose chromatography column in Matejtschuk compare to the purification step of Van Urk shown here on the left of slide 64?

A. Yes. As I had mentioned previously, this is anionic exchange chromatography. That means the anions are the negative charges. And you can see -- which is the same, that's your general heading -- and then preferably the matrix is the commercial anion exchange matrix, DEAE Sepharose-FF from Pharmacia. And, again, the FF means Fast Flow. So it's the same material. Actually, made by the same manufacturer.

Q. How does the Matejtschuk DEAE Sepharose chromatography step compare to the purification step of Berezenko shown on the right of slide 64?

A. You can see it's the same process. Again, without belaboring it too much, it's anion exchange chromatography. And you can see the highlighted portion where it states, preferably the matrix -- okay, here's the third word now -- so it's the media, the resin, and the matrix. These guys can't come up with one word.

So preferably the matrix is the commercial anion exchange matrix, DE, which is exactly the same, they want to save two letters for some reason, DE Sepharose-FF from Pharmacia. It's the same as the DEAE Sepharose Fast Flow. And so it's the same material.

Q. Thank you. Dr. DeFilippi, if a person of ordinary skill in the art wanted to remove endotoxin from albumin, would the process need to change depending on the

source of the albumin?

A. No, it would not.

Q. And if we can move to slide 65, please. Let's turn to aggregated albumin.

Does Van Urk teach a person of ordinary skill in the art how to obtain recombinant human serum albumin with less than 2 percent aggregated albumin using its purification process?

A. Yes.

Q. What does Van Urk say about the level of aggregation that is obtained using its purification process?

A. It's clearly highlighted on the left where Van Urk states there may be up to 1 percent dimeric, but no larger polymers or aggregates are detectable. So those would be less -- sorry -- and the "up to" means it could include the 1 percent or less. There we got it.

Q. And would a person of ordinary skill in the art expect to achieve the same results with recombinant human serum albumin produced in transgenic rice?

A. Yes.

Q. Now does Berezenko teach a person of ordinary skill in the art how to obtain recombinant human serum albumin with less than 2 percent aggregated albumin using its purification process?

A. Yes.

Q. And what was the resulting level of aggregation in Berezenko's process?

A. Well, since, as you can see on the right, Berezenko states that there is at least 99.5 percent monomeric albumin in their preparation, the balance is 0.05 percent, but it would actually be less than that. So below 0.5 percent of polymers and dimers, aggregates and dimers.

Q. And would a person of ordinary skill in the art reasonably expect to achieve the same result of Berezenko if they started with recombinant human serum albumin produced in transgenic rice?

A. Yes.

Q. Now if we go to slide 66, please, and maybe slide 67. Dr. Wilken compared the function of recombinant human serum albumin from yeast and rice in her testimony previously.

And is this one of Dr. Wilken's demonstratives on slide 67, Dr. DeFilippi?

A. Yes, it is.

Q. Is the example she included here from the '951 patent?

A. Yes, it is.

Q. Which products were being compared in this example?

A. These are -- you can see on the title next to the

A, inside of the box, it's a comparison of Cellprime, Seracare, and Cellastim albumin in cell culture, and there's also a negative control included in the text here.

Q. Is Cellprime an albumin produced in transgenic yeast?

A. I believe it is, yes.

Q. Okay. And do you recall that the patent applicant pointed to this example as proof that Berezenko's yeast-produced recombinant albumin was inferior to rice albumin? Do you recall that from the prosecution history?

A. Yes, I do.

Q. And have you seen any evidence that Cellprime is produced using the purification process of Van Urk -- I'm sorry. Let me ask a new question.

Have you seen any evidence that Cellprime was produced or purified using the process of Berezenko?

A. I don't believe so.

Q. Have you seen any evidence that Cellprime was purified using the process of Van Urk?

A. I don't believe so.

Q. Have you seen anything that would link Cellprime specifically to the disclosures in Berezenko?

A. No.

Q. Now how would you characterize the performance of Cellprime that was selected for inclusion in the '951

patent?

A. Well, as we already discussed, there are many different ligands. And so without knowing what ligands are associated with the albumin, it's going to be hard to decide what is coming from what source. In other words, the albumin or the ligands, what is imparting benefits or missing and giving a lack of a benefit.

Q. Would you agree that the data that was selected for inclusion in the '951 patent appears to show that Cellprime is not as good as Cellastim?

A. It would appear from this graphic, yes.

Q. Okay. And, again, Cellprime is produced in yeast and Cellastim is produced in rice?

A. Yes.

Q. Now is the data selected by Ventria for Cellprime representative of the performance of recombinant human serum albumin produced in transgenic yeast generally?

A. It depends on --

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. GIANNELLI:

Q. Ventria relies on a patent to Dr. Yang to argue that Van Urk and Berezenko were somehow deficient in their teaching. So I'd like to look at the Yang patent, which is shown on slide 70.

Dr. DeFilippi, you reviewed the Yang patent at CX-1041?

A. Yes, I have.

Q. Okay. Did anything in the Yang patent change your conclusions about Van Urk or Berezenko?

A. No, it did not.

Q. Okay. Now Ventria points to the quote on the left.

Do you see anything in the quote on the left that would undermine any teachings of Van Urk or Berezenko?

A. No. I see those as commercial aspects, not relating to the inventions.

Q. And I see here it mentions that certain approaches are not suitable for industrialized production either due to low expression level or high production costs.

Dr. DeFilippi, did the claims of the '951 patent require industrialized production?

A. I did not see anything to that effect, no.

Q. And did the claims require low production costs?
A. Also I did not see anything to that effect, so the answer is no.
Q. Do any of the factors addressed in the quote on the left have anything to do with the claims of the '951 patent?
A. Not that I can see, no.
Q. Let's look at the quote on the right, which Ventria also relies on. And here the Yang patent states that, however, due to the substantial differences of the impurities among the rice grain, yeast, and plant suspension cells, those prior art cannot be directly used for separating and purifying rHSA from rice grain.
And so, Dr. DeFilippi, what I'd like to explore is what impurities are being referred to here.
Do you have an understanding of what impurities the Yang patent is referring to here?
A. Yes. Yang is --
MR. HENEGHAN: Objection, Your Honor.
JUDGE MCNAMARA: Just a moment, please. Mr. Heneghan, what's the basis of your objection?
MR. HENEGHAN: My objection is basically foundation. Dr. DeFilippi has no way of knowing what was meant by the word impurities as used in this entry. It's just speculation on his part.

JUDGE MCNAMARA: I think if you can point to language in the specification or the claim or even in the prosecution history, that you need to do, as you know, Dr. Giannelli.

MS. GIANNELLI: Certainly. I should have advanced to the next slide for that last question.

So if we could go to slide 71, please, I think this will all become very clear.

JUDGE MCNAMARA: I'm also going to make a point here. Dr. Giannelli, you have done a lot of leading also.

MS. GIANNELLI: Okay.

MR. HENEGHAN: I've been reluctant to object, Judge, given the time constraints.

JUDGE MCNAMARA: I know. I know. I know you will be mindful of that going forward and try and do less leading and characterization in the questions themselves.

MS. GIANNELLI: Okay.

Q. Dr. DeFilippi, what were the impurities that the Yang patent was focused on removing?

A. His impurities are what are called nontarget proteins. That is also known as host cell protein. Those are indicated on the left.

Q. Now does the Yang patent discuss removing endotoxin?

A. No, the patent does not. The Yang patent does

not.

Q. Does the word endotoxin appear in the Yang patent?

A. It does not appear in the patent, no.

Q. And to be clear, is endotoxin a nontarget protein?

A. Endotoxin is not a nontarget protein. Double negative, but I think it's clear.

Q. All right. Let's discuss aggregated albumin. If you could refer to the quote on the bottom of this slide.

Can you please read that into the record, Dr. DeFilippi?

A. The quote on the very bottom states, the rHSA has a purity of more than 99 percent (monomer plus dimer and polymer) by HPLC.

Q. So does the Yang patent characterize aggregated albumin as an impurity?

A. The patent does not.

Q. Does the Yang patent say anything about whether prior art processes could be used to remove endotoxin from albumin produced in transgenic rice?

A. Endotoxin is not addressed, so no.

Q. Does the Yang patent say anything about whether prior art processes could be used to achieve less than 2 percent aggregated albumin in recombinant human albumin

produced in transgenic rice?

A. I don't believe he addresses polymer separately, no, or the -- yeah, polymer aggregate.

Q. If we look at slide 72, this includes the same passage we saw a couple of slides back.

In the context of the Yang patent, does this passage refer to endotoxin?

A. Are we talking the passage on the left?

Q. My apologies if I misspoke.

Looking at the passage on the right, in the context of the Yang patent, does this passage refer to endotoxin?

A. No.

Q. In the context of the Yang patent, does this passage refer to aggregated albumin?

A. No.

Q. And did anything in the Yang patent impact your conclusions regarding Van Urk or Berezenko?

A. No.

Q. If we could please move to slide 73.

Dr. Wilken also discussed in her expert report disclosures of a publication by Chen shown here, which is JX-24. And, in particular, I believe she quoted the highlighted section. So if you could please read that into the record.

A. The highlighted section -- this is from the year 2013. The highlighted section states, the downstream processing of recombinant biopharmaceuticals varies depending on the properties of the product and the expression system.

Q. Do you recall Dr. Wilken relying on this statement in her arguments?

A. Yes.

Q. Now if albumin is expressed in different systems, would you require a different purification process to remove endotoxin?

A. No.

Q. If albumin is being expressed in different systems, would you require a different purification process to reduce aggregated albumin?

A. No.

Q. Did anything in the Chen publication change your opinions regarding Van Urk or Berezenko?

A. No.

Q. So let's turn to Secondary Considerations. Ventria argued that certain --

MR. HENEGHAN: Your Honor, I have an objection before we get into this. Dr. DeFilippi was not proffered as an expert on secondary considerations.

JUDGE MCNAMARA: That is true.

MR. HENEGHAN: He was identified and he wrote a report, but he was not proffered in this trial for that purpose.

JUDGE MCNAMARA: Was that an oversight, Dr. Giannelli? He was not.

MS. GIANNELLI: I think that the scope of his expertise relates to the real-world considerations. I don't believe that Dr. Wilken was -- I'm not understanding maybe -- let me just give this a moment on the phrasing.

He has certainly a lot of real-world expertise and can evaluate evidence of unexpected results. That's directly in his wheelhouse. And so argument relates to protein purification.

And his conclusions as to the others will be more along the lines of whether or not any of the real-world evidence changed his opinions based on the prior art. And their arguments are all directed to areas within his expertise.

JUDGE MCNAMARA: Mr. Heneghan, your response to that?

MR. HENEGHAN: My response, Your Honor, is that secondary considerations, particularly the way they are presented in this case, present a unique area of expertise, which the Respondent has not -- did not move him in as an expert in that area. Whether or not it was on oversight, I

don't know. But, to me, we accepted him as an expert based upon the scope of their proffer, and this is beyond that scope.

MR. GUARNIERI: Your Honor, the Staff --

JUDGE MCNAMARA: Mr. Guarnieri, go ahead.

MR. GUARNIERI: Thank you, Your Honor. I think this clearly goes to the weight of the expert's testimony. I realize this is a merits issue, but Mr. Heneghan can explore this on cross and establish whatever he wants that he thinks is something he can establish about Dr. DeFilippi's expertise as applied to a subject area, but I've never heard of an expert being proffered on a particular legal doctrine as opposed to just whatever his technical --

JUDGE MCNAMARA: They are all being proffered on particular legal doctrines. Let's face it. Come on. Seriously. Across the board, Mr. Guarnieri.

MR. GUARNIERI: That's true, Your Honor. I suppose what I meant was we generally don't proffer experts for experts in infringement or experts in technical domestic industry. We say expert in -- he is an expert in the particular science in the cases that we're involved in.

JUDGE MCNAMARA: That's not my experience. That may be the correct way to do it. That has not been my experience. And I go back now quite a few years on this.

And quite frequently, if you read the reports and the proffers, we're offering Dr. So-and-so or so-and-so on infringement and on these -- their CVs give you their technical background, but they are quite clear in the record what they are offering for on the legal topic.

So, with all due respect, it doesn't really -- it may seem like semantics, but I have thought about this from the beginning. I have never seen such a huge crossover in any area of law that I've worked in than the expression and the provision of what amount to sometimes mixture of law and fact and, often, just pure legal conclusions.

But, in any event, I'm going to take it under advisement, Mr. Heneghan, and it will go to the weight of the evidence and how I evaluate the credibility of the experts.

MR. HENEGHAN: I would just say now, then, Judge, I understand that and that's -- of course that's fine, but I will cross-examine him but without waiving that objection, if that's okay.

JUDGE MCNAMARA: Well, that's going to be a hard one. That's a hard one to tread, but you can see if you can do that.

MR. HENEGHAN: Thank you.

JUDGE MCNAMARA: Mr. Guarnieri, I'm not saying that to embarrass you, but every single -- every single

brief I see coming across my desk involves experts opining on infringement and invalidity and on the legal topics per se. That's the way it's been done here from the very beginning.

MR. GUARNIERI: I understand, Your Honor.

JUDGE MCNAMARA: I know you do. It's not just semantics. I think from the beginning I looked at this. The same thing with a person of ordinary skill. Even this day, after all the years I've heard this, I keep going, who -- I know who defined it, but it's, come on, everybody disagrees even -- I'm sorry -- about plain and ordinary meaning. Everybody disagrees about that. And that's often a mixed question of fact and law.

So, in any event, let's keep going, Dr. Giannelli. I've taken this under advisement, and it's provisional.

MS. GIANNELLI: Okay. Thank you, Your Honor. This is Max Giannelli on behalf of Healthgen again. I will say that, as part of his role evaluating validity and obviousness, secondary considerations are a required component of that. So we had to show him their arguments so that he can be exposed to them. Otherwise he wouldn't have all the information that he needed to address obviousness. It's all part of the same analysis.

So, with that in mind...

Q. If we could have --

THE WITNESS: If I could just make one statement for the court reporter? My name is DeFilippi. People have mixed it up a little bit. Just so she knows the correct word. I don't mind people mispronouncing and drop off the "De" all the time. That's not an issue. I just want to make sure -- I think, as Al Capone said, you can say anything you want, but get my name spelled correctly. Thank you.

JUDGE MCNAMARA: A lot of good that did him ultimately.

THE WITNESS: No relation. No relation.

JUDGE MCNAMARA: Okay. I think we have it. Thank you, Dr. DeFilippi.

THE WITNESS: You're very welcome.

Q. Mr. Fisher, if we could go back to slide 74 of RDX-1C, and secondary considerations on slide 75.

Dr. DeFilippi, you recall that Ventria argued that certain real-world evidence supports the nonobviousness of the claims of the '951 patent?

A. I do recall that, yes.

Q. Did any of the arguments that you considered from Ventria or Dr. Wilken change any of your opinions on the obviousness of the claims?

A. No.

Q. Now looking at the first factor, Ventria argued that removing endotoxins was unexpected.

Do you agree with Ventria?

A. From a technical standpoint, no, that was not an unexpected result.

Q. Why is that?

A. Because it had already been shown in multiple publications that it could be done and how that end would be achieved in a scientific fashion.

Q. Ventria also argued that there was a long-felt unmet need for nonanimal human serum albumin.

And my question -- do you recall that argument?

A. I do.

Q. Was recombinant human serum albumin from nonanimal sources commercially available prior to the '951 patent?

A. Yes. And, of course, the yeast-derived product is the perfect example of a nonanimal source of the recombinant human serum albumin, the yeast expression system. I don't know if I said that.

Q. And in fact was recombinant human albumin from transgenic rice already commercially available prior to the '951 patent?

A. Yes, that also, yes.

Q. Now Ventria also argued that others had failed to

produce proteins in plants.

Do you recall those arguments?

A. Yes.

Q. Do you recall seeing any evidence that others had tried and failed to make recombinant human albumin meeting the limitations of the claim of the '951 patent?

A. Outside of rice, no.

Q. Did any of Ventria's arguments or evidence regarding failures of others to produce proteins in plants change any of your conclusions in this case?

A. No.

MS. GIANNELLI: For a very brief discussion of commercial success, we need to go on the Ventria confidential record. And I can confirm that we have no participants from Healthgen.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. GIANNELLI:

Q. Dr. DeFilippi, did any of the evidence cited by Ventria or Dr. Wilken regarding real-world evidence or secondary considerations change your conclusions regarding the obviousness of claims 1 and 11 through 13 of the '951 patent?

A. No.

MS. GIANNELLI: Your Honor, I pass the witness.

JUDGE MCNAMARA: Okay. Thank you. I think now might be a good time to take a break. It's 11:20, approximately. So why don't I see you back here at about 25, 26 before 12.

(Proceedings recessed at 11:21 a.m.)

(In session at 11:41 a.m.)

JUDGE MCNAMARA: Good morning, everyone. I guess it still is.

Mr. Heneghan, you're up?

MR. HENEGHAN: I'm off the mute now.

JUDGE MCNAMARA: Mine has been acting -- I've just been having difficulty with mute and unmute and video the last couple of days. I'm not sure why. Who knows. As long as it works.

CROSS-EXAMINATION

BY MR. HENEGHAN:

Q. Dr. DeFilippi, did you observe Dr. Wilken's testimony on Friday?

A. Yes, I did.

Q. So you heard her testimony about her experience in the lab with transgenic plants, correct?

A. Yes.

Q. You do not have that type of experience, do you?

A. I do not have that type of experience with transgenic plants, correct.

Q. Looking at your slide from your direct of your experience, none of that experience applies to plants, right?

A. That would be a correct statement in a sharp focus, yes.

Q. Well, I intend to stay in a sharp focus this whole time, so we'll start with that.

You do not have experience producing or purifying recombinant proteins expressed in plants, do you?

A. I do not.

Q. You haven't ever done any work or research developing any genetically modified plants, have you?

A. I have not.

Q. You also haven't ever done any actual research

yourself in the field of the production of recombinant human serum albumin in transgenic plants, have you?

A. With that sharp focus, correct, yes.

Q. You have never used recombinant human serum albumin for cell culture, have you?

A. I may or may not have. I have not used it hands-on, but other people in the lab possibly could have, but I believe not. Let's just say no. That would be the most honest answer.

Q. Well, let me refresh your recollection.

Do you recall having your deposition taken on July 30th of this year?

A. I do, yes.

Q. I asked you some questions. We were on video, and I asked you some questions, and you answered them under oath, correct?

A. Completely correct, yes.

Q. Let's turn to page 143 of that deposition, pages 19-21.

Ms. Hitchens, if you could play clip 11, please.

(Video clip played)

Q. Have you ever used recombinant human serum albumin for cell culture?

A. Have I personally? No.

(End of video clip)

Q. Does that refresh your recollection about whether you have ever used recombinant human serum albumin for cell culture?

A. Yes. And it's basically what I just said, yes.

Q. We can take that clip down, Ms. Hitchens.

And you've never used recombinant human serum albumin produced from rice, right?

A. I have not, correct.

Q. Can we take that clip down? Thank you.

And you've never worked with a plant-derived recombinant human serum albumin aside from this case, right?

A. Correct.

Q. And for this case you did not physically handle either Ventria's products or Healthgen's products at all, correct?

A. Correct.

Q. Now you would agree with me that scientific knowledge about the topics discussed by you in your report changes over time, right?

A. Science always changes, correct.

Q. But you did not do any independent research or investigation to determine whether your opinions were current and accurate or supported in the literature, did you?

A. I did look through the literature to answer

various questions, and some of the publications were more recent and some of the publications were older.

Q. Let's go back to your July 30th deposition again, then.

Ms. Hitchens, can you play clip number 2, please.

(The following video clip was played:)

Q. What I'm specifically interested in is your actual opinions in this case and whether or not you did any independent research or investigation to determine whether or not your understanding and belief about the issues in this case was current and accurate and supported in the literature?

MS. GIANNELLI: Objection, form.

A. I did not take that approach.

(End of video clip.)

Q. We can take that clip down now, Ms. Hitchens. I will move on to my next question.

A. I just point out that's not inconsistent with what I just said. Subsequent to that I have done a little more work. So there is no inconsistency. That was at that point in time.

Q. Well, you have not done any work regarding albumin or recombinant albumin since 1972, correct?

A. I'm sorry. You're really going to have to define "work." Are you talking work in the laboratory or other

kinds of work? Please define your question a little more carefully for me, please.

Q. Are you having trouble understanding that question?

A. I have a tremendous ability to understand the question, and I also understand that the question is not really as precise as it could be, if I want to give a precise answer.

Q. Okay. Well, let's go to your first deposition in this case.

Do you recall that on May 3rd, 2021, you gave a deposition during the claim construction phase of this case?

A. Yes.

Q. And my colleague Matt Kamps was asking you questions at that time.

Do you recall that?

A. He may have. I don't remember the name.

Q. Okay. And you answered those under oath, correct?

A. Absolutely I did, yes.

Q. So let's look at page 138, beginning at line 16, and going to line 21.

Ms. Hitchens will blow that up for us in a second.

The question there, beginning at line 16 is:

Okay. My question, though, was since 1972, have you done any work either as a consultant or in an academic capacity about albumin generally and more specifically recombinant albumin?

Answer. No.

That's what you were asked then and that's what you answered then, correct?

A. Correct.

Q. I'd like to now turn to some of the slides that you presented during direct examination. I'd like to ask you a few questions. Let's start with your slide 10 from your direct examination.

You recall this slide, don't you, Dr. DeFilippi?

A. Yes, I do.

Q. And in your testimony you pointed out the fatty acid binding sites in the figure on the right, correct?

A. Yes, I did.

Q. And those fatty acids are coming from the host, correct?

A. Not necessarily. They could be coming from the host.

Q. Well, while the amino acid sequence is the same regardless of the host, the albumin is not always the same, correct?

A. Say this again.

Q. While the amino acid sequence is the same regardless of the host, the albumin is not just the same, is it?

A. The albumin is exactly the same, not the albumin plus any of a dozen or more different ligands. Those are two different things. The albumin is not changed, the albumin.

Q. The amino acid sequence doesn't change, right?

A. The amino acid sequence does not change, correct. And that was demonstrated, as you well know.

Q. But the ligands bound to the albumin depend on the host, correct?

A. No, that is not correct.

Q. And there are, I think as you just said, dozens of ligands, if not thousands of ligands, that an albumin can bind, correct?

A. I'm not going to go up to thousands. There are quite a few ligands known to bind, and one can postulate that there are other unknown ligands that would also bind. One example would be like ibuprofen. Before ibuprofen existed, it did not bind to albumin, but, once it did exist and people researched it, they found out it bound to albumin.

Q. Can we agree that there are many, many ligands both known and unknown?

A. I would agree with that comment, yes.
Q. Now let's look at your slide 11 from your direct, and I have a question for you.
You used this slide to say that the rHSA in these two examples are identical, but there is no value in these for endotoxin, is there?
A. There is no endotoxin presented, because this is talking about the albumin, not materials associated, potentially associated, with the albumin. So that is correct. The endotoxins are not mentioned at any point on these two tables.
Q. So your answer is yes? There's no endotoxin?
A. I believe that would be the short answer, yes.
Q. Let's try to stick with the short answers, if we can.
A. If we can, I shall.
Q. There's also no value for either of these boxes for albumin, is there?
A. These are biochemical properties of the albumin being tested. So your question is non sequitur. It's not answerable.
Q. Well, isn't the short answer that, yes, there's no albumin value reported?
A. No. The answer is no. They all relate to albumin.

Q. The only thing about these two tables that's identical are just the nine properties listed, right?

A. It's only listing what it's missing. To me, that's an odd question. It's not listing what it's not listing, so that is correct, it's not listing what it's not listing.

Q. Let's go to your slide 13. I assure you I'm not going to go through all 77 slides one by one. I promise.

A. I thank you for that.

Q. Your slide 11 is this FDA guidance document. Do you recall that?

A. Yes.

Q. And it talks about sterile drug products?

A. Yes.

Q. Cellastim is not a drug product, right?

A. As far as I know, it's not, but, again, I've already said before, don't give me brand names too much because I don't always recall. I know the biochemistry.

Q. Well, this guidance has nothing to do with Cellastim; is that fair?

A. This has to do -- let me look at it -- there's no mention of Cellastim. I think that's the correct answer.

Q. Would you agree with me that if Cellastim is not a drug product, this FDA guidance on drug products is irrelevant to Cellastim?

A. No, because one conceivably could at some point use a particular brand name compound in other applications.

Q. Is it your belief that experts in the field on which you are opining would rely upon this kind of reference in relation to something that's not a drug product?

A. One has to rely upon all the data available. So they would rely upon this in making a decision.

Q. Let's look at your direct slide 14. This is the reference to that EMEA document.

You recall that, right?

A. Right. That's the European Medicines Agency evaluation document, yes.

Q. And if we look in the lower blown-up box, the one that says Recombumin 20 percent, do you see the highlight on the bottom, the bigger box on the bottom?

A. Yes, I do see that.

Q. At the end of the first line, there's a product in italics.

That's a yeast, isn't it?

A. Saccharomyces cerevisiae is definitely a yeast, yes.

Q. And Recombumin 20 percent.

Recombumin is the product of the Van Urk and Berezenko references, isn't it?

A. It is likely, because it's the same company,

which is Delta Biotechnology Limited, but I don't know -- excuse me, let me finish the sentence --

Q. Of course.

A. -- I don't know -- sorry?

Q. I didn't mean to interrupt. I'm sorry.

A. Oh, okay. Yeah. It's from the same company, but I can't say for a fact it was used in their product. One can speculate it was.

Q. Along the same lines, the Van Urk and Berezenko references are from the same research group, right?

A. I believe I just said that. They are both from Delta Biotechnology.

Q. Let's take a look at your direct slide 15.

Now this is a different product, but also a yeast product, correct?

A. Well, it's a product produced by a different manufacturer, and it is also, I believe -- it probably says it somewhere -- is a yeast product.

Q. Well, if you look at the sort of blow-up in the page in the middle, the first item in the left-hand column is Production System.

Do you see that?

A. Yes. Now I can see it. I could not see it previously. Yes, I see it.

Q. I understand. It's pretty small.

A. Thank you.
Q. I knew where to look, so I knew where it was.
A. There you go.
Q. And Pichia pastoris, that's also yeast, correct?
A. Definitely. That's a different species, different genus of yeast, yes.
Q. And when we look in the right-hand column, under purity you had highlighted where it says "low endotoxin"?
A. Correct.
Q. But we don't really have a value for endotoxin? It just says low.
A. Correct.
Q. And this is a sales catalog, right?
A. As far as I know, it is. I call these things tear sheets. You tear it out and hand it to the customer.
Q. So it's not an analytical document or a scientific document? It's a marketing document; right?
A. Well, it describes what the product is to the customer. It's in a catalog.
Q. Let's look at slide 40 from your direct presentation. As I said, we're not going to look at every one. We're going to jump ahead.
A. Very good.
Q. This is the slide where you pointed out that Van Urk makes mention of corn as a grain.

And corn is a grain, of course. We agree with that, right?

A. Yes. It's one of the three major cereal grains is how they usually define it.

Q. But Van Urk has no -- explains no process specifically for expressing the product from the corn, does it?

A. From the point of view of genetics and expression, he does not specifically describe the genetics -- the way to get the gene into corn. I believe that is correct.

Q. And also Van Urk provides no process for purifying the product expressed from the corn, specifically for corn, does it?

A. He already states it can be used, his purification process, can be used in plants. And my read of Van Urk gave me no indication that it could not be used for the purification of recombinant HSA produced in plants.

Q. And that's based upon all of the documents you reviewed for your opinions in this case, right?

A. Well, plus my experience in purifying numerous proteins.

Q. Let's turn our attention to the Berezenko reference, okay?

A. That's fine.

Q. Now just to confirm, you are not claiming -- let's talk about just anticipation first.

To confirm, you are not claiming that claims 12 or 13 are anticipated by Berezenko, correct?

Let me show you --

A. I just blanked on the claim.

Q. That's okay. Let me show you the opening slide 40 from the Healthgen presentation, the opening slide, not the direct slide --

A. Oh.

Q. -- from the opening statement.

So this shows that Berezenko is only being offered as anticipation of claims 1 and 11, meaning that it's not being offered for anticipation of claims 12 and 13.

You agree with that, right?

A. Yes. That's how we presented it, yes. I presented it.

Q. So Berezenko in claims 12 and 13, that's a settled issue.

Berezenko does not anticipate claims 12 and 13, right?

A. It's not addressed at any level, so yes.

Q. Right. You're not offering that opinion?

A. Concerning Berezenko, yes.

Q. Okay. Now the Berezenko reference is directed to

a human serum albumin product derived from yeast, correct?

A. Say this again.

Q. Sure. The Berezenko reference is directed to a human serum albumin product derived from yeast, right?

A. Well, that plus directing towards the ability to use their purification process for yeast produced in many different production strains -- we call these production strains -- and including plant cells.

Q. I understand that's your opinion. But the Berezenko reference is about expressing rHSA from yeast, right? That's the top -- the general topic of that reference?

A. Well, the general topic, but it's applicable to more than just yeast.

Q. Okay. You agree with me that yeast is not a plant, right?

A. It is currently not classified as a plant. Fifty years ago there was considered overlap, but that's found not to be the case.

Q. Well, let's leave 1972 in 1972.

Now, at this point, yeast is not a plant, correct?

A. Well, it's been redefined more than that. There are protists and eukaryotes and the whole bit, but, yes, if you look at the branch, and I could pull one up at some

point in the future to show you, of course, we wouldn't pull it up now, you can see on the evolutionary scale it's right next to the plants, but it is not a plant itself.

Q. Plants and yeasts are different kinds of organisms, aren't they?

A. They are, yes.

Q. And one of the differences is that rice is grown in a field exposed to the elements and unprotected from contaminants and impurities, right?

A. Believe it or not, the exact same phrase can be used for yeast, the way you said it, but I understand where you're going. Go to a vineyard and I will show you yeast growing in the field unprotected exactly the way you just described it.

Q. Is that the kind of yeast that Van Urk and Berezenko refer to when they talk about their process?

A. Yes --

Q. Grown in a field, in a vineyard?

A. Yes. Saccharomyces cerevisiae is the yeast. The way your question is phrased, my answer is correct. Ask me a different question, you might get a different answer.

Q. The yeast that is used in the Van Urk and Berezenko references is not grown in a field and then used in that system, is it? It's grown in a lab in a sterile environment and then put into a closed system with vessels,

right?

A. When they apply it to their system, that is correct. But trust me, yeast is grown in the field, as I said. We're belaboring the point. You can proceed.

Q. The yeast in Berezenko and the yeast in Van Urk starts out without the impurities that rice picks up in the field in this specific context, right?

A. No. It would have impurities that the rice grown in the field would have.

Q. Well, Healthgen's Dr. Yang, in one of his patents, acknowledges the difference between the process for yeast and the process for plants, correct, in particular, rice, correct?

A. I believe that's correct.

Q. Let's call up CX-1041, please.

A. The computer people have to come in. I now have the middle part of my screen asking me to do an update, and I don't want to touch it. I will destroy the system. So someone who knows what they're doing, please come in and X that puppy out. I don't know. I'm not touching anything. If you want things screwed up, I can do it.

Q. Dr. DeFilippi, in my experience, the relationship between when the update pops out and how soon I have to be somewhere is always correlated.

A. There we go.

JUDGE MCNAMARA: Dr. Giannelli, can you have someone from your team take care of that?

THE WITNESS: It's already taken care of. Thank you. One of the two main problems, the other one is minor. So we're fine. We can move forward. They ran in like crazy. You didn't see them, but they came very quickly.

Q. Dr. DeFilippi, Exhibit CX-1041 is up on the screen now.

Do you see that?

A. Yes, I do.

Q. And that is Dr. Yang's '107 patent. It's U.S. Patent No. 10,428,107.

Do you see that?

A. Yes, I do see that.

Q. And the lead inventor on that patent is Healthgen's Dr. Yang, right?

A. I see the name Yang, et al., and then under Inventors Daichang Yang, it says Hubei (CN). That's the description there.

Are you asking the assignee?

Q. No.

A. Okay.

Q. That was my next question.

The assignee of that patent is Healthgen, right?

A. Healthgen Biotechnology Company Limited, yes.

Q. So Ms. Hitchens, could we go to column 2 of the '107 patent, and let's highlight lines 25 and 26, and then also 33 through 36.

We'll get this highlighted and I'll ask you a few questions, Dr. DeFilippi.

Do you see the highlighted portions of the specification of the '107 patent?

A. Yes, I do.

Q. So in order to get the '107 patent, Dr. Yang and Healthgen acknowledge at lines 25 and 26 that, quote, at present, the techniques for extracting rHSA from yeast and plant suspension cells have been reported.

Right? That's what they say there.

MS. GIANNELLI: I'll object to the wind-up in the question as assuming facts not in evidence or just including an improper assertion about including something in order to get the patent.

JUDGE MCNAMARA: I need to look at the question, because I think maybe I heard something -- I heard something different. Let me just go back to the transcript.

MS. GIANNELLI: The language I was objecting to is just "in order to get the '107 patent."

JUDGE MCNAMARA: Oh, I see. Yes.

MR. HENEGHAN: I'll rephrase, Judge. That's fine.

JUDGE MCNAMARA: I think that's a good idea. Thank you.

MR. HENEGHAN: No problem.

Q. Dr. Yang and Healthgen make a representation in the specification of the '107 patent at lines 25 and 26 of column 2 that, quote, at present, the techniques for extracting rHSA from yeast and plant suspension cells have been reported.

That's what they say, right?

A. That is what is written there, correct.

Q. Okay. And then farther down Dr. Yang and Healthgen include in the specification of the '107 patent, quote, due to the substantial differences of the impurities among the rice grain, yeast and plant suspension cells, those prior art cannot be directly used for separating and purifying rHSA from rice grain.

Isn't that what that says in Dr. Yang's '107 patent?

A. That is what that says -- what is it -- from lines 33 through 36 in this particular column, yes.

Q. Dr. DeFilippi, during your direct examination Dr. Giannelli asked you if you had identified any prior art, and you said you did.

Do you recall that?

A. Yes.

Q. That's not true, is it?
A. That is not --
MS. GIANNELLI: I'll object because I don't believe that Mr. Heneghan has properly quoted any question that I asked during my direct examination.
JUDGE MCNAMARA: What's the quote again, Mr. Heneghan?
MR. HENEGHAN: The quote is, Dr. Giannelli asked Dr. DeFilippi if he had identified any prior art as part of his opinions, and he said that he did.
JUDGE MCNAMARA: I'm sorry. Go ahead, Dr. Giannelli. What's your objection?
MS. GIANNELLI: I was wondering where that is in the transcript, and I believe the question I asked was if he had identified any art that I anticipated -- any anticipatory art.
MR. HENEGHAN: I'm happy to limit my question to that, Judge. I wasn't trying to get broader than that.
JUDGE MCNAMARA: Okay. Then let's go there.
Q. Dr. DeFilippi, during your direct examination Dr. Giannelli asked you if you had identified any art as an anticipatory reference, and you said you did.
A. Yes.
Q. That's not true, is it?
A. Well, I'm talking about such art as Van Urk and

Berezenko.

Q. And my point is the three prior art references that form the basis of your invalidity opinions, Van Urk, Berezenko, and Deeter, I'm sorry, and Deeter also is obviousness, were provided to you by counsel.

You did not identify them, right?

A. Oh, you see, I would interpret that concerning independently, did I independently discover those or did I discover those independent of counsel, no, but one always talks with counsel on these subjects. Indeed, this was presented to me by counsel, but there are other items that I came up, and sometimes I don't remember where they came from.

In this particular instance, Van Urk and Berezenko, those had been presented to me for my consideration.

Q. And for the obviousness analysis, also Deeter was presented to you by counsel, right?

A. For my consideration, yes.

Q. Let's talk for a minute about a document counsel didn't give you. We talked a little while ago about Dr. Yang's '107 patent, Exhibit 1041. We're now putting up on the screen CX-1063. Once we get it up on the screen I'll ask you a couple questions about it.

You can see Exhibit CX-1063, doctor?

A. It says that in the upper right corner, yes.
Q. And this prosecution history document is one that you did not review in forming your invalidity opinions, correct?
A. Well, I have not seen this cover, so I assume the balance I had not seen either, yes.
Q. Well, we can take a look at your materials considered list from your report, or you can just take my word for it that it's not on there.
A. I will take your word for it.
Q. Thank you.
A. And I mean that sincerely. I don't think you're making things up, of course.
Q. Now let's turn to page 401.
MS. GIANNELLI: Before -- could we go back to the first page? I was having trouble seeing the date on the document. Can we go back to the first page just for a moment?
MR. HENEGHAN: We'll blow it up so you can see it.
MS. GIANNELLI: I was just trying to see the date. I'm sorry. Sorry, Tom.
JUDGE MCNAMARA: For the record, it's August 10th, 2011 that it's signed. Is there a different date? Because I couldn't see. The print is so small. That's what

jumped out at me. Is there a different date on it?

MS. GIANNELLI: I think that might be the only date, so I think that answers my question. Thank you, Your Honor.

BY MR. HENEGHAN:

Q. Let's turn to page 401 of Exhibit CX-1063, and blow up the last paragraph on that page and highlight it starting on the fourth line, starting with the words, quote, the Examiner, then to the end of the paragraph.

Do you see that, Dr. DeFilippi?

A. Yes, I do see that.

Q. In the fifth highlighted line, do you see the reference -- I'm sorry, the fifth line altogether, the second highlighted line, the reference to yeast Pichia pastoris?

A. I see the term Pichia pastoris, yes.

Q. And that's yeast, right?

A. That is a species of yeast, correct.

Q. Then in the third line of the highlighted portion there's a sentence that begins, the first Yang declaration.

Do you see that?

A. Yes.

Q. That tells us that Dr. Yang submitted a sworn declaration to the Patent Office in relation to the prosecution of this patent, right?

A. I don't know.
Q. You're familiar with patent prosecution, aren't you, doctor?
A. Yes. Yes.
Q. And you know that inventors sometimes submit declarations to Patent Office to answer questions that come up during prosecution?
A. Yes. And I've actually submitted a few declarations -- well, my attorney at the time did, yes.
Q. Or to respond to Office Actions based on rejections to try to overcome those rejections, right? That's standard operating procedure, isn't it?
A. Almost invariably, yes.
Q. So here we have a reference to the first Yang declaration. So we can assume that -- I keep saying Yang -- Dr. Yang submitted a sworn declaration under penalty of perjury just like all declarations are, right?
A. Right. I didn't realize this was a submission to the Patent Office. Yes, now I know exactly what you're talking about, yes.
Q. Because you haven't seen it before. I understand. It's not your fault.
So it says the first Yang declaration actually demonstrates that when the methods in Ohmura, which was a prior art reference that was being discussed, are used to

purify recombinant human serum albumin from a crude extract from the transgenic rice grain, the purity and yield are much inferior to that obtained using the presently claimed methods.

Do you see that?

A. Yes, I do see that.

Q. And you were not provided with this reference, were you.

A. I don't recall having seen it, so that would be correct.

Q. You did not consider this reference in forming your opinions on validity or the disclosures of the Van Urk and Berezenko reference, did you?

A. Yes. But I also must point out they are not addressing endotoxins when they are presenting terms such as purity and yield, and they are not presenting dimers, polymers, aggregates. So absent the clarification, it's hard to determine what the situation was here. I suspect they're talking about host cell protein, which is not part of the claims we're discussing.

Q. Based upon your review in the last five minutes.

A. Based upon my review, period, I see no mention of endotoxin.

Q. But you never considered this document in your opinions in this case.

A. I hadn't seen it. If it had been presented to me, I just don't recall having seen it. That's the honest answer.

Q. Fair to assume that Healthgen had this document? It's their patent.

A. Well, if it's their patent, I don't see how they would not have it. But, again, discussing endotoxins, et cetera.

Q. But they didn't see fit to give it to you?

A. I don't know -- sorry.

JUDGE MCNAMARA: I don't know how he answers that one, Mr. Heneghan.

MR. HENEGHAN: I'm sorry, Judge. I withdraw that question. I'm sorry.

Q. Let's look back at CX-1041. That's the Yang '107 patent that we looked at a little while ago. And if you look at -- there's a section called, in the left-hand column, called unrelated application -- I'm sorry -- Related Application Data.

A. You're going to blow this up for me, I hope.

Q. We are. Me too.

A. Okay. Please proceed. I'm sorry.

Q. And so you can see from this that there is a reference to application number 14/676,727.

Do you see that which is highlighted?

A. I see that portion highlighted, which is what you just read, yes.

Q. So that application shows or this representation shows that the '107 patent was a continuation of that earlier application, right?

A. That appears to be correct, yes. Don't ask me too much about patent -- the law and subtleties. I've had over a dozen patents, but I try to avoid that part as much as possible.

Q. I promise we won't get into what's a continuation, what's not, all that kind of stuff.

A. Continuation-in-part as well, so...

Q. Let's go to CDX-6.14, which is a slide that we prepared for this examination, a demonstrative slide.

So this slide shows, on the left-hand side, part of the first page that we were just looking at of the '107 patent. It shows that patent number, ending in 727 -- I'm sorry -- the application number ending in 727. And on the right we have a page out of the 727 application. You can see that. It's got a red box around it.

Do you see that?

A. I'm taking your word for it. It's just barely discernible to me.

Q. Okay.

JUDGE MCNAMARA: To me too. There we go.

MR. HENEGHAN: We're blowing it up, Judge.

THE WITNESS: A little better. With significant squinting, I should be able to read, yes.

Q. Let me just put in the record. What's blown up here is a page from Exhibit CX-1065, in particular, page 511 of the history of the 727 application, which is cited on the front page of the Yang '107 patent.

Okay?

A. (Nodding head up and down.)

Q. Now let me ask you some questions about that right-hand box.

A. Sure. You're going to blow up again, correct?

Q. We are.

A. There we go.

Q. We're in the process of doing that right now.

Now this, again, is a document you did not see before, right?

A. As far as I can recall, that is correct.

Q. And if we look at -- in the yellow highlighted part, there's a sentence that is underlined and in bold. Do you see that? It says, but the first Yang declaration specifically addresses the very point and proves it false.

Do you see that?

A. I see those words, yes.

Q. Okay. And then in the green highlighted part, a

couple lines down, this reference says, thus, the same protein purification procedure does not necessarily achieve the same or even similar results using different host sources.

Do you see that?

A. I see those words, yes.

Q. So in the 727 application, Dr. Yang and Wuhan Healthgen submitted a declaration to the Patent Office that stated that yeast-expressed protein purification systems are inapplicable to plant-expressed protein purification systems, didn't they?

A. No. No. I don't see that.

Q. Well, let's read the part that's highlighted in orange. At the bottom of this excerpt from page 511 of the 727 prosecution history for the 727 application:

"Between, 1, actual experimental data supplied in the first Yang declaration sworn under the penalty of perjury, and, 2, mere speculation based on a false belief pointedly disproved by the actual data, the Examiner has unfortunately chosen to rely on the mere speculation. Reconsideration is requested."

And aren't they talking about the mere speculation that you're also engaging in relation to what the Van Urk and Berezenko references disclose?

A. The keyword is "speculation" now, isn't it?

Q. Yes, it is.

A. Well, I'm basing my comments on my experience involving protein purification, and what I said is consistent with my experience, which is not the same as speculation. As a matter of fact, it's a bit separated from speculation. I'm -- it might be a more proper term.

Q. In arriving at your opinions in this case, you did not consider these two references authored and sworn to by Dr. Yang and Healthgen and presented to the Patent Office? These were not given to you for your consideration, right?

A. I did not -- again, as I said before, I do not recall having seen these particular publications.

Q. And other than Dr. Yang's patent itself, you are not aware of any peer-reviewed literature that discusses taking a purification system used with one transgenic species and using it with a different transgenic species, are you?

A. Say this again.

Q. Sure. Other than Dr. Yang's patent, you are not aware of any peer-reviewed literature that discusses taking a purification system used with one transgenic species and using it with a different transgenic species, are you?

A. Offhand, I do not recall having seen such a publication.

Q. You're not aware of any.
A. Offhand, I do not recall having seen such a publication.
Q. And you certainly don't identify any such publication in any of your reports, right?
A. I believe that is correct.
Q. Dr. DeFilippi, I would like to turn your attention to the Van Urk reference now.
Okay?
A. That's fine.
Q. You are also claiming that Van Urk is an anticipatory reference, right?
A. Yes.
Q. And just to confirm, you're not claiming that claim 13 is anticipated by Van Urk, right?
A. If I recall correctly, right.
Q. That is a settled issue. No anticipation of claim 13, right?
A. Well, no anticipation, yes.
Q. The Van Urk reference, like Berezenko, is directed to a human serum albumin product derived from yeast, right?
A. Right.
Q. And at least for the portions of Van Urk and Berezenko that you cite for your anticipation opinion, these

two references are basically identical, aren't they?

A. I would say they are very similar.

Q. You were here for the opening statements on Thursday, weren't you?

A. Yes, I was.

Q. So let me show a slide that we made that is based upon the slide 39 in Healthgen's opening. When I say based upon, it's just -- I'm sorry, slide 39 from the opening -- our demonstrative 6.3.

Sorry about that. A little miscommunication between Ms. Hitchens and I. Certainly my fault, no question. Our 6.3 -- the computer is a little slow. Sorry, Judge.

Judge, could I just take one minute to confer with Ms. Hitchens? I think my numbering is out of order somehow.

JUDGE MCNAMARA: I'm going to blame the time change.

THE WITNESS: It gives me an opportunity to get a sip of water.

JUDGE MCNAMARA: Sure.

THE WITNESS: Thank you.

JUDGE MCNAMARA: We're now at 12:30. Mr. Heneghan, would this be a good time to stop for lunch or is it just too early yet?

MR. HENEGHAN: It's not too early, Judge, and maybe I can get better organized.

JUDGE MCNAMARA: Why don't we stop for lunch, and I'll see you back here in 45 minutes. So it will be about 13 past 1:00. So we're taking a shorter lunch break. So I will see back here then.

MR. HENEGHAN: Thank you, Judge.

MS. GIANNELLI: Thank you, Your Honor.

(Proceedings recessed at 12:28 p.m.)

AFTERNOON SESSION

(In session at 1:15 p.m.)

JUDGE MCNAMARA: Okay. Good afternoon, everyone. Thank you.

Mr. Heneghan, if you're ready to go, shall we go?

MR. HENEGHAN: Thank you, Judge.

JUDGE MCNAMARA: Or proceed.

MR. HENEGHAN: Thank you.

BY MR. HENEGHAN:

Q. Dr. DeFilippi, just to give you some context, we were talking about the similarities between Van Urk and Berezenko when we broke, if you recall.

Let me show you now the slide that I actually now have the right number for, which is our demonstrative slide 6.4. This is part of what was Healthgen's opening slide No. 39 from the openings on Thursday.

These are portions of Van Urk reference that you say anticipate claims 1, 11 and 12 of the '951 patent, right?

A. You need to blow that up for me, please.

Q. Oh, sure.

A. Much better. Thank you.

Q. Should I repeat the question?

A. Please do.

Q. Okay. So this is from Healthgen's opening slide

No. 39, and it is essentially a summary or synopsis of the points from Van Urk that you say anticipate claims 1, 11 and 12 of the '951 patent, right?

A. Yes.

Q. Now let's look at our demonstrative slide No. 6.5, which is a similar slide from Healthgen's opening No. 40.

And this discusses the portions of Berezenko that you say anticipate claims 1 and 11, correct?

A. Correct.

Q. Now let's look at slide 6.6 from our demonstrative set, which shows a side-by-side comparison of the two slides.

Do you see that?

A. Yes, I do.

Q. Okay. So this shows the summaries of both Berezenko and Van Urk from the opening slides of Healthgen, and we have color coded the summaries to show what they have in common.

Do you see that?

A. Yes. I like those colors. They stand out. Thank you.

Q. Thank you. The blue goes with the blue, the pink goes with the pink, orange with orange.

That makes sense, doesn't it?

A. You cannot miss them. Thank you.
Q. Essentially, this shows that everything you said in Van Urk is also present in Berezenko, right?
A. I would never say everything, but I suspect everything.
Q. The main points you summarize for your anticipation points from Van Urk are also contained in your summary for Berezenko; is that fair?
A. Yes.
Q. And, in fact, if we look at RDX-0001C.38, which is one of your opening slides, Healthgen's opening slides, this makes the same point, right? It has the same list of claim elements and then a checkmark in both Van Urk and Berezenko for each of those, right?
A. Yes, to indicate that they were satisfied, those claims were satisfied by this prior art.
Q. Right. By either Van Urk or Berezenko?
A. This is correct.
Q. And if we also look at, from the opening, slide 64, which is RDX-001C.64, we also see that one of the sentences from Van Urk is identical to the same sentence in Berezenko on that point, correct?
A. Very close to identical, not identical, but very close to identical.
Q. The only difference being that in Van Urk it's

referred to as DEAE Sepharose-FF and in Berezenko it's simply DE Sepharose-FF? Otherwise identical, right?

A. Yes, that was my point. Thank you. Yes.

Q. Let's look at JX-0001, which is the '951 patent in this case. If we go to the second page of that and blow up maybe the top third or so of that, and highlight the top reference in the right-hand column.

There's Berezenko right there on the face of the '951 patent, right?

A. Yes. The name Berezenko is right there, yes.

Q. Indicating that Berezenko was before the Patent Office and considered by the Patent Office when the '951 was granted, right?

A. Well, it was partially considered, yes.

Q. In your opinion, looking back at it, you think it was only partially considered, right?

A. As I recall, when I was looking at it previously, yes.

Q. Let's now go to our Demonstrative Exhibit 6.7. This was a slide that you showed during your direct testimony. I believe it was marked slide 67 from your direct testimony deck.

Do you remember this slide?

A. Yes, I do.

Q. I'd like to direct your attention to the

editorial comment on the right-hand side. We can maybe blow that up, the bullet point there.

This is a point you were trying to make about Dr. Wilken's testimony, right?

A. Yes, you're right. It was editorial, expressing an opinion.

Q. And it's not an accurate description of her testimony, though, is it?

A. It doesn't say testimony. It says data. So the data here is cherry-picked. That is to say, certain values were pulled out of other sets of data and presented here.

Q. And you were present for at least -- or at last watching or listening in on Dr. Wilken's testimony, right?

A. Yes, I was.

Q. And her actual testimony was only about the three samples shown, and she does not claim that this is data that applies to all yeast-derived rHSA, does she?

A. I don't recall if she did or not, but, again, this is not referring to her words directly. This is referring to the data.

Q. Well, let's take a look at her testimony. If we look at demonstrative Exhibit 6.8. I can make a representation to you, this is from the transcript of Dr. Wilken's testimony, and it notes -- starting here at page 326, line 1, she says, and there are three different

recombinant albumin evaluated here and compared to a negative control.

Her testimony is just about those three albumins, right, not all yeast-derived albumins?

A. That is what she is referring to here, yes.

Q. Let's return to Van Urk for a moment. We can take that slide down for now. Thank you. We can just take it all the way down.

In your opinion regarding the amount of aggregated albumin contained in the product of the Van Urk reference, you base that on testing done by SDS-PAGE with a reducing agent, don't you?

A. I'd have to see the data to answer that question properly. You're talking -- data from Van Urk?

Q. Your opinion about Van Urk and what it shows about the elements of the '951 patent related to aggregated albumin, you base that opinion on testing done by SDS-PAGE with a reducing agent, don't you?

A. Not for unaltered albumin. As I said earlier, the SDS and the reducing agent will act towards converting the aggregates and dimers to monomers.

Q. But, in your opinion, in your report -- and by report I mean your opening report, the one on validity, your first report in this case -- the very first line of the paragraph in your report directed toward this, paragraph

150, says that Van Urk evaluated its rHSA using SDS-PAGE with a reducing agent, right? That's what it says.

A. I'll accept that comment.

Q. Okay. In fact, let's take a look at that paragraph, if we can see demonstrative Exhibit 6.9.

MS. GIANNELLI: If we could, for completeness, could we have paragraphs 149 and 150 shown together.

JUDGE MCNAMARA: Yes, I would like to see the context, but let him show 150 first. It's a little larger. And it certainly helps my eyes first and then we'll put them together. And I'm sure that that can be done.

MR. HENEGHAN: It can. It will just take us a second to actually go to the report to that page.

JUDGE MCNAMARA: Sure. Dr. DeFilippi, can you see the size here?

THE WITNESS: As presented, it is quite adequate, yes. Thank you.

JUDGE MCNAMARA: Yeah. Good. That's for me too.

Q. Let me just ask you about this, and then we'll go to the paragraph before and after as well.

You recall this paragraph from your report, Dr. DeFilippi?

A. I have no reason to believe it's not accurate.

Q. Okay. And do you recall at your deposition under questioning from Ms. Bhattacharyya, you stated that your

reliance on reducing SDS-PAGE for invalidity in light of your opinion on infringement made your opinion on invalidity a stretch? Do you recall that?

MS. GIANNELLI: I'll object to the mischaracterization of the exact question posed. I believe that there's more context to that. And the question posed was if reducing SDS-PAGE was the only technique in Van Urk. And so I believe that there's a little bit more nuance to that issue.

MR. HENEGHAN: Well, let's play it from the deposition.

JUDGE MCNAMARA: Sure.

MR. HENEGHAN: Starting at page 325, line 16, and carrying over to page 326, line 15. It's clip 21.

MS. GIANNELLI: We may need to back that up to get the full context of what's being discussed, but I'll reserve my comment until we see what's played.

JUDGE MCNAMARA: I think that's already been made clear.

(Video clip played)

Q. ... does not identify any other assay for determining the level of aggregation; is that correct?

A. That is correct.

Q. So if there is no other assay to rely upon, I mean, do you really believe that this is an invalidating

reference given your positions on infringement?

A. I'd have to go back and look through the patent, would be my honest answer there. As it stands alone, if this is the only proof, then that might be a stretch.

(End of video clip)

MR. HENEGHAN: That's the end of the clip, Your Honor. Why don't we show the report page with 149, 150, and 151.

Is that significant -- I mean sufficient, Dr. Giannelli, or did you want more paragraphs than that?

MS. GIANNELLI: I think the ones we had in mind were just 149 with 150. Thank you, Mr. Heneghan.

MR. HENEGHAN: Just 150, not 151? Okay. That will make it easier to read too.

THE WITNESS: We might have to come back to what you just did if we're addressing that.

MR. HENEGHAN: Sure.

JUDGE MCNAMARA: I think Dr. Giannelli will be able to deal with that quite well.

BY MR. HENEGHAN:

Q. Dr. DeFilippi, your paragraph 150 states that the Van Urk also evaluated its rHSA using SDS-PAGE with a reducing agent, right?

A. In context, that is right.

Q. Now looking at the '951 patent, there is nothing

in the claims of the '951 that precludes anyone from using SDS-PAGE reducing to measure for aggregated albumin, is there?

A. There was no statement precluding that, but you will get a statement from me when you're finished with your questions.

Q. Well, let's play from your deposition on July 30th beginning at page 275, line 2 to line 17. This would be clip 22.

(The following video clip was played:)

Q. Would you agree with me that, if we look through the claims here, that the claims are not limited to these properties being determined by any particular analytical method?

A. There was no mention of an analytical method that I recall. Let me do a quick glance.

Q. Sure.

A. See if I remember correctly. Yeah, I don't see any method -- mention of a method or a location where they're performing the method or any mention of shipping, none of the above.

(End of video clip.)

Q. So that was your testimony back on July 30th in this case, correct?

A. It would appear so, yes.

Q. Dr. DeFilippi, let's talk about obviousness now, okay?

A. Well, wait.

JUDGE MCNAMARA: No, no. Dr. DeFilippi, Dr. Giannelli will come around.

THE WITNESS: I understand. You already mentioned that. My error. Thank you.

MR. HENEGHAN: We can take down the document for a moment until we're ready for a new exhibit.

THE WITNESS: Thank you, Your Honor. I appreciate that.

Q. Dr. DeFilippi, you recognize that the Deeter reference on its own does not meet all of the limitations of the '951 patent, right?

A. I'm sorry. Could you say that again? I was just listening to "Dr. Filippi" again, the mispronunciation. I'm sorry.

Q. I'm trying.

A. I know you are. So my mind wandered. It was not criticism. Again, my mind just wandered for a moment. Thank you.

Q. I think of it as two names, "Duff" and "Filippi."

A. From the beginning, I said you can call me Dr. Lou, but I'll get hell if I repeat that again -- or heck, sorry, heck.

Q. So the question was, you recognize that the Deeter reference on its own does not meet all the limitations of the '951 patent claims, right?

A. On its own... okay. Yes.

Q. Yes, you agree?

A. Yes.

Q. Okay. So you also cite Van Urk and Berezenko in combination with Deeter for your obviousness opinion, right?

A. Yes.

Q. But in your obviousness opinion, Van Urk and Berezenko don't cover anything more than they cover in the anticipation analysis, right?

A. In the analysis?

Q. Right.

A. Well, they cover a lot of things. I don't know how to answer that question.

Q. So this is what I'm trying to get to, Dr. DeFilippi. You've taken your Van Urk and Berezenko anticipation analysis and opinion and added to it Deeter to fill in some blanks for the obviousness analysis, right?

A. In light of Deeter, yes.

Q. There isn't something more from Van Urk and Berezenko other than what you've already identified in your anticipation opinion, right?

A. I don't recall if there was something more or

not. That's my honest answer.

Q. Well, can you identify anything about Van Urk or Berezenko that's not included in your anticipation argument that you believe applies to your obviousness argument?

A. The phrase "I don't recall" should cover that. I just said I don't recall. So I can't answer something that I don't recall.

Q. Let's look at your side-by-side comparison of Deeter and the '951 patent that was originally shown in your slide 56.

Do you recall that?

A. I guess I'll see it in a minute.

Q. It's coming. We're waiting for it to pop up here.

A. Sure. There it is. To answer your question -- let me answer your question. Yes, I recall it. Thank you.

Q. Okay. And what you're trying to show here is that Deeter and the '951 patent describe this same process, right? That's the point here?

A. This same process, this same process as far as it goes here, yes.

Q. And let's go to demonstrative slide 6.10.

This process is limited just to the expression process, correct?

A. I believe that's right. Let me look towards the

bottom.

Q. Would you like us to blow anything up a little bit?

A. Please do. And I believe I will be disagreeing with that, but blow it up so I don't misspeak.

Q. I will blow up the Deeter half, since you pointed out they are the same, and then we'll see if we need to blow it up further from there.

A. Right. Go to just the 0105 or the 104 through the 105.

Q. Sure. That last paragraph?

A. Yeah, that's as good as any.

Q. Okay.

A. Okay. So now if you'd repeat your question, please.

Q. These two processes are both limited just to the expression, correct?

A. Through the 104, yes. I need to look at the 105.

Q. It's on the bottom half there blown up.

A. Yes, I understand.

Q. One on top of another.

A. That's what my pointing finger means. I'm sorry. I am reading it currently. So just give me a moment or two.

The top half, the 104 paragraph excerpt, would appear to be addressing the expression. They are talking

about expression casette, boom, everybody knows we're talking about moving genes around, so that's fine.

Now as soon as you get to, upon transformation transgenic plants were generated, that is not expression, and was sent to a greenhouse, certainly not expression of a gene, where transgenic plants grew to maturity.

So when you're done bombarding plasmids, you can see you have three up from the top, three up from the bottom of the top paragraph, plasmid AP 1504 was also used via bombardment based transformation following the procedure described previously, yes, that's your transformation.

Now after the words "upon transformation," new subject.

Q. Are you done, doctor?

A. You could probably tell from my silence, but, yes, I am done.

Q. Why don't we go back to the side-by-side.

Neither of these processes are about purification, are they?

A. As soon as you shrink it, I would then ask you to please, starting with "upon transformation," blow that up, and I believe you are incorrect.

Q. Upon transformation is near the end of the 104 paragraph, and then show that with the 105 paragraph, all blown up, please.

How's that?

A. That is fine.

Q. Okay.

A. It's in a greenhouse growing -- please, then, repeat your question and I shall address it.

Q. Neither of these processes show a process for purification, do they?

A. They certainly do.

Q. Let's go to slide demonstrative 611.

Do you recognize Table E3 and Table E4 from the '951 patent?

A. Yes, I do.

Q. And these two tables show differences between the old process for Cellastim and the new process for Cellastim, correct? We'll blow them up separately once we get past the preliminaries.

A. Don't ask me two questions at once. That is correct.

Q. Okay. So let's blow up the Table E3.

So this Table E3 shows values for testing of Cellastim made with the old process, right?

A. Yes, which we also called the Deeter process.

Q. Right. And that testing was done in 2008 between dates in February and March, right?

A. As written, yes.

Q. And the results for endotoxin here are shown in the fourth column, all in the double digits, right, except for one value of 4.4, right?

A. They probably dropped that sample. Who knows. Yes, you're completely correct.

Q. Speculation aside, an average of 44.97 for those values, right?

A. Yes. I assume they averaged all the numbers, largest to smallest quotes -- sorry -- larger than 80, I'm sure they just used as 80, but I see no reason to believe that's not correct.

Q. Let's blow up Table E4 from the other half of the slide.

So this is a table of testing done with Cellastim made under the new process, right?

A. That is right.

Q. The process from the '951 patent, correct?

A. Correct.

Q. And that shows testing on samples done between February and September of 2009, right?

A. Yes, that is correct.

Q. And the fourth column here shows endotoxin levels all below 1 EU per milligram of albumin, right?

A. That is right.

Q. For an average of 0.36 for the endotoxin,

correct?

A. Correct.

Q. So these two tables in the '951 patent show significant differences in the amount of endotoxin in the tested samples, correct?

A. That is correct.

Q. Now you've also testified today that the Huang reference, and that's H-U-A-N-G, is part of your obviousness analysis, right?

A. Right.

Q. And your slide 42, we're showing on the screen, Exhibit RDX-001C-42, and that's the Huang reference, right?

A. Yes, it is.

Q. It represents -- the blowups here and the highlighting represents your testimony today about what's important about the Huang reference; is that fair?

A. Repeat that? I'm sorry.

Q. Your slide here, RDX-0001C.42 from your direct testimony, shows your testimony from today about what you think is important from the Huang reference; is that fair?

A. That would be fair.

Q. Okay. Now let's look at our Demonstrative Exhibit 6.12.

Now the sections from your prior slide that are now outlined in green are quotations from the Huang

reference, right?

A. From the Huang reference, yes.

Q. But they are quotations from the Huang reference that you did not set forth in your report; isn't that right?

A. I do not recall whether I set forth these quotations or not in my report.

Q. While you cited to Huang for other points in your report, you never included these quotation inside your report, did you?

A. I just answered that, but I'll repeat it. I do not recall if I mentioned these in my report or not.

Q. Well, the record will reflect whether you did or not.

Let's talk for a minute about secondary considerations or objective indicia of nonobviousness, depending on how formal we want to be. Okay?

A. Okay.

Q. Let's look at the slide 63 from the Ventria opening.

It's coming. I can almost hear the computer grinding. There we go.

So, doctor, I think you mentioned that you were present during the opening, so you heard me talk about this slide at that time?

A. I was present at the opening, and I listened to

what you said, yes.

Q. And let me represent to you this is a page from the '951 patent, a page that contains column 31 of that patent, and what we have highlighted here on the screen are column 31, lines 37-52.

Do you see that?

A. Yes, I do.

Q. Blow that up a little bigger.

And in the specification of the '951 patent, it states, at line 39, that proteins surprisingly enhanced the cell growth and viability.

Do you see that?

A. I see that comment there, yes.

Q. And then starting at line 50 to 52, the specification also says that unexpectedly improved activity and stability, they offer significant improvements compared to the use of standard recombinant or purified proteins.

Do you see those two comments?

A. I see those two comments.

Q. And in your report on secondary considerations you did not offer any opinion challenging those statements of unexpected result, did you?

A. Again, I don't recall if I specifically addressed those or not.

Q. Okay. Well, why don't we call up on the screen

pages from your opening expert report, and these would be -- this is Exhibit RX-70, and we're going to look at pages 87 to 90. Unless you happen to have a copy of your report with you, you're welcome to look at that too, if the paper is better for you. Otherwise we can look at it on the screen.

What I would suggest is you just give Ms. Hitchens direction to go to the next page when you're ready.

So if we scroll down that page --

A. Keep bouncing around.

Q. And you can see in section D, Secondary Considerations, take a minute to review that.

A. Now what is it that you're asking me to look for?

Q. I'm happy to tell you again. So in your report you did not offer any opinion challenging the statements I read to you from the '951 patent about unexpected results. That's my question. Did you challenge those statements from the patent? And there is more of your secondary considerations opinion on the next page. Just let us know when you're done with this and we'll turn to that one.

A. All right. Next page or next portion.

Q. And I think there's a couple of full pages. We'll show them to you half a page at a time so they are easy to read.

A. Very good.

Q. Let us know when you're done with this half page and we'll go to the next.

A. I will let you know when I'm done reading. Thank you.

Q. Okay.

A. Okay. Next, please. Okay. Next, please.

That's so far addressing unmet needs. I'll continue.

Q. I think there's only one more page after this.

A. Thank goodness. Next, please.

Q. This is the last section of that section of your report.

A. Very good. Thank you. Very good.

And I attest to the fact that I'm not a financial expert, as written towards the bottom there.

Q. So let me go back to my question after you reviewed your report on this issue.

In your report, you do not offer any opinion challenging the statements on unexpected result that I read to you from the '951 patent, do you?

A. I do not.

Q. Let's talk about copy. You know that patents are publicly available documents once they issue, right?

A. Certainly they are, yes.

Q. And you also know that the applications for

patents become publicly available sometime before a patent is issued or is granted, right?

A. That is right.

Q. I would like you to assume that the specification contained in the application that eventually issued as the '951 patent was made public no later than 2011.

Will you assume that?

A. I'll take that assumption.

Q. So Dr. Yang did not have to be working at Ventria when the technology covered by the '951 was developed or when the patent issued to be able to infringe the '951 patent, did he?

A. That sounds like a legal question. I don't address such things.

Q. Are you refusing to answer?

A. I'm saying I don't have the background to answer whether he is infringing or not infringing. That, to me, sounds like a legal question. I really don't have an answer. I'm not being evasive.

Q. Okay. Well, let me ask it a little differently.

A. Sure.

Q. Dr. Yang did not have to be working at Ventria -- first of all, with the assumption I gave you before about information available in 2011, okay, Dr. Yang did not have to be working at Ventria when the technology covered by the

'951 patent was developed or when the patent issued to be knowledgeable about the content of the application for the '951 patent, did he?

A. That I will not disagree with.

Q. And the fact that Dr. Yang left Ventria before the '951 patent issued has nothing to do with whether the information in the '951 patent application was available to him or anyone else in the public, right?

A. See, I don't know when that information was collected in the lab. I just -- I don't have the data to give a really accurate answer there.

Q. In addition, on the topic of copying, you did not offer any opinion challenging Ventria's assertion of copying, did you?

MS. GIANNELLI: I will object here. Ventria did not assert copying until the rebuttal expert report of Lisa Wilken. It was completely absent from their final contentions. And so I will object to that -- to that question. Because there was nothing to which he would have responded. So your question is very misleading, as has been part of this whole series.

MR. HENEGHAN: Your Honor, you're muted, I think.

JUDGE MCNAMARA: Would you care to respond?

MR. HENEGHAN: I would, Your Honor.

Dr. DeFilippi's opinions on secondary considerations came in

his opening report, and so I wouldn't have expected him to know what Dr. Wilken's opinion was on this until she responded. And Dr. Giannelli is welcome to redirect him on this issue if he has an opinion now, but he has never offered an opinion before. That's the only point I'm making.

JUDGE MCNAMARA: Okay. So, Dr. Giannelli?

MS. GIANNELLI: I just thought the question was unfair because you said he didn't respond to something and you had made zero -- he endeavored to respond to every allegation fairly disclosed in your final contentions. The fact that you chose to withhold some until the rebuttal report does not mean that Dr. DeFilippi failed to respond to them.

JUDGE MCNAMARA: I think that's fair.

MR. HENEGHAN: Okay. I'll ask the question a different way, Judge.

Q. Dr. DeFilippi, you have not offered any opinion on copying, have you?

A. On copying, did you say?

Q. Copying, yes. The objective indicia of obviousness known as copying.

A. I did not express an opinion concerning the concept of copying.

Q. Okay. Thank you.

A. Ask me if I understand the concept of copying.
Q. Let's talk about long-felt need.
A. Certainly.
Q. You did offer an opinion about long-felt need, didn't you?
A. Yes, I did.
Q. And you just reviewed that when you were looking for the other opinion, right? You had a chance to see it?
A. Well, I don't remember when I looked at it, but I did look at it.
Q. Didn't you --
JUDGE MCNAMARA: I'll note it is fair to give witnesses a chance to recollect what they have said.
MR. HENEGHAN: Absolutely, Judge. I was just actually setting up the question by noting that it was part of what he just looked at in his report. That's all. If he wants to look at it again, he is welcome to, but he looked at it five minutes ago.
THE WITNESS: I didn't understand your question to mean that. And the answer is, yes, I did look at it five minutes ago.
Q. I apologize. I asked probably kind of a convoluted question, which sometimes happens.
A. No issues. No issues. Thank you.
Q. On the issue of long-felt need, you agree that

before 2009 the presence of endotoxins in biologically derived products was a major concern, correct?

A. It's always been a major concern, including before 2009, and subsequently.

Q. And prior to 2009 there was no rHSA product -- I'm sorry. Let me start again.

Prior to 2009 there was no rHSA produced in transgenic rice that had less than 1 EU of endotoxin per milligram of albumin, was there?

A. Not in transgenic rice, I don't believe. Other expression systems, there was very low, as we already discussed.

Q. But my question was directed to transgenic rice.

A. Right. And I believe I already answered that. I can answer it again, if you like. That's no problem.

Q. And you do not know of any companies other than Ventria and Healthgen that offer recombinant human serum albumin produced from plants, do you?

A. Companies, no.

Q. Let's talk about commercial success. You've acknowledged that you're not a financial expert, right?

A. Absolutely, yes.

Q. Let's look at Exhibit CX-0958.

Dr. DeFilippi, am I correct that this is not a document that you considered in your opinion on commercial

success?

A. I don't believe I've ever seen this particular document.

Q. And am I also correct that you did not consider whether Ventria's sales have been impacted by outside challenges, did you?

A. I did not.

Q. In your opinion on commercial success you didn't account for Healthgen's sales, did you?

A. I didn't account for anybody's sales. I just had the numbers for Ventria solely.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

JUDGE MCNAMARA: Just keep us posted.

MS. HOEKEL: Your Honor, Complainant would like to call Dr. Wilken back to the stand, please.

JUDGE MCNAMARA: Yes. You're there, Dr. Wilken, I can see.

THE WITNESS: Yes. Good afternoon.

JUDGE MCNAMARA: You're still under oath, so you're fine.

LISA WILKEN, Ph.D.,

having been previously duly sworn and/or affirmed on her oath, was thereafter examined and testified further as follows:

DIRECT EXAMINATION

BY MS. HOEKEL:

Q. Ms. Hitchens, if we can pull up Exhibit 2 from Dr. Wilken's demonstratives.

MS. HOEKEL: Can you still hear me, Your Honor?

JUDGE MCNAMARA: I can hear you.

Q. Dr. Wilken, we talked about your background and qualifications in your previous testimony, correct?

A. Yes.

MS. HOEKEL: Can you hear Dr. Wilken, Your Honor?

JUDGE MCNAMARA: Very well at this point.

MS. HOEKEL: One second, Your Honor. We're having a little bit of a technical issue that we want to make sure we resolve before we get going.

Q. Dr. Wilken, we talked about your background and qualifications when you testified beginning last Friday.

And, Your Honor, given the qualifications that we established with Dr. Wilken last week, we would like to offer Dr. Wilken as an expert on the facts of the secondary considerations of nonobviousness with respect to nexus, unexpected results, long-felt need, failure of others, and copying.

JUDGE MCNAMARA: Okay. Did you agree on this?

MS. HOEKEL: I don't believe we discussed it in advance, but I think it was in her report.

MR. SHAFFER: There's no objection, Your Honor, other than what we discussed earlier with the fact that they did not disclose copying as part of their contentions and the first time we saw it was in her rebuttal report on invalidity. With that, for the record, there's no other objection.

JUDGE MCNAMARA: Okay. Thank you.

You can go ahead, Ms. Hoekel.

Q. If we can look at slide 3, please, of Dr. Wilken's demonstratives.

Dr. Wilken, did you prepare some slides to assist

the Court in following along with your testimony today?
A. Yes.
Q. Can you tell the Court just generally what this slide reflects?
A. Those reflect a summary of my opinions in the matter.
Q. We're going to go through those opinions.
Did you consider, again, the claims of the '951 patent, as are displayed on slide 4 of your demonstrative?
A. Yes.
Q. And if we can look at slide 5, please.
Did you apply the definition of person of ordinary skill in the art in rendering your opinions?
A. Yes.
Q. If you can pull up slide 6, please, Ms. Hitchens.
Dr. Wilken, were you here for Dr. DeFilippi's testimony today?
A. Yes.
Q. And also on Monday?
A. Yes.
Q. Did you hear Dr. DeFilippi say that yeast and rice were essentially interchangeable for purposes of purification?
A. Yes.
Q. Do you agree with that statement?

A. I don't.
Q. Why don't you agree with that statement?
A. So, first, they are from entirely different kingdoms.
Q. What does that mean when you say "they are from entirely different kingdoms"?
A. So they have significant differences, structural difference, functional difference that distinguish one from another.
Q. Can you give us examples of kingdoms?
A. So animals, plants, fungi, protists, and bacteria.
Q. And those are each their own kingdom?
A. Yes.
Q. And why else do you disagree with Dr. DeFilippi's statement?
A. So plant cells are distinguishable from these cells in terms of plant cells are autotrophs, meaning that they harness energy from the sun and they are able to produce these organic molecules; whereas, organisms, such as yeasts, are heterotrophs, or they rely on the production of these molecules for their energy, among others.
And, in addition, in general, plant cells are multicellular, whereas, yeast cells would be unicellular, in addition to the differences in the composition of the

biomolecules that are harnessed inside.

Q. If we can look at page 7 of your demonstratives, please.

A. So this continues those differences. As I mentioned, the plants are multicellular, so we also consider that we have -- even within one plant system, we have stalks stems, leaves, seeds, and so forth.

Q. And why is that important to your opinions today?

A. Because this is important in terms of where the expression and accumulation of your product lies, and that comes into play specifically in the purification process, because the intention -- the intention of that -- those steps are to discern or discriminate between the product and the impurities.

Q. Let's look at slide 8, please.

And you were just talking about the differences between expression and purification.

What is being described here on your slide 8?

A. This shows the variabilities or the options available for choosing a recombinant expression system in plants. So, first, we have various different types of organisms, the bacteria, fungi, animals, plants.

And then when we go one step further, let's say we're going to select a plant, then the next consideration is do we produce it in a cell culture, meaning that we're

growing those cells in a bioreactor for which those cells can either secrete the product into the media for which those cells are grown, or we can retain the product inside those cells, or we can produce it in plant components, for example, producing them terrestrially and accumulated in various parts of the plant. So we can have, for example, a seed-based expression or even target the product to a leaf.

Q. And why does that matter?

A. That would present a different profile of impurities that we need to be able to discriminate between that -- those properties and those of the recombinant protein.

Q. Is a person of skill to use a different method of purification and extraction based on where the protein appears in the host?

A. Absolutely. So if you express something within a seed, that's going to be -- it would look differently than if you express it within a leaf. That's because we have different impurities and we need to address those impurities differently.

Q. And in that middle triangle, you just talked about seed- and leaf-based, and above it it says tissue culture.

Do you see that?

A. Yes.

Q. What kinds of hosts express their proteins in tissue culture?

A. So you would grow cells in a bioreactor, something like the yeast expression system that we have discussed in Van Urk and Berezenko is that they are producing their rHSA in a cell culture, so in a bioreactor grown in media, and the product is secreted into the media. It could also be plant cell culture as well. So there's different types of cell culture systems that you could use.

Q. And why does it matter between the terrestrial system versus like a cell culture system?

A. So in one case, if you have a cell culture, this is within a bioreactor in confined conditions, you can -- you can sterilize the media prior to inoculating that culture, and you can also have better control of your process in terms of what types of potential contaminants that are introduced through the process.

Q. You heard Dr. DeFilippi talking about yeast on grapes in his testimony, correct?

A. I heard him speaking about yeast in the field, yeah.

Q. And is that the kind of process for protein extraction that the Berezenko and Van Urk references are discussing?

A. No. In fact, this is, as I mentioned, an

extracellular product, which means that they are producing the rHSA, which is secreted or transfers from inside the yeast cell to external to that. So it would be -- the impurities would be in the depleted media for which those cells are produced.

Q. What do you mean by "depleted media"?

A. So the cells are going to be grown in media which provide nutrients for those cells to grow. And so, as they grow, they are going to consume some of that nutrients. And then, in addition, of course, through the cell growth and product production phase there are going to be components that are secreted out into the media. So it's a little bit different mixture of impurities.

Q. Is there a different mixture of impurities between yeast grown in a tissue culture and yeast grown in a field?

A. Yes, absolutely, especially if you're considering intracellular versus extracellular, in addition to sterile conditions that you're creating to grow the cells in a bioreactor and just the additional process control that you have in a plant-based type of environment -- or I shouldn't say plant-based. What I mean is like in a building, in a controlled production environment.

Q. When you said "plant," did you mean like manufacturing?

A. Yeah. I meant manufacturing plant, yeah. I just wanted to clarify.

Q. If we look at the third triangle on this slide, what are you depicting in the third triangle here?

A. That is another level of control. Even with -- let's say, we select a seed-based expression, an accumulation system, that we can even accumulate, in some cases, a recombinant protein to a particular compartment within that cell.

Q. Maybe the easiest way to demonstrate this is, if we can go back, Ms. Hitchens, to slide 6.

What do you mean by you can accumulate the protein in a particular compartment of the cell?

A. So in this particular example, with the '951 patent, they are accumulating the recombinant protein within the rice seed. So it's not expressed throughout the entire plant, meaning the leafs of it or the roots, that will not accumulate the products that are actually directing the expression or the accumulation of that particular recombinant protein to within the seed of the rice.

Q. Let's look at slide 9, please.

And we saw this slide in your direct exam, correct?

A. Yes.

Q. And what is it that you're depicting on the

right-hand side of this slide?

A. These are the general downstream processing steps used to process the plant tissue. So in this case we're discerning between leaf-based systems, seed-based systems, which you see in the middle, and on the right we'll see bioreactor-based systems.

So the bioreactor-based system would be something like the rice cell culture that we heard discussed this morning. The middle one would be the rice seed, which is what we have in this case. And then a leaf would be, for example, producing it in tobacco, or even the leaf of a rice plant, which is not our case here, but even in plant systems and plant systems alone, the downstream processing steps vary depending on the type of plant tissue that you're processing.

Q. Where would the '951 patent fall on this chart at the top when we have leaf-based, seed-based, and bioreactor-based? Where is the '951 patent in this process?

A. The '951 is using a seed-based production system for the recombinant human serum albumin.

Q. And the Berezenko and Van Urk references are discussing what kind of system?

A. Those rely on a bioreactor-based system, and not even the intracellular approach. They are using extracellular, which means that the protein is going to be

excreted or secreted into the media, and so it's going to be in a liquid phase at the very beginning of the downstream processing.

Q. Is that important to your analysis of validity in this case?

A. Certainly. Yes.

Q. Why is it important?

A. One, just the impact of localization, you're going to have a different, very different protein -- or impurity profiles of that. So in one case, of course, we're retaining it inside the seed, and so, of course, that's going to be specific to the rice-based system, and, in particular, rice seed.

And in the other case we're going to have the presence of other, as I mentioned, depleted media, which just means it's the media that have used some of those nutrients. There's going to be some waste products present in there, but certainly that would be a different background than what you would expect in a rice seed.

Q. Let's look at a slide that we saw from Respondent in Dr. DeFilippi's testimony, which is RDX-1C-46, please, Ms. Hitchens.

Did you see this slide in Dr. DeFilippi's testimony?

A. I did, yes.

Q. And on the left-hand side -- well, the slide is titled "Combining Deeter and Van Urk or Berezenko."

Do you see that?

A. I do.

Q. On the left-hand side it says, Deeter: rHSA.

Do you see that?

A. I do.

Q. And it says, produced in transgenic rice, correct?

A. Yes.

Q. Does Deeter -- and then what does the bullet point under that say in Respondents' slide on the Deeter box?

A. "Endotoxin present and readily detected."

Q. Does the Deeter reference use the term "endotoxin"?

A. No.

Q. On the right do you see the Van Urk or Berezenko box?

A. Yes.

Q. Does Van Urk or Berezenko tell you how to remove -- strike that.

What does it say under Van Urk or Berezenko in this chart?

A. "Purify rHSA to remove endotoxin."

Q. Does Van Urk or Berezenko teach one of skill how to remove endotoxin from rice, from transgenic rice?

A. No.

Q. Let's look at, let's see, slide 64 of the Dr. DeFilippi presentation, please.

And this slide shows some disclosure -- sorry. I'll wait until it comes up.

Do you see this slide, Dr. Wilken?

A. I do, yes.

Q. Did you see this slide when it was being discussed in Dr. DeFilippi's testimony?

A. Yes.

Q. And what is, just generally, being described with respect to the Van Urk and the Berezenko references here?

A. So they are discussing anion exchange chromatography in each.

Q. Does the Deeter reference teach anion chromatography, anion exchange chromatography?

A. Yes, they use anion exchange.

Q. And what evidence do we have from the Deeter reference that the endotoxin levels in Deeter were likely not less than 1 endotoxin unit per milligram, as required by the claims of the '951?

A. I think that's clear in the '951 patent.

Q. Let's pull up Exhibit JX-01, the '951 patent.

Where would you like us to look in this reference, Dr. Wilken?

A. Table E3 and E4.

Q. Okay.

A. I believe.

Q. We can pull those up.

I apologize, Your Honor, I don't have the page number. We'll pull that up really quickly.

JUDGE MCNAMARA: Just as long as you blow it up a bit or we're all going to have the same problem. We're going to go blind before our time.

Q. The first part --

A. Is that it?

Q. Ms. Hitchens, for the first part, can you just pull up the top half so we can see it really big.

Okay. What is this Table E3 from Exhibit JX-1?

A. This is showing various production batches for Cellastim using the old process presented in Deeter, and it reports the endotoxin concentration in EU per milligram for several different batches, and the corresponding impact of that on cell viability.

And we see the impact -- as you increase the dosage or how much rHSA is present in the cell culture, we see a decrease in the viability of those cells in culture.

So in this case this is where the problem came to

light in that there is a contaminant that is impacting the performance of this given rHSA.

Q. What does slide E3 in Joint Exhibit 1 tell us about the endotoxin levels in the Deeter prior art reference?

A. They were significantly higher.

Q. What are some of the numbers that are given for endotoxin, so we have them in the written record, please?

A. They go from 4 -- just over 4 to 91.8, with an average of about 45 EU per milligram.

Q. And then if we can look at Table E4 in Joint Exhibit 1, please.

If you can describe for the Court, again, what's shown in Table E4.

A. What this shows is using the new process proposed in the '951 patent, the resultant endotoxin concentration in EU per mgs is substantially reduced. So we have an average over all the batches to about .36 EU per milligram.

And what we also see is that, when the concentration of rHSA was increased in cell culture, the significant decrease in cell viability was not demonstrated as it was when there was high concentrations of endotoxin present in the rHSA.

Q. If we can look at Respondents' demonstrative slide 52 from Dr. DeFilippi's testimony, please.

Did you see this slide in Dr. DeFilippi's testimony?

A. Yes.

Q. And did you hear him testify about nonpyrogenic?

A. Yes.

Q. And what is nonpyrogenic, for the Court?

A. Basically, there's no fever-causing agents present.

Q. Pyro means what?

JUDGE MCNAMARA: Fire.

A. What I had mentioned, pyrogenic.

Q. What does the word pyro tell us?

JUDGE MCNAMARA: Go ahead.

A. As I -- pyrogenic means negative impact or, I guess, fever-causing.

Q. Does the data that we just saw from the Deeter -- I'm sorry. Let me start that over.

Does the data that we saw from the '951 patent suggest that the anion exchange that was disclosed in Deeter, Van Urk, and Berezenko, give a person of skill a reasonable expectation of success to get the levels of endotoxin below 1 EU?

A. No.

Q. Why is that?

A. One, there is a difference, I would say -- one,

they apply anion exchange throughout the process in Deeter, and yet the endotoxin was still present in substantial amounts, which indicates that the separation of that endotoxin is not as straightforward as implied.

This also -- since it was co-purified with the rHSA, there's an indication that some of the endotoxin can also be bound to HSA. It is known that endotoxin can bind with HSA, which makes it particularly problematic in removal of that particular molecule.

In addition, the other patents express their production system is yeast, and I would not expect that the endotoxin-loading in performance to behave the same, one, because they have a different impurity profile, and, two, we can assume that, when you're producing something in a cell culture versus terrestrial in the field, that you're going to have endotoxin to the same extent.

In addition, endotoxin is a rather general term for a fragment of a cell wall that can differ in terms of molecular weight and even potentially a charge, and so it's not as straightforward as it's implied.

Q. Let's look at Respondents' Exhibit, Demonstrative Exhibit, slide 10, please, from Dr. DeFilippi's testimony.

We've seen this slide a couple of times, correct?

A. Yes.

Q. And we're going to -- we can blow up the

right-hand side just to make it a little bit easier to see.

What is depicted in this slide on the right-hand side that's titled "Albumin Fatty Acid (FA) Binding Sites"?

A. So this is a three-dimensional representation of albumin.

Q. And I think Dr. DeFilippi testified to this, but what are the spaces that are marked with the FA?

A. This would be potential sites for fatty acid binding to the albumin molecule.

Q. What kind of fatty acids do we find bound to albumin?

A. Those would be based on the production system.

Q. What do you mean they are based on the production system?

A. Those fatty acids are coming from whatever, for example, yeast or potentially rice. Those -- that is where the fatty acids are introduced into the HSA.

Q. Do you expect, as one of skill in the art, to have different molecules, different substances, bound to those fatty acid binding sites dependent on which host the recombinant human serum albumin was produced in?

A. Absolutely. There's a wide variety of various fatty acids and fatty acid structure. It's a general term that has certain characteristics, but that how many -- how long the carbon chain is and the particular either saturated

or unsaturated, the bonds present, would depend on what organism is producing those fatty acids.

Q. And do those fatty acids go along with the albumin when it is extracted?

A. They certainly can, and they have been demonstrated to do so.

Q. Did you hear Dr. DeFilippi testify that it didn't matter what host produced the recombinant HSA?

A. Yes.

Q. Do you agree with that testimony?

A. No.

Q. And why not?

A. Because this is a good example of how it does matter. The host or the production system does leave a fingerprint in terms of the product, the final product and the product composition. And that is important to the overall function and performance of that particular product.

Q. Did you hear Dr. DeFilippi's testimony that the ligands that are bound to albumin don't come from the host?

A. I did.

Q. Did you agree with that testimony?

A. No. It's been shown that some of the ligands that were bound, in particular the '951 patent, are directly from the host, and I think that's clear in other cases. For example, in the plasma-derived HSA, it's clear that the

contaminants are a concern, which is why there's a drive to produce another source of HSA.

Q. Do you recall Mr. Heneghan asking Dr. DeFilippi whether it mattered that Van Urk and Berezenko disclosed specific examples of purifying recombinant human serum albumin in yeast instead of transgenic rice?

A. Yes.

Q. Do you recall Dr. DeFilippi saying, no, the protein is identical in all cases, and, therefore, it's going to behave identically on the various chromatography resins?

A. I did. I heard that.

Q. Do you agree with that?

A. Absolutely not.

Q. And why is that?

A. Because each system has a different set of proteins, and so protein is a very general term to describe molecules that have various physical chemical properties, meaning they have different sizes, they have different solubilities, and they have different charges.

And even in the rice system, right, the mere expression or accumulation of the recombinant human serum albumin even shifts the production of native proteins, the proteins that the rice typically produces. There's actually a shift in those -- accumulation of those native proteins to

accommodate for the high expression of the recombinant human serum albumin.

So not only does the, for example, protein profiles differ between plant systems or even other types of organisms, but even within the same plant system, the mere fact that plants have limited resources and they have to be able to produce all these different products, and producing a recombinant protein, especially when at high expression level, can shift the metabolic profile and impact the impurities that you see.

Q. I'm going to ask Ms. Hitchens to pull up Exhibit RDX- -- a demonstrative from Dr. DeFilippi's testimony, slide 11.

Did you see this in his testimony?

A. I did.

MR. SHAFFER: Your Honor, I'm sorry. I object. I let the last slide go. None of this was disclosed to us. They had their slides in advance. I don't think any of this was in their expert report. And I haven't heard any -- she is addressing this for the first time. This wasn't disclosed.

MS. HOEKEL: They are Healthgen slides and we're just using them to discuss Dr. DeFilippi's testimony.

MR. SHAFFER: Okay. I'm sorry, Your Honor, I think you're on mute.

JUDGE MCNAMARA: These are Healthgen slides. So they are just doing --

MR. SHAFFER: Okay.

JUDGE MCNAMARA: Yeah, they're good.

MR. SHAFFER: Okay. Thank you, Your Honor.

Q. Dr. Wilken, do you see here in the -- we can pull this from the '951 patent on the right. We can use it from the patent.

But it shows some particular properties of recombinant human serum albumin?

A. Yes.

Q. And do you see that the -- do you understand what the rHSA on the right-hand side of this chart is reporting?

A. This is the recombinant human serum albumin compared to the plasma-derived HSA.

Q. And where is the recombinant human serum albumin from this chart being produced?

A. I believe the E2 would be from the '951.

Q. Yes. Is this rice-derived?

A. Yes.

Q. And then if we can look at Healthgen's Exhibit -- I'm sorry -- Demonstrative Exhibit 15, slide 15.

And this was New Century Pharmaceuticals catalog. If you see the production system on this slide -- if we can blow that up, Ms. Hitchens, at the bottom in the middle --

what production system is the recombinant human serum albumin being made in in this reference?

A. This is Pichia or yeast-based.

Q. And do you see the physiochemical properties here?

A. I do.

Q. And do you see a difference between the physiochemical properties of the yeast-based system and the rice-based system disclosed in the '951 patent?

A. We have a difference in both the isoelectric point, the PI. In one case we have 4.7 in the yeast-based, and in the rice-based here we have an isoelectric point of 5.3.

We also have a one amino acid difference, which provides a very small change in the molecular weight or molecular mass.

Q. Are those physiochemical properties important to a person of ordinary skill in the art?

A. Very important. Any type of charge-based separation could be impacted based on that isoelectric point or even interactions between that product and any impurity present in the extract for that matter.

JUDGE MCNAMARA: Can you just explain to me briefly what an isoelectric point is so that I understand that?

THE WITNESS: Sure. So what an isoelectric point is, is the pH for which that protein would carry a net zero charge. So proteins have all these amino acids and some of those amino acids carry a charge. And so what that tells us is, if we go above that isoelectric point, that protein well carry a negative charge. If we go below that pH, 4.7 here, that protein will carry a positive charge.

So whenever we're picking, for example, conditions for separation using a charge-based chromatography, for example, we need to have a pH that would be suitable to give the protein the charge we need.

So it helps us understand what charge our protein would carry. So we could use that to be able to purify the protein or even extract the protein or try to even minimize interactions, let's say, between an impurity present and that given protein, because it can be based on electrostatic or charge.

JUDGE MCNAMARA: Go ahead. Thank you.

Q. If we can pull up slide 10 from Ventria's demonstrative slides that you prepared in this case for this testimony.

Did you look at the prosecution history of the '951 patent, Dr. Wilken, in rendering your validity opinions?

A. Yes.

Q. Okay. Can you tell us whether the applicant discussed the importance of host in the prosecution of the '951 patent?

A. Yes, that was an important consideration.

Q. Okay. And do you see on the left-hand side the sentence or the excerpt starting, "claims have been rejected"? Do you see that?

A. Yes.

Q. What is your understanding of the narrative underneath that?

A. So my understanding is that the applicant is asking for consideration due to the fact that those skilled in the art would recognize that the recombinant albumin that's produced by a transgenic plant or the rice is different from naturally occurring mammalian albumin, and that this is demonstrated in data presented in the application through comparison of both yeast-derived and serum-derived albumin.

Q. And we'll get to the figure in the patent. We looked at it on your direct exam, I believe, on infringement, but we'll look at it again in a minute.

But what is Cellprime?

A. Cellprime is the yeast-produced recombinant human serum albumin.

Q. And do you recall who manufactures Cellprime?

A. Cellprime is, I think, Novozymes.
Q. And then what is Seracare?
A. Seracare is a bovine serum albumin.
Q. And what did the Examiner say about the difference between the three sources of recombinant -- I'm sorry. Let me start that over.
What did the applicant say about the three sources of albumin?
A. What did -- could you --
Q. What did the applicant say about the differences in the three sources of albumin?
A. So that the albumins performed had different effects on the viability of the cultured cells.
Q. And what are you depicting on the right-hand side of this slide?
A. Is the response to the applicant's explanation, which led to a withdrawal of the initial rejection due to the fact of the data provided evidence that the production system used had resulted in a product that had differential effects on cultured cells in comparison to the other products.
JUDGE MCNAMARA: Can you just leave that there a moment? Sorry, Ms. Hoekel. I just want to finish reading.
MS. HOEKEL: Sure.
Q. I was just going to clarify also, Dr. Wilken, is

the statement on the right from the Patent Examiner?

A. Yes.

JUDGE MCNAMARA: We're okay.

MS. HOEKEL: Okay, Your Honor.

Q. Let's look at slide 11, please, of your slide deck.

Did the Examiner also examine -- address prior art?

A. Yes.

Q. And what prior art is being examined -- let me start that over.

What prior art is being discussed on slide 11 on the left-hand side?

A. It is the Berezenko patent.

Q. Is that the Berezenko patent that Respondent has been alleging renders the claims invalid in this case?

A. Yes.

Q. What did the Examiner say about Berezenko?

A. He says they initially had the claim rejection, but, with consideration of this patent, that the rejection had been withdrawn in light -- in the comparison of the Cellprime products, so they are indicating the connection here between the Berezenko patent and the Cellprime product, and that this product performed differently in the cell culture compared to the rHSA produced by a plant.

Q. What did the Examiner say about the difference in activity?

A. It supports the argument that the products are distinctly different based on the production system.

Q. And what document are you showing on the right-hand side of this slide?

A. This is the Examiner's statement for reasons of the allowance.

Q. And what did the Examiner say in allowing these claims?

A. That this is -- that the specification demonstrates that the albumin produced in the transgenic plant had different effects on the cultured cells in comparison to other systems, and that, accordingly, the structure was different than the naturally occurring mammalian albumin.

Q. Do you agree with that conclusion of the examiner?

A. Yes.

Q. Let's look at slide 12, please.

Is it your opinion that the produced in a transgenic plant is a structural limitation?

A. Yes.

Q. Does the '951 patent itself explain the differences between plant-derived and other host-derived

that you've been discussing --

A. Yes.

Q. -- this afternoon?

What does the '951 patent say about those differences?

A. So that it indicates some potential mechanisms by which produced in a transgenic plant is a structural limitation, that proteins can be differentiated from proteins that have been purified from other organism, according to three criteria.

One, it can comprise different patterns of modification compared to proteins produced in different organisms that can be identified by mass spec analysis.

Two, that the proteins produced in a plant will comprise a different set of bound cofactors, lipids, and contaminating proteins, that's because these are derived from the host organism, compared to the same protein produced in a different expression system, or one purified from a different source.

And, three, that the proteins produced may exhibit a different biological activity compared to the same protein -- compared to one produced or purified from a different source. And that may arise from various differences.

Q. Are those differences true for yeast versus rice?

A. Yes.
Q. Let's look at slide 13, please.
What is depicted on slide 13?
A. This is cell viability data. So looking at the performance of the -- of serum albumin in cell culture. So on the x-axis we see the dosages of albumin from .5 to 10 mg per mL, and on the y-axis this is the cell viability.
Q. Where is this figure taken from?
A. This is from '951 patent.
Q. And what does this data show to one of skill in the art?
A. So if we look at Cellastim, which are the black bars that you see within the figure, the cell viability was significantly higher than that of the yeast-produced human serum albumin.
Q. Did you look at any Healthgen publications in rendering your opinions in this case?
A. Yes.
Q. And did you find Healthgen publications that supported your opinions in this case?
A. Yes.
Q. Let's look at slide 14. And if you can explain to the Court what is the reference that you call out on slide 14?
A. This is a peer-reviewed journal publication with

Dr. Yang as an author.

Q. What does this publication -- how does this publication contribute to your opinions on validity?

A. This discusses some of the challenges of producing human serum albumin, in particular, from a rice-based expression system.

So if we look at the right side there, we see some passages that we should highlight, in that, one, the downstream processing, which would be a purification process, as we're discussing, varies depending on the properties of the product and the expression system, in that even rHSA from different hosts could have different biochemical properties.

And they have demonstrated that their particular rice-based HSA does have different performance in particular categories. And this is attributed to the different fatty acids that are present in the rHSA which are derived from the rice.

Q. The different fatty acids in the rice, different from what fatty acids?

MR. SHAFFER: Your Honor, I'm sorry to interject. I just want to note for the record that this is an article from 2013. I don't think the date has been suggested.

JUDGE MCNAMARA: I think that's helpful. Thank you.

MS. HOEKEL: I apologize, Your Honor. We can show that. That's on the front of the slide, and we'll make sure that's in the record.

JUDGE MCNAMARA: We've got that problem with the small print overlapping documents.

MS. HOEKEL: I apologize, Your Honor.

Q. What is the date of this publication, Dr. Wilken?

A. 2013.

Q. I think my question was, the statement on the right that you read said, OsrHSA has an improved thermal stability in liposomes compared with pprHSA, possibly due to the presence of different fatty acids in OsrHSA.

Do you see that?

A. I do see that.

Q. And what difference is being called out here?

A. The impact of the production system, so fatty acids derived from the production system. So this indicates that -- two things -- that, one, it could impact the actual rHSA, and, in particular -- also the ligands that are bound to the rHSA.

Q. And this article is from 2013, correct?

A. Yes.

Q. How many years after the application of the '951 patent is that? Do you recall?

A. I believe it's -- was it one year? I think it

was 2012 or 2011, if I'm remembering.

Q. If I told you the '951 patent was filed in 2009, does that refresh your recollection?

A. Oh. Sorry. Yeah.

Q. Did you look at any Healthgen marketing materials in rendering your opinions?

A. Yes.

Q. Let's look at slide 15, please.

MS. HOEKEL: Your Honor, this is a Healthgen document, and we have looked, and we don't have a date on this particular document. As it was produced to us, it does not have a date on it.

MR. SHAFFER: Is this CBI?

JUDGE MCNAMARA: Is this confidential?

MS. HOEKEL: Yes. We can go on the Healthgen CBI record briefly.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. HOEKEL:

Q. I believe we are off the confidential record probably for the rest -- almost to the end at least.

Okay. So if we can look at Exhibit CX-1051, please, and if you can identify this, Dr. Wilken?

A. This is a journal publication, a review article discussing recent developments in processing of recombinant proteins and looking at particular expression hosts and process development.

Q. What is the date of this article?

A. This is a date of 2019.

Q. And where was this article published?

A. In frontiers.

Q. And is frontiers a reputable journal?

A. Yes.

Q. And who was the -- what organization sponsored this paper?

A. This one is Defense Research and Development Establishment. It's a scale-up facility.

Q. And what are you using this reference for in relation to your opinions on validity?

A. The complexity in the indication that there really is not a one-size-fits-all approach in developing the

downstream processes for plant-derived recombinant proteins or any recombinant proteins, for that matter.

Q. Let's look at slide 18, please. Let's do the same thing for slide 18. Let's pull up Joint Exhibit 23, please.

And if you can tell the Court what Joint Exhibit 23 is, please.

A. This is a book chapter discussing a case study of production of human serum albumin in transgenic rice.

Q. And what is the date on this chapter?

A. I believe it was 2018.

Q. Who are the authors of this book chapter?

A. We have five different authors here including Dr. Yang.

Q. And if we can look at page 4 first of the document. And there's a section, 1.2.2 Downstream Processing. Do you see that?

What is the Yang paper discussing in this section?

A. The challenges associated with developing downstream processes for the recovery of recombinant HSA. In general, the downstream processing cost is a significant portion of the overall production cost, and the challenges include those of the host cell protein, and that the criteria of developing a particular composition is quite

challenging.

Q. Do you recall in your previous testimony there being some discussion about a particular picture of a gel that appeared in the He paper?

A. Yes.

Q. And the He paper is from quite a while ago, correct?

A. About 2011. I'm not remembering off the top of my head, but, yeah, I was thinking 2011, just from memory.

Q. I just want to pull up page 18 of this document and ask if you recognize anything from page 18 of the Yang manuscript.

A. Yes, if we look at Fig. B there, we see that characteristic little smudge on the gel, which we have seen in numerous different Healthgen documents.

Q. Is it your opinion that that is the same gel that we saw in the He paper?

A. Yes.

Q. If we can go to slide 19 of your presentation, please.

What document do you see called out on slide 19?

A. This is a peer-reviewed journal publication in Biotechnology Advances.

Q. Who is the author of this publication?

A. Myself and my prior Ph.D. advisor.

Q. If Ms. Hitchens can pull up the date on this paper.

And what is the date of this paper?

A. 2011 is when it first was available online.

Q. And if we can look at the portion that you called out on your slide on the right, and if you can tell the Court why you included this in your opinion.

A. This shows -- initially the focus on plant-based system is really the focus on the upstream or how much of that protein you could accumulate. But there was still significant advancements or breakthroughs that were needed to be done in the downstream processing.

So really at the point only a few novel cost-effective downstream processes had been introduced despite the many years of trying. So there were two main reasons -- we attribute two main reasons for this lack of breakthroughs.

One would be the lack of funding for academic and nonprofit, but, two, the perception that previously developed methods for other recombinant proteins or other proteins from other hosts would be suitable for plant systems, which was found to be -- which was certainly not the case. And the sheer number of the number of different plants that were used also hindered advancements in the field, because of the complexity and the variability between

each.

Q. You say here the perception that previously developed methods for other protein expression hosts. What were some previously developed methods for other protein expression hosts in 2011?

A. In general, like what are general downstream processing techniques?

Q. No, what were the other --

A. Systems --

Q. -- the other protein host systems that there had been methods developed for?

A. Just, in general, very common would be bacterial systems. E. coli is very common for recombinant proteins. Yeast-based systems have been used. Mammalian systems have been used. Plants were still very much in trying to make a breakthrough. And really it was case-by-case studies at this point studying one particular host and one particular protein.

Q. Let's look at slide 20. Again, this is a slide from the prosecution of the '951 patent; is that correct?

A. Yes.

Q. At the top left it says, "claim 35 is rejected as being anticipated by Berezenko." Do you see that?

A. I do.

Q. Is that the same Berezenko reference that

Respondents rely on in this case?

A. Yes, I believe so.

Q. And what did the Examiner say Berezenko taught?

A. Initially they indicated that it taught highly purified albumin that had no detectable aggregates or endotoxins here.

Q. Did the Examiner make arguments in light of Berezenko?

A. Yes.

Q. What did the applicant argue in response to the Berezenko rejection?

A. So in this case, which we see in the box below, that the applicant noted that the Berezenko is a Novozymes patent, and relates to the Cellprime product that is compared in the patent application that -- which is the data we have looked at.

So this particular Cellprime product was expressed in a yeast-based system, and that the data indicated that there was a different impact of -- on cell growth when used in a cell culture.

In addition, the claim albumin produced in the plant with low endotoxin was five times more active in promoting the viability. So this demonstrated a uniqueness about the '951 patent.

And they also indicated that there was no basis

for assuming that the low endotoxin levels would inherently be present in Berezenko.

Q. And then what did the Examiner do after this applicant argument?

A. So in light of that justification and a demonstration, then the rejection was withdrawn.

Q. If we can look at the next slide, please, slide 21.

Dr. Wilken, did you hear Dr. DeFilippi testifying, and you saw in his report that -- about the impact of the Deeter reference on the patentability or the validity of the '951 patent?

A. I did, yeah.

Q. And did the Examiner look at the Deeter reference when examining the '951 patent?

A. Yes, it was considered.

Q. Okay. And what did the Examiner do when it initially considered Deeter?

A. So initially the Examiner rejected the claims as being unpatentable over Deeter.

Q. And then did Ventria submit additional information?

A. Yes.

Q. And do you call that information out on this slide?

A. Yes.

Q. And what was the information that Ventria provided the Examiner?

A. So this was the evidence shown in Table E3 and E4, which we looked at prior, which showed the impact of the process, one, presented in Deeter, the old process, and the resultant endotoxin concentration, and the performance of those in cell culture, and compared that to the resultant rHSA composition prepared using the new process presented in the '951 patent, the corresponding concentration of endotoxin in the sample, and the demonstration of the impact or the lack of the significant difference in cell viability based on the dosage of rHSA in that sample.

Q. And what did the Examiner do in response to these applicant arguments?

A. So after consideration of the information, the Examiner withdrew the rejection.

Q. The rejection in light of which reference?

A. The Deeter.

Q. If we can look at slide 24 in your presentation.

Have you seen slide 24 before, Dr. Wilken?

A. Yes.

Q. Was Dr. DeFilippi asked some questions about this in his testimony?

A. Yes.

Q. At the bottom right of the Berezenko discussion -- do you see that?

A. Yes.

Q. -- what does it say in the yellow box?

A. In the yellow box it says, the albumin of the invention is at least 99.5 percent monomeric, preferably essentially 100 percent monomeric.

Q. And is that information disclosed in the Berezenko reference? That's a quote from Berezenko, correct?

A. Yes.

Q. Let's pull up Berezenko, which I believe is Joint Exhibit 27.

Does Berezenko have claims that discuss this aspect of the disclosure?

A. Yes.

Q. And can we look at claim 1, please, of Berezenko, which is on page 25.

What is being claimed at the beginning of claim 1 in Berezenko, Dr. Wilken?

A. They are claiming highly purified albumin, which is at least 99.5 percent monomeric.

Q. And then does Berezenko disclose a method for measuring monomeric content?

A. They do.

Q. Do you recall where that is?
A. I believe it's claim 17. It's definitely on the right-side column.
Q. Let's look at 17, please.
A. It's around that area.
Q. Is this what you're referring to, Dr. Wilken?
A. Yes.
Q. If you could read into the record what claim 17 of Berezenko says?
A. An albumin containing formulation according to claim 1, wherein 99 percent of the protein is albumin when assayed by reducing SDS-PAGE at a loading concentration of 1 mg per mL.
Q. Let's look at slide 25, please.
We talked in your examination, Dr. Wilken, that Berezenko was examined substantively by the Examiner, correct?
A. Yes.
Q. Do you have an opinion as to whether the Van Urk reference -- do you have an opinion as to whether or not Van Urk was examined by the Examiner?
A. Although not directly in front of the Examiner, when we looked at the overlap, those were significantly -- I mean, they are consistent with one another, one from that perspective in terms of the content, next is the inventor

group and the organization, and the author group for which these documents came from.

Q. What do you mean by the overlap in the inventor group?

A. So if we see on the right side there in the inventor group, that we see also Van Urk in the Goodey patent, which was listed, and then in the Berezenko we see him on both patents, the first and second one listed there, and all of them are filed with Delta Biotechnology.

Q. If we can look at slide 26 of your demonstrative.

What is shown here on slide 26, please?

A. That neither the Van Urk nor Berezenko anticipate or render obvious the asserted claims, particularly that neither disclose any proteins produced in a transgenic plant, specifically recombinant mammalian albumin in a transgenic plant, certainly not a recombinant human serum albumin in a transgenic plant, certainly not in transgenic grain or transgenic rice.

Q. And if we can look at the next slide, please, slide 27.

What are you explaining on slide 27?

A. That even if one assumes that the recombinant mammalian albumin produced in a transgenic limitation appears in Van Urk and Berezenko, claim elements for which they have been presented are not arranged in the references

in the manner claimed, and that neither of the disclosures of Van Urk and Berezenko enable a person of skill in the art to arrive at the claimed invention of '951 without having to resort to undue experimentation.

Q. Look at slide 28, please.

Do you have an opinion as to whether Van Urk, I think that's what you just told us, enables the claimed invention?

A. I do not believe Van Urk enables the claimed invention.

Q. Why is that?

A. If we look at the 103-page disclosure, plant is mentioned a total of five times in the context of a list of many different organisms, including essentially all live cells that we have -- animals, plants, bacteria, any production system -- and that the process in the purification for genetically modified yeast does not apply to our particular case, and there are no examples or description for the expression, the growth, the production, extraction, or purification of rHSA from any other organisms other than yeast, and certainly not from a plant system or transgenic rice.

Q. Let's look at slide 29, please.

Is endotoxin mentioned in Van Urk?

A. They mention it once.

Q. And in what context?
A. They mention an unknown drug product, which is not specified exactly what that could be, of one of -- the rHSA in yeast expression system with their yeast purification process -- it's mentioned in these two examples, and then a list of potential characteristics, which are many different aspirational characteristics that their product should entail.
Q. Let's look at slide 31, please.
Dr. Wilken, why is it your opinion that Berezenko does not render -- does not anticipate or render the claims obvious?
A. So we know that, again, the plants are significantly different from yeast. It's only mentioned, again, in passing that the developed process is examples are specific to yeast.
And in their disclosure there's no description of the expression, growth, production, extraction, or purification of rHSA from any other organism other than yeast, certainly not from transgenic grain or rice.
Q. Let's look at slide 32.
Does Berezenko discuss endotoxin levels?
A. They mentioned endotoxin twice.
Q. In what context?
A. That in a list of potential aspirational

characteristics of these produced rHSA, and then in a description suggesting that the medium for yeast-produced recombinant human serum albumin can be ultrafiltered to potentially remove endotoxin.

Q. Let's look at slide 34, please.

Do you have an opinion as to the effect of the Deeter reference in view of Van Urk or Berezenko on the asserted claims?

A. That claims 1 and 11 through 13 are not obvious over Deeter in view of Van Urk or Berezenko.

Q. And why is that?

A. That the '951 patent demonstrates the differences between the claimed invention and the product of Deeter. Specifically one great example of that would be the difference in endotoxin levels and the impact of those endotoxin levels on the performance.

That Deeter was considered by the U.S. Patent and Trademark Office alone and in combination with other art. A person of skill in the art would not have been motivated to take an already purified plant-derived recombinant human serum albumin and combine it with yeast-specific purification methods, particularly one that doesn't even specify impacts of various methods on those components.

And that Van Urk or Berezenko in view of Deeter would not provide someone skilled in the art an expectation

of success of achieving the claimed invention highlighted here, and that each Van Urk or Berezenko in view of Deeter do not disclose each limitation of the asserted claims.

Q. Let's look at 35, slide 35.

If you can tell the Court what you're depicting on slide 35, please.

A. This is looking at endotoxin levels in the old Deeter process versus the new '951 patent process. And so we just are looking at the batches on the x-axis, so looking at several different batches, and the resultant endotoxin content on the y-axis in EU per mg dry protein.

Q. Did the Examiner of the '951 patent look at the Deeter prior art?

A. Yes.

Q. Let's look at slide 37, please.

We talked a little about the prosecution history earlier, but what did the Examiner say about Deeter and the '951 patent?

A. So the rejection of claims as being anticipated by Deeter was withdrawn in view of the applicant's declaration, which demonstrates that the compositions that were arrived at from Deeter are not capable of achieving the same endotoxin levels as specified in the '951 patent. And, thus, the Examiner withdrew the rejection.

Q. Let's look at slide 38, please.

You understand in this case that Healthgen is taking the position that a person of skill would combine Deeter with these other references, correct?

A. Yes.

Q. Do you agree?

A. I don't.

Q. Why?

A. One, in Deeter, we already had a purified rHSA, and, not only that, but it was derived from rice system. And the purification techniques and processes presented in both Van Urk and Berezenko call out the purification steps with respect to particular yeast-derived impurities. And we have a few different implications here.

One, we have different impurities, and, so, as we noted, whenever we're looking at downstream processing or purification steps, we need to discriminate between the properties of the impurities and the recombinant protein, and so they would not be suitable to apply one particular system to the other.

In addition, if you have already a purified rHSA sample, and where do you start, which process do you use. We've shown in Deeter already that simply using anion exchange chromatography is not effective in reducing the endotoxin content below the claimed composition.

Q. Let's look at slide 39 to that point.

What is your conclusion on slide 39?

A. That Van Urk or Berezenko do not disclose any purification techniques specific to removing endotoxins from plant-derived rHSA certainly.

That they do not even provide data indicating the levels of endotoxin for any product thereof.

And, in fact, Deeter does not mention endotoxin at all within the patent, indicating it's hindsight.

At that time it was not known of the significant impact that that endotoxin could have on the performance of the rHSA.

Q. Does Van Urk or Berezenko in combination with Deeter disclose the claimed cell culture media supplement containing less than 1 endotoxin unit of endotoxin per milligram of albumin in plants?

A. No.

Q. Does Van Urk or Berezenko in combination with Deeter disclose the claimed cell culture media supplement containing less than 2 percent aggregated albumin in plants?

A. No.

Q. Let's look at slide 40, please.

Why do you have that opinion?

A. So Van Urk or Berezenko do not disclose any specific purification technique for achieving less than 2 percent aggregated albumin that would be applicable to a

plant-derived rHSA. And Deeter, in fact, does not disclose aggregated albumin at all.

Q. Let's look at slide 41.

Do you have an opinion as to whether this same combination renders the dependent claims obvious?

A. Van Urk or Berezenko in combination with Deeter does not render the dependent claims obvious either.

Q. Let's look at the Huang reference very briefly. Let me ask you if the Huang reference adds anything that wasn't in Deeter?

We can look at slide 42.

Does the Huang reference add anything that wasn't disclosed in Van Urk, Berezenko, or Deeter with respect to the dependent claims?

A. No.

Q. What does Huang teach?

A. Huang is -- the focus of this particular paper is to improve the production of rHSA in a rice cell culture secreted into the media as well. So it's really a focus on the upstream part of the rHSA production process, not on achieving said compositions of rHSA capable of performing or -- encompassing the claims of the patent.

Q. Lastly, Dr. Wilken, do you have opinions about whether the -- there are some objective indicia of nonobviousness for the asserted claims?

A. Yes.

Q. If we can look at slide 43, please.

What are you showing on slide 43?

A. That there is a nexus between the DI products, the domestic industry products, and the asserted claims of the '951 patent.

That we see that the results of the invention were unexpected. We have looked at data showing the old versus the new process, and the impact of that on the performance.

That the invention satisfies long-felt need, but which was unmet in the industry. Others have tried to produce this particular product and have found significant challenges and have failed to solve those challenges.

And that another demonstration of the nonobviousness would be the implication of Healthgen's copying the claimed invention demonstrates its nonobvious.

Q. Let's look at slide 44 very briefly.

What are the products shown on slide 44, Dr. Wilken?

A. These would be the Ventria's domestic industry products.

Q. And you testified in your earlier testimony last week about whether or not these products satisfied the limitations of the '951 patent. Do you recall that?

A. Yes.
Q. And what was your opinion?
A. I believe they embody the claimed invention of the '951 patent.
Q. Let's look at slide 45.
Do you have an opinion as to whether the '951 patent achieved unexpected results?
A. Absolutely. The fact -- the mere fact that we don't see in any discussion of endotoxin nor has it been discussed in the plant-derived industry with regards to this particular product, that techniques had to be researched and developed to achieve the low endotoxin levels that is demonstrated in the '951 patent.
We see a different approach being applied in the '951 patent where they are using a detergent. The detergent is used because the endotoxin had been copurified, which meaning -- means that the traditional purification steps used did not remove the endotoxin. The endotoxin must have been copurified and likely bound to that product, which means that the company, in this case Ventria, had to research and develop, and we see some of that research and development part within the '951 patent, in order to develop steps to remove the endotoxin from their product such that it meets the claim limitations.
Q. Do you have an opinion, Dr. Wilken, as to whether

or not there was a long-felt need for the invention in the '951 patent?

A. Yes.

Q. And I'm going to pull up a Healthgen press release, which is RX-50, I believe. We can go down to the section that says, according to --

JUDGE MCNAMARA: You're fading a little bit, Ms. Hoekel.

MS. HOEKEL: I'm sorry, Your Honor. I think we all are at this point.

JUDGE MCNAMARA: There's no doubt, at least for me.

MS. HOEKEL: Maybe we can take a break before Mr. Shaffer's cross so we can all get a little caffeine or something.

Q. Do you see the top paragraph of this Healthgen press release?

A. Yes.

Q. And what does it say?

A. It says, according to Healthgen Biotechnology, OsrHSA provides an excellent solution for an animal-free medium, has higher purity and excellent batch consistency compared with fetal bovine serum, plasma-derived HSA or pHSA and BSA, which is bovine serum albumin.

Q. And the year on this document is? Do you see the

year?

A. Yes. The year is 2019.

Q. Thank you. And were you aware that other companies tried and failed to create plant-derived recombinant human serum albumin before Ventria's invention?

A. I believe Ventria was the first to produce a recombinant HSA in rice or in plants.

Q. Okay. And I'm going to ask you to look at Joint Exhibit 139, please.

And if you can tell the Court what Joint Exhibit 139 is?

A. This is a discussion of commercial potential of using plants for the production of recombinant proteins.

Q. What is the year of this publication?

A. This publication is from 2019, and it's from the Fraunhofer Institute, which is one of the leading research institutes in the world regarding plant-derived recombinant proteins.

Q. If we can look at your slide 47, please.

Did you provide an excerpt from this article?

A. Yes.

Q. And what does the excerpt that you provided say?

A. This highlights some additional challenges, we have discussed some of those today, facing the recombinant production in plants.

First was the yield challenge or the ability to be able to accumulate sufficient amounts of these products, and then, ultimately, the purification challenge, and so that inconsistent product quality and difficulties with larger scale downstream processing.

So that indicates, if we have inconsistent product quality due to the unique fingerprint upon the -- left upon the plants, and the inability to just migrate old purification techniques or steps to new systems, and that there have only been a few cases in which plants have demonstrated economic advantages compared to established and approved commercial processes, and some industry reluctance to switch to plant-based production systems.

Q. Do the criticisms of commercial products -- excuse me.

Are the criticisms -- let me start that all over again.

In some of the publications we've seen today, are the criticisms of commercial-scale companies consistent with those that we've seen of research-based companies?

A. Absolutely. It's been a challenge to bring these products to market. It's hard to change and embrace new production systems, the regulation aspect, being able to produce and express recombinant proteins in plants that are produced in the terrestrial environment, and then addressing

and trying to overcome the reluctance of that process. So it's been a long process.

Q. Were those same challenges present in the research community?

A. Absolutely. Yeah.

Q. And if we can look at the last slide, which is slide 48.

Do you have an opinion as to whether Healthgen copied Ventria's patented technology in the '951 patent?

A. When we look at the '951 application, it would have been available or published in 2011. We have an indication that the founder was employed by Ventria. There are a number of other plant systems that one could potentially use for the expression.

And the other indication is we really have two players in the world for rice-derived rHSA, which is Ventria and Healthgen. And we have also seen how the products meet the limitations of the '951.

Q. Thank you, Dr. Wilken.

MS. HOEKEL: Your Honor, I will pass the witness.

JUDGE MCNAMARA: Okay. Thank you. Will we have enough time, Mr. Shaffer, to take a ten-minute break, and will you have enough time, then, to finish by 6:00?

MR. SHAFFER: That's my hope, Your Honor, absolutely.

JUDGE MCNAMARA: What's the downside here? Tell me what the alternative possibility is.

MR. SHAFFER: Well, we've gotten bogged down a little bit with some of the duration of some of the responses to some simple questions in the past, so I'm hoping we can move this along in this next examination.

With that, I have it scheduled for about an hour. So, yes, I think a break would be welcomed by all, and my expectation is that we will be done by 6:00.

JUDGE MCNAMARA: I don't know about your math, but we're getting pretty tight. Let's take ten minutes.

MR. SHAFFER: Perfect.

JUDGE MCNAMARA: We'll see how that goes.

Dr. Wilken, how are you holding up?

THE WITNESS: I'm doing good. Thank you.

JUDGE MCNAMARA: Ms. Kinkade, how are you holding up? Are you still with us?

THE REPORTER: Yes, I'm here.

JUDGE MCNAMARA: You're indefatigable, I swear. I don't know how you do it, but you do do it.

Okay. Thank you. I'll see you in about ten minutes. I'll see you at about 4:40.

(Proceedings recessed at 4:29 p.m.)

(In session at 4:40 p.m.)

JUDGE MCNAMARA: Hello everyone.

MR. SHAFFER: Hello, Your Honor.
MR. GUARNIERI: Hello, Your Honor.
JUDGE MCNAMARA: There you are, Mr. Guarnieri.
I don't see Dr. Wilken. There you are.
Ms. Hoekel?
MS. HOEKEL: We're having to charge the mics between sessions so they don't die on us like they did the other day.
JUDGE MCNAMARA: They can be troublesome.
Dr. Wilken, are you ready to go?
Mr. Shaffer, I think the floor is yours.
MR. SHAFFER: For the record, it's Rob Shaffer, and with me for the presentation on cross-examination today is Brooke Wilner.
JUDGE MCNAMARA: Okay.
MR. SHAFFER: We can go on the public record, Your Honor, if we're not, but I believe that we are.
JUDGE MCNAMARA: May I see Brooke Wilner?
MR. SHAFFER: Yes. She is sitting right next to me.
Hello. How are you?
MS. WILNER: I'm great. Thank you. How are you?
JUDGE MCNAMARA: I'm fading but I'm listening. Just be aware.
MR. SHAFFER: Your Honor, I think we all are.

JUDGE MCNAMARA: Okay.

CROSS-EXAMINATION

BY MR. SHAFFER:

Q. Good afternoon, Dr. Wilken.

A. Good afternoon.

Q. As an initial matter, you would agree that a person skilled in the art would readily understand that a purified recombinant human serum albumin product serves as a cell culture medium supplement, right?

A. It has been used as cell culture media component.

Q. So that's a yes, doctor?

A. I believe it has been used, yeah, or the human albumin certainly has been used, yes.

Q. And you would agree that, based on the Deeter patent, a person of skill in the art would know how to make recombinant human serum albumin from a transgenic plant, right?

A. Of a particular composition.

Q. Is that a yes, doctor?

A. Yes, of a particular composition.

Q. Okay. Now in your presentation just now you compared the disclosures -- you compared the disclosures or teachings in the prior art reference of the claim limitations, right?

A. Sorry. I missed that last part. I didn't hear.

Q. Sure. As part of the prior art analysis, the proper analysis is to compare the disclosures or teachings in the prior art reference to the claim limitations, right?

A. Yes.

Q. And, for anticipation, they can either be found either expressly or inherently in one reference, right?

A. Okay. Yes.

Q. Okay. And you understand that Healthgen asserts two different prior art references on anticipation, separately Van Urk and Berezenko, right?

A. Yes.

Q. And there's no dispute between the parties here that they are both prior art to the '951 patent, right?

A. They are considered as prior art here, yes.

Q. And you also understand for this exercise you have to -- we're going through an obviousness determination as well, right?

A. Yes.

Q. And for that analysis, you're supposed to put yourself back in the time to February 2009 and imagine that you're a person of ordinary skill in the art, right?

A. Yes.

Q. And for purposes of this case, you understand, generally, that that hypothetical person would include at least a Ph.D. with a minimum of two years' experience,

right?

A. Yes.

Q. Okay. But you actually weren't in that position in February 2009 at the time of filing the provisional application in the '951 patent, were you?

A. I got a Ph.D. in August 2009 and had been working on plant-derived recombinant proteins for six years at that time.

Q. Okay. So you got your Ph.D. later that year, right?

A. In August 2009.

Q. Okay. But to determine whether Ventria's invention was obvious, you have to put yourself back in that 2009 as a person of ordinary skill in the art, right?

A. Yes.

Q. Okay. And a person in 2009 is presumed to know all the relevant prior art, right?

A. Yes.

Q. And that's true even if an actual Ph.D. scientist might not have known about it, right?

A. Even if a -- I'm expected to know what -- could you repeat that? I'm not sure I followed what you said.

Q. Sure. A person of skill in the art in 2009 is presumed to know all of the relevant prior art, correct?

A. Yes.

Q. Okay. And that's true even if an actual Ph.D. scientist might not have known about a particular piece of prior art, right?

A. Yes.

Q. Okay. Now one of the things you said that you're going to do as part of your analysis would be to evaluate the differences between the claimed invention and the prior art; is that right?

A. Yes.

Q. Okay. But you really didn't do that, did you? You didn't go claim element by claim element and compare it to the prior art?

A. I looked at all the claims of the prior art, yes.

Q. Okay. But you understand that's what's required to show the differences between the claims and the prior art, right?

A. Yes.

Q. You need to compare the claim language of the '951 patent to the prior art, right?

A. That's my understanding, yes.

Q. Okay. And for obviousness you understand you're supposed to look at the prior art as a whole, not just the individual references, true?

A. That's what I understand.

Q. Okay. But you didn't do that either, did you,

doctor?

A. I wouldn't say I didn't do that.

Q. Okay. If we could have RDX-006.2.

And RDX-006, Your Honor, is my cross slide deck, so I'll refer to it just as slide 2.

Dr. Wilken, this is your direct slide 4, right?

A. Yes.

Q. And these are the asserted claims in this case, correct?

A. Yes.

Q. Can you show me where the claim subject matter in any of these claims is directed to any specific purification step or process or method?

A. We have the process that is specifically targeted for this particular production system. In terms of the endotoxin, I think it's pretty clear in the '951 patent, the section regarding using detergents and a subsequent hydrophobic resin to remove the detergent for removal of endotoxin from the product.

Q. Okay. So you're talking about -- okay. You sort of -- I think I gathered from your direct testimony, you're sort of dividing it up into a couple different categories. And if I mischaracterize it, but to just to kind of break it down, there's upstream processes; is that fair?

A. Yes.

Q. And then there's sort of the expression itself, right?
A. Upstream is the expression.
Q. Okay. And then there's downstream processes after it's actually expressed into recombinant human serum albumin, right?
A. Yes.
Q. Okay. And you would agree with me, though, that Deeter, the Deeter patent, discloses the upstream processes and the alleged invention here deals with downstream processes; is that fair?
A. So the -- they have expression in rice of recombinant human serum albumin in Deeter.
Q. Okay. So we're talking about the downstream processes here, right, and for the '951 patent, that's what you talked to?
A. I think the claim, the unique -- claim composition due to, as we see in the claims, right, we have a unique composition of a cell media supplement --
Q. Okay.
A. -- the unique --
Q. We're talking about purification, doctor. Let's stay on the purification point.
A. Okay.
Q. I want to ask the question again because I didn't

get an answer.

Can you point to me where in the claim language of either claim 1, 11, 12 or 13 of the '951 patent where the subject matter is specifically directed to purification steps, processes, or methods?

A. If we could look at the -- I believe it's either example 3 or 5 regarding the use of detergent, and then a subsequent hydrophobic resin.

Q. So you're talking about the specification, doctor. We're going to get there. But it's not in the claim language itself, right?

A. Oh, in terms of that particular process.

Q. Correct.

A. Yeah.

Q. The words right in front of you. It's not in the claims, right?

A. Yes. I understand now.

Q. Okay. And but you do -- and you talk to this. You talked about the purification process, you talked about the data of the purification process, that is disclosed in the '951 patent, right?

A. We -- the endotoxin composition, yeah.

Q. Right. And the '951 patent calls it a, quote, new process, right?

A. Yes.

Q. Okay. And they call it -- they refer to it specifically as B0000C, right?

A. Yes, I believe so.

Q. Okay. And that was different than what was referred to as the old process, right?

A. Yes.

Q. Okay. And the old process is what was disclosed in Deeter, correct?

A. Yes.

Q. And in the '951 patent they refer to the old process as just B0000, four zeros, with no C, correct?

A. I believe so. We would just need to refer to that table. I believe it's listed in the table what they called the old process or the --

Q. Okay. There's an old process and a new process, right?

THE REPORTER: Counsel, if I could just ask if you could try not to overlap each other.

MR. SHAFFER: Oh, yes. Sorry, Ms. Kinkade. Of course.

Q. All right. And all of this was explained in detail to the Examiner through a declaration that Ventria submitted to the Patent Office by a Dr. Lorne Jordan from Kansas State, right?

A. We see -- yeah, we looked at some of those

submissions to the Patent Examiner, if that's what --

Q. You looked at his declaration, Dr. Jordan's declaration, right?

A. Yes.

Q. Do you know Dr. Jordan? He's from Kansas State.

A. I do not know him.

Q. Okay. And Dr. Jordan specifically told the Patent Office what the '951 patent's purification steps were, correct?

A. I don't believe those purification steps were disclosed in that particular portion that we looked at today.

Q. Okay. So you don't have an understanding one way or the other whether he disclosed the new purification steps and how they were different from the old process disclosed in Deeter; is that fair?

A. I don't remember that -- if they were disclosed specifically there. They are certainly disclosed in each of the patents.

Q. Okay. So you didn't talk about that on direct just now, right, the differences?

A. I did not discuss that.

Q. Okay. If we could have slide 26, please, from my cross slides.

Could we just go to JX-2, please?

This is the prosecution history. If we could go to page 711, please.

Could we go to the first page of this? This is Dr. Jordan's declaration. If you could just blow that up for us, please, Mr. Fisher.

All right. And this is the declaration that I think was pointed to in one of your slides, right?

A. Yes.

Q. Okay. Can we go to paragraphs 6 and 7 of this declaration? And if we could enlarge those, please.

This is Ventria's argument to the Examiner about the difference between the purification steps in the reduced endotoxin levels in the '951 patent versus Deeter.

And he says, in paragraph 6, following the above concepts, the initial process B000 -- that's Deeter, right?

A. Yes.

Q. -- was designed, example 5, that's what you were pointing to, the data there, however, this approach still resulted in high endotoxin levels, 44.97 EU per mg average, right? That's the data that you quoted, right, doctor?

A. Yes, I believe so.

Q. And it also had high detergent levels, 445.31 ppm average, which was detrimental to cell viability in a dose-dependent manner as noted, right?

A. Yes.

Q. And he goes on. He says, thus, a more advanced process, B0000C, was designed using TR-X-100 detergent and SDR (PALL) hydrophobic resin. Do you see that?

A. Yes.

Q. Paragraph 7, if we could blow that up please, Mr. Fisher.

Do you see that, doctor?

A. I do.

Q. So he is describing the more advanced process. It has two steps. One, it uses a detergent, and, second, it uses a hydrophobic resin. Do you see that?

A. I see those two steps listed.

Q. Okay. And he says, this new approach unexpectedly resulted in endotoxin reduction. Do you see that?

A. Yes.

Q. Okay. Are you aware of the steps that were disclosed in Deeter for purification of endotoxins, doctor?

A. Yes.

Q. All right. Do you know what they were? What were they?

A. They have several anion exchange steps. They have an ultrafiltration step. They start with a pH, low pH extraction. I know they have several anion exchange steps, ultrafiltration.

Q. Okay.
A. Yeah. I don't know the exact sequence, but I know in general.
Q. Okay. Fair enough. So I looked at it a little bit more closely last night. They use a filtration step in step one, which is a passthrough filter separated by protein size; is that fair?
A. So they use -- the first -- are you talking about --
Q. I'm talking about -- I'm sorry. I'm talking about the old one, the old one.
A. Yeah, but where were you starting the process? Is this after extraction or before?
Q. This is the downstream process for purification of endotoxin.
A. Extraction is part of that. So I'm just wondering if it's before extraction or after extraction.
Q. We're referring to B0000, the one that Dr. Jordan was referring to.
A. So each of them has extraction, that's what I'm just curious about.
Q. Okay. But, as you said, they use a filtration step, and you said they use a column, correct?
A. So they have anion exchange, they have a filtration step, it could be either, you know, dead end for

large particles, or they could also have a cross-flow. I would need to refer back to give you specifics.

Q. Okay. And, in fact, both Deeter and the '951 patent both disclose filtration steps and a Q-Sepharose column. Does that ring a well?

A. Yes, Q-Sepharose is included. That's anion exchange.

Q. The only difference between the two, as Dr. Jordan notes here, is the step of a detergent and the hydrophobic resin, right? That's what he says.

A. No, there's also a different extraction process. So we have a pH 7, I think it's -- I believe it's pH 7 range, a more neutral pH extraction rather than pH 4.7 or somewhere in that range.

Q. When you say "we," you're referring to who, doctor?

A. So in the new '951, the extraction is pH 7. If we look at the old process, the extraction is pH -- it's in the 4 to 5 range. I think it's 4.9 or so.

Q. So the pH changes a little bit. It becomes a little bit, more, what, acidic, doctor?

A. What's become --

Q. Under the new process, it becomes more basic; is that right?

A. So you would have -- I mean, it depends what

you're talking about. If you're just extracting it, that's going to extract different impurities as well. It's going to have a slightly different profile than if you were to do so at a low pH.

Q. Dr. Jordan didn't explain any of that to the Patent Office. He said the more advanced process uses two steps, right, that's what he said?

A. It's one part -- that's a very important component. It's not easy to remove those endotoxins.

Q. That wasn't my -- I understand, doctor. That's what he told -- that's what Ventria told the Patent Office as the difference between the old process and the new process, right?

A. That's one change in the process, absolutely.

Q. It's fair to say by 2009, doctor, that there were many known processes for purifying albumin, right?

A. There were a lot of purifications for albumin. I would agree.

Q. Okay. And it was well-known by a person of skill in the art that albumin could be recovered and purified from recombinant cell cultures by well-known methods, correct?

A. There are well-known methods to use, absolutely. I would say, yes.

Q. And, doctor, a POSA before the '951 patent could have easily searched a number of different patents and

published applications and related publications and would have been provided many possible methods for preparing and purifying albumin, right?

A. You would see the common purification steps.

Q. So that's a yes, doctor?

A. Yeah, you could look at literature, absolutely. You can look at literature. Does it apply is another question.

Q. And, doctor, even based on your own writings, you've acknowledged that a person of skill in the art of previously developed methods for other protein expression hosts would also be suitable for plant systems, right?

A. I don't think they are suitable for plant systems. In my experience there's a lot of challenges we've had which are unique to plant systems.

Q. Okay. Well, if we could have CDX-5, please, or my slide 5.

This is an article that you wrote, doctor, in 2012; is that right?

A. Yes.

Q. For the record, this is CX-0901. It was written or published in 2012.

Doctor, these are your own words under section entitled Purification 3.2. And you're talking about plant-made recombinant proteins, right?

A. Yes. We're saying in general, yes, yes, this is a summary over plant made recombinant proteins, yes.

Q. Okay. And you state, in your own words, purification of plant-derived proteins, similar to other protein production systems, is dependent on protein properties and host cell impurities, and utilizes similar strategies for purification development as other heterologous expression systems, right?

A. Yes. This means that --

Q. Doctor, are those -- those are your words, right?

A. Yes. I just want to --

Q. If you want to explain it, you can do that with your counsel.

A. Okay.

Q. Those were your words, correct?

A. Yes.

Q. And if we could have slide 6, please.

You mentioned the Goodey patent on direct. This is another prior art patent. In fact, this patent, a person of skill in the art would understand actually claims purification steps with respect to albumin solutions, right?

A. This is purifying albumin.

Q. Okay. And turning to Van Urk, we know from Van Urk's disclosure that it teaches a person of skill in the art how to purify recombinant human serum albumin to

less than 1 EU, true?

A. I don't believe it specifies less than 1 EU and it's from yeast.

Q. It's from yeast, but it specifies less than 1 EU, right?

A. I don't believe it gives less than 1 EU or measure directly in reporting those values.

Q. If we could have slides 7 and 8, please.

Van Urk does, in fact, disclose a number of different ways to purify recombinant human serum albumin, right?

A. We see a lot of different operations that could be used.

Q. Okay. And let's talk a little bit about them, because we didn't talk about too many in detail. But it lists cation exchange chromatography, right?

A. Yes.

Q. And anion exchange chromatography, right?

A. Yes.

Q. And affinity chromatography, right?

A. Yes.

Q. And diafiltration, that's mentioned in the B000C process in the '951 patent as one of the steps, right?

A. Yes.

Q. And ultrafiltration, that was another step we

just talked about, right?

A. Yes. Those are usually together. They are two different operations in the same operation, so it's using the same step but different functions, yeah.

Q. Okay. And then a second affinity chromatography step, right?

A. Yes.

Q. Okay. So another way that a person of skill in the art can try to purify or increase the purification of endotoxins is to repeat some of these steps. That's a pretty common practice, right?

A. These are the tools that all the purification scientists have available. What's important to note is that they perform differently depending on the types of impurities that you have present, right.

Q. Right.

A. The invention is to separate the recombinant protein from impurities, and, thus, that's where the challenge comes.

Q. Understood. All right. So a bunch of the prior art, and even the '951 patent, discusses those approaches, correct? I think you testified --

A. Yeah, those are unit operations.

Q. Okay. And Van Urk discloses that, I believe you mentioned this on direct, that its recombinant human serum

albumin is nonpyrogenic, right?

A. It says that general term, yes, nonpyrogenic, yes.

Q. And you understand that a person of skill in the art would take that to mean free of endotoxins, right?

A. Endotoxin is one part of nonpyrogenic. There's a lot of different factors and not all of them are addressed. So it could -- it is part of the pyrogenic substances, so it could be encompassed there within that.

Q. Certainly endotoxins are pyrogens, right?

A. Yes. Yes, I would agree.

Q. Okay. And a product free of endotoxins should be nonpyrogenic, true?

A. If it says essentially free, so it depends what that essentially free below the limits mean, right. It's not specified.

Q. Okay. You understand that patents and prior art patents and references are presumed to be enabled, right?

A. Yes.

Q. You didn't talk about that on direct, did you?

A. I didn't, no.

Q. And you didn't actually go through any of the specific teachings in any of the cited patents in particular, did you?

A. I didn't -- no, I didn't go through the processes

each used.

Q. And you didn't give any specific reasons for why a person of skill in the art in a lab can't take an albumin protein expressed from Deeter, for example, or from a yeast or from corn or from some other expression system and run that albumin protein through a column or diafiltrate or rinse it with a detergent, just like the '951 patent tells you to do, right?

A. I can explain whatever you need to -- if you want further explanation, I would be happy to provide that.

Q. But you didn't provide that explanation on direct, did you?

A. I didn't specify the potential differences for each impurity, but what I did specify is that we cannot expect reasonably that you're going to take your unique system with rice-derived recombinant protein with the rice impurities and place it in that step and say that that's going to perform the same.

Why? Because they each have different properties, both the impurities, we know they do, and so we would not expect that we can take that same solution and expect that it come out with the same results. It's not likely, very unlikely.

Q. But you understand that a person of skill in the art had Deeter, right? I believe you testified that Deeter,

quote, had already provided recombinant human serum albumin derived from rice, correct?

A. They did, but --

Q. Okay.

A. -- the main issue was the endotoxin certainly was one of those aspects that --

Q. Understood.

A. -- wasn't known, yeah.

Q. You heard Dr. DeFilippi walk through what a person of skill in the art would know based on the disclosure in Berezenko, right?

A. I heard him discuss the Berezenko patent this morning.

Q. If we could have slide 9, please.

For the record, Your Honor, this is going to be -- this is RDX-6C, slide 9.

Berezenko provides detailed guidance on how to purify recombinant human serum albumin, correct?

A. From yeast.

Q. From yeast. But he has a number of different tables, correct?

A. Yes.

Q. Table 3, Table 4?

A. Yes.

Q. 5, 6, 7, 8, correct?

A. I see those tables there, yes.
Q. I think we all agree that the expression system in Deeter is the same expression system as found in the '951 patent, right?
A. It appears they are expressing, yes.
Q. Okay. And you agree --
Now I believe you testified on direct, tell me if I'm wrong, because -- that Deeter was missing also less than 2 percent aggregated albumin as well, right?
A. That wasn't in the claimed compositions.
Q. Okay. But Ventria did not argue that to the Patent Office to try to overcome that anticipation rejection; they just focused on the endotoxin, right?
A. We see the direct impact in that particular application, yeah.
Q. Okay. So through the purification steps, it not only removes the endotoxins that are removed, but also removes the other impurities like aggregated albumin; is that fair?
A. Yeah, which is -- which is challenging, if you think about -- you have to use --
Q. Doctor, could I get a yes to that before you explain? That was a yes?
A. Well, I wanted to substantiate, but could you just repeat that again? Because I always want to make sure

that my opinion is accurately reflected.

Q. Okay. So through the purification steps, you're not only removing the endotoxins, but you're also removing other impurities like aggregated albumin, fair?

A. In the '951?

Q. In Deeter or the '951.

A. There would be different considerations there, because we have potential additional sources for aggregate formation due to the endotoxin removal. There could be, yes.

Q. Okay, doctor. By your opinion --

Actually, if we could go to slide 25 of my deck, please. Thank you, Mr. Fisher. This is Deeter example 7.

You understand from your review of the prosecution history that the Examiner, when he found that Deeter was an anticipatory reference, that he found less than 2 percent aggregated albumin limitation in example 7, right?

A. So this is just giving purity so which can be different. So it's not pointing out aggregates in any sense here. So you have to look in the context here.

Q. Okay. But you understand that the Examiner found that the 98 percent based on SDS-PAGE, that he found that the less than 2 percent aggregation had been met, right?

A. No. I don't have that understanding that that

was used by the Examiner to say that was below the 2 percent.

Q. You reviewed the --

A. Sorry. It gives purity from 90 to 98 percent here.

Q. Okay, doctor. That's fine. If you don't have an understanding one way or the other, that's fine.

And it's your position here that this disclosure that shows SDS-PAGE of 98 percent doesn't give you enough information, right? That's your position? That's what you just said, right?

A. What I'm saying is that SDS can glean different information. So when you just say purity, purity doesn't automatically mean aggregate. Aggregate means we're looking for an aggregate within the protein sample. So those have different meanings.

And so unless it's specific -- unless we can refer to that, then we can't say that just because you report a purity directly that that's also what you're inferring upon that data.

Q. Okay. Let's go back to endotoxin for a moment. You don't point to anywhere in the literature that says an endotoxin in yeast is different than an endotoxin in rice, fair?

A. Fair, but I think we have a clear difference

between a terrestrial production system and one that is produced in a bioreactor with controlled environment would likely have a difference in that composition.

Q. Well, of course, doctor, you're going to have more bacteria in some places in a room versus a field where there may be, you know, animals residing, more bacteria in one place than the other, right?

A. You're going to have different -- you have a completely different environment, so you can't transcribe one and say this is our situation.

Q. Right. But the endotoxins --

A. -- also is a general term used to describe, you know, this particular component of a cell wall. It doesn't maintain -- this is an exact molecular weight that's going to be maintained throughout. It's the exact same concentration, which also impacts purification performance. And so there are a lot of variables there to consider.

Q. Doctor, endotoxin is a molecule from the cell membrane of a Gram-negative bacteria, right?

A. It's a fragment of a cell wall.

Q. Okay. And you agree that aggregated albumin are impurities as well, right?

A. Excuse me?

Q. Do you agree that aggregated albumin are impurities in recombinant human serum albumin as well?

A. Aggregated albumin can be impurities.
Q. And those would want to be removed as well, right, just like endotoxins?
A. So we, traditionally, if there would be an impact, it depends on the particular application. So if there is a negative impact based on that particular application, then certainly that would be something you would want to do if you had an indication of that.
Q. Doctor, isn't there a much easier answer than that? Isn't that what the goal of the '951 patent is to get less than 2 percent aggregated albumin? There's a reason for that, right? That's the goal to get less aggregated albumin, right?
A. That's the goal in the patent, but I wouldn't say it was always known that that was important to the performance of that particular formulation and product.
Q. Unlike endotoxin, which everybody knew, as you mentioned on direct, that fewer endotoxins in recombinant human serum albumin was a good thing, right?
A. Well, traditionally, in pharma, endotoxin is bad. I don't think it was known, for example, based on the, you know, every type of cell culture may need different concentrations of HSA, which would bring with it different amounts of endotoxin.
Q. Okay.

A. So I do think, through their evaluation, that they determined, I think they were -- it's not something I would automatically assume. In fact, I've been working on rice-derived purification since 2003. And I myself haven't given major consideration to endotoxin at that point in our process development.

Q. All right, doctor. On direct you provided some opinions that the recombinant human serum albumin disclosed in the '951 patent is more active than the prior art recombinant human serum albumin. Do you remember that testimony?

A. Compared to yeast?

Q. It's a simple --

A. I'm just asking, can you just clarify? You said it was more active in the cell culture is what you're saying based on activity here.

Q. Correct.

A. Yes, we compared that, yes.

Q. And you understand that improving the growth of a cell in cell culture in the preamble of claim 1 of the '951 patent, as it's been construed in this case, is non-limiting, right?

A. Is what? Excuse me?

Q. Is non-limiting. It's non-limiting.

A. So that's my assumption. Sorry.

Q. Okay.
A. That's my understanding.
Q. You understand that there's a reason for that, right?
A. That it's not limiting?
Q. That it's non-limiting, and why Ventria stipulates it to be non-limiting, right?
A. I'm not sure exactly what you're asking me here.
Q. Okay. All right. Let's try to walk through this a little bit.
A. Yes.
Q. You understand that Ventria during prosecution attempted to claim that improved activity, right? You kind of were around the edges on this in your direct testimony, right?
A. Yeah, we talked about improved -- are you referring to the prior patent?
Q. To the prosecution history, right.
A. Of the '951?
Q. Of the '951 patent, yes.
A. Yeah, I see what you're saying. Okay, yes.
Q. And the Examiner rejected that claim, right?
A. I suppose so, yes.
Q. Okay. And, in response, Ventria amended the claim and withdrew from its claim any claim to any

improvement.

If we could have slide 23, please.

And this, Your Honor, is JX-2 of the prosecution history at page 665. If we could blow this up.

So here was the claim that later became claim 1, and under prosecution at the bottom Ventria originally had the claim wherein said supplement or complete medium improves growth of a cell in cell culture medium comprising said supplement or complete medium.

Do you see that, doctor?

A. I see it.

Q. And do you see the strikethrough?

A. I do see that.

Q. And you see where they added it back up into the preamble? Do you see that?

A. Yes.

Q. And you understand that this was Ventria's own doing, right?

A. I would assume so. I didn't see who modified this, but I would assume so.

Q. Okay. And by taking it out of the claim and putting it into the preamble and making it non-limiting, that it's not a claim requirement. Do you understand that, doctor?

A. Yes.

Q. Okay. I believe you also attempted to diminish the teaching of Van Urk and Berezenko because they only disclose one example; is that fair?

A. Could you please speak a little bit louder? I didn't hear the last part.

Q. No problem. Happy to repeat it.

Why don't we set the stage. Let's turn to the enablement testimony you gave for the prior art. I want to talk about your testimony on Van Urk and Berezenko.

And I think, at least with Van Urk, you attempted to diminish the teachings of Van Urk and Berezenko because they only disclose one example, and that was to a recombinant human serum albumin derived from yeast, right?

A. Yeah, I think one of them speaks about a blood example potentially, if I remember right.

Q. Okay. Well, you understand, doctor, that -- you understand that the '951 patent only gives us one example of recombinant human serum albumin and that's expressed in rice, correct?

MS. HOEKEL: Objection, Your Honor. I believe Mr. Shaffer is getting towards arguments related to whether the '951 patent is enabled, and your order on the motion in limine said that Healthgen will be permitted to cross-examine Dr. Wilken with respect to non-enablement arguments regarding Van Urk and Berezenko. And I think that

question was with respect to number of examples in '951, which would lead to the 112 arguments.

MR. SHAFFER: May I respond just very briefly, Your Honor? I'm not trying to get to any enablement argument.

JUDGE MCNAMARA: That was a yes.

MR. SHAFFER: I'm sorry. Thank you, Your Honor. I'm not getting to any 112 arguments on the '951. I'm only making the point that she tries to diminish the teachings of the prior art by saying that they disclose only one teaching embodiment, when, in fact, that's what the '951 patent does too. That's all, Your Honor. And I made my point. I'm going to move on.

JUDGE MCNAMARA: Okay.

MR. SHAFFER: Thank you. May I proceed, Your Honor?

JUDGE MCNAMARA: Yes.

MR. SHAFFER: Thank you.

Q. You do understand, doctor, that the '951 patent only gives us -- you understand that the prior art patents are presumed enabled, I think you said that earlier. And that goes for, not only the claimed but also the unclaimed disclosures as well, correct, everything that it teaches?

A. Okay.

Q. And it's Ventria's job here to show that the

prior art is not enabled, right?

A. Yes.

Q. You didn't do that, did you, doctor.

A. I wouldn't agree with that.

Q. Okay. As of at least 2003, a person skilled in the art would understand that transgenic plants had become an alternative for cell culture systems for recombinant protein expression, true?

A. Did you say "cell culture systems"?

Q. I did.

MS. HOEKEL: You dropped down a little bit, Mr. Shaffer.

MR. SHAFFER: I'm sorry. I'm happy to repeat my question. I'm sorry about that.

Q. As of at least 2003, a person skilled in the art would understand that transgenic plants had become an alternative for cell culture system for recombinant protein expression, true?

A. So plant cell culture system -- you're asking me if plant cell culture systems have been an option for recombinant protein production.

Q. I'm just asking you if you agree with that statement I just read.

A. It was an option potentially to use a cell culture. I think cell culture have been accepted a little

bit sooner because they mimic the traditional platforms a little bit better.

Q. If we could have slide 12, please.

Dr. Wilken, this is another one of your papers that I was reading from. This is a 2017 paper. I guess it's a presentation of yours. It's RX-374.

If we could blow up the highlighted area, please.

MS. HOEKEL: It's RX what?

MR. SHAFFER: 374.

MS. HOEKEL: Thank you.

Q. Reading from your presentation, doctor, I said, a popular example of -- actually I read the first part.

Transgenic plants have become an alternative for cell culture systems for recombinant protein expression due to the exclusion of possible mammalian pathogens and virus contamination as well as the high expression level of recombinant proteins which reduce purification requirements and create a more effective method. Do you see that?

A. Yes.

Q. And you cite to a 2003 article for that statement, right?

A. Yes.

Q. So a person of skill in the art would understand, based on your statements in your 2017 article that cites to 2003, that transgenic plants have become an alternative for

cell culture systems for recombinant protein expression, right?

A. So you could potentially use those for expression. Are they being commercially used in marketing, that's another story, right? This is just the beginning of when this was all really starting to develop where the focus was --

Q. Doctor --

A. -- on expression, yeah.

Q. Well, based on that statement, let me ask you this question, doctor.

A. Okay.

Q. Is it your contention now that the claim is to an industrial process or commercial process?

A. What I'm saying is, in terms of acceptance here, right, are they -- is it possible to produce a product in a plant? Yes, right? Was the technology there? It was in progress, right? Those are two different things, right? This isn't, you know, a research portion.

Q. Okay.

A. Sure, yeah, it can be used. We have been evaluating the use of plants.

Q. Okay. And you're happy to enlarge on that with your counsel.

You do understand from the patent itself and what

it teaches a person of skill in the art, doctor, that numerous types of appropriate expression vectors and suitable regulatory sequences were known in the art for a variety of plant host cells, right?

A. There was sequences known for plant -- a variety of plant cells?

Q. Plant host cells, yes.

A. So there are various plant expression systems, if that's what you're asking. I'm not sure what the sequence aspect was.

Q. I'm just asking if you agree that the patent teaches a person skilled in the art that numerous types of appropriate expression vectors and suitable regulatory sequences are known in the art for a variety of plant host cells.

A. For plant what?

JUDGE MCNAMARA: Host cells, I think is what he said.

A. Okay. So there were plant -- various transgenic plants and various strategies for expressing, if that's what the question was.

MS. HOEKEL: Your Honor -- excuse me, Mr. Shaffer.

Your Honor, I have an objection that we don't have an Exhibit RX-374 or an Exhibit CX-374 or an Exhibit

JX-374. So I'm not sure what exhibit this is. I just want to make sure we're all clear.

JUDGE MCNAMARA: Okay. I think he said -- well, he was referring at one point to the patent prosecution, JX-2 at 665, I think.

MS. HOEKEL: But the paper that --

JUDGE MCNAMARA: But there's no RX-374.

MS. HOEKEL: Right. That was the number he gave for the paper that's on the screen, Your Honor. We don't have an RX-374.

MR. SHAFFER: It was disclosed to them at the beginning of cross-examination per the ground rules, Your Honor. This is Dr. Wilken's paper.

Q. Is that correct, Dr. Wilken, is this your paper?

A. This was a conference paper.

JUDGE MCNAMARA: Hold on. Did you provide it to them, though?

MR. SHAFFER: We did provide it to them.

MS. HOEKEL: My team is telling me they don't have a copy of it. If it's a Dr. Wilken paper, I won't belabor the point. We just don't have a copy of it, or at least not a copy that was marked as such and provided.

MR. SHAFFER: That's correct.

JUDGE MCNAMARA: So that will be provided, if it hasn't been.

MR. SHAFFER: Absolutely. If it hasn't been, I'm sorry, I thought it was provided at the beginning of cross. I will check on that right away.

Thank you, Ms. Hoekel.

Q. Just to be clear, though, Dr. Wilken, this is a presentation from ASABE Meeting Presentation of 2017 entitled Purification of Recombinant Human Serum Albumin from Transgenic Rice Extracts by you and a colleague, correct?

A. One of my graduate BSMS students.

Q. Okay. Thank you.

And, in fact, Dr. Wilken, you understand that the Van Urk prior art reference discloses that recombinant human serum albumin may be used in a cell culture, correct?

A. Yes.

Q. Okay. And you understand that Van Urk discloses that albumin is, quote, used to supplement media used for growing high eukaryotic cells and further expressly discloses that albumin of the present invention may be used in cell culture, correct?

A. They suggest it may be used for that. It could be potentially.

Q. And, doctor, you understand that the recombinant human serum albumin disclosed by Van Urk would have the amino acid sequence of native human albumin, true?

A. That's what they are indicating here.
Q. Okay. And, like Van Urk, Dr. Berezenko also discloses recombinant human serum albumin -- sorry, it's getting late in the day, Your Honor -- that may be used in cell culture, correct?
A. There's a potential, I think it's mentioned in one location that it could be.
Q. Okay. Let's have RDX-6.13. This is my slide 13.
All right. Here it is. This is the Berezenko reference. It says, albumin is used to treat patients with severe burns, shock, or blood loss. It is also used to supplement media used for growing higher eukaryotic cells.
In this specification the term "albumin" refers generically to human serum albumin and/or recombinant human albumin; is that right?
A. I see what you're -- yeah, I see that there.
Q. Okay. And the recombinant human serum albumin disclosed by Berezenko would have the amino acid sequence of native human albumin, correct?
A. I believe so.
Q. Just as the recombinant human serum albumin disclosed in the '951 patent would have, correct?
A. The amino acid sequence?
Q. Uh-huh.
A. Yes, mm-hmm.

Q. And the albumin produced --

JUDGE MCNAMARA: Is that a yes?

THE WITNESS: Yes.

JUDGE MCNAMARA: Thank you.

Q. And the albumin produced in accordance with the invention is preferably human albumin, correct?

A. In the Berezenko?

Q. In the Berezenko and in the '951 patent, correct?

A. They are doing human serum albumin that they are producing.

Q. And Van Urk, in fact, also discloses recombinant human serum albumin produced in transgenic plants, right?

A. It mentions transgenic plants, although I don't see any further indication. It doesn't mention rice specifically. It does say transgenic plant in passing.

Q. Correct. It says, transgenic plants. It also says tobacco, potato, or corn (maize), right, which is a grain. You'll agree with that?

A. Yes.

Q. And Berezenko also discloses recombinant human serum albumin produced in transgenic plants, right?

A. I wouldn't say it discloses. I said it mentions that in a laundry list, but it doesn't show how that could be done.

Q. You understand that a person of skill in the art

reading Berezenko would have the Deeter reference to guide them in making a transgenic plant, right?

A. Yes.

Q. Okay. And many expression systems are known, including plant cells. That's what it says, right?

A. That's a very broad category. There are plant cells, yes. Plant cells -- that sounds like a cell culture to me, again, which is very different than the terrestrial seed system we have here, but it is a plant.

Q. And Van Urk also discloses that plant-derived recombinant human serum albumin can have less than 2 percent aggregated albumin, right?

A. It can have less than 2 percent aggregate? I don't think they specify in the claim that it's less than 2 percent as such.

Q. Well, let's take a look at it. It's Van Urk, and I'm on slide 17 here, Your Honor.

Van Urk discloses recombinant human serum albumin containing up to 1 percent dimeric albumin and no larger albumin aggregates, correct?

A. That's given in the patent. I don't think that's specified in the claims, if I remember.

Q. Right. It's in the patent. It's not claimed, correct?

A. That statement is in the Van Urk patent, yes.

Q. Okay. And that's pretty clear, isn't it, doctor, that we're talking about 1 percent dimeric albumin and no larger albumin aggregates, right?

A. That's what it says in that statement.

Q. Okay. So we know that that's less than 2 percent, correct?

A. Yes, if it's based strictly on that. It says may be up to 1% dimeric but no larger, so that would indicate that could be the case.

Q. Just to be clear, that's less than 2 percent aggregated albumin as taught by Van Urk, correct?

A. They are saying that there may, yeah, that could be the case. I don't know if --

Q. Well, it's saying up to 1 percent. So we know it's less than 2 percent, correct?

A. That's what's claimed, yeah -- not claimed, sorry. That's what's indicated here in the text.

Q. Okay. And as formulated for injection, the disclosure here is done by gel permeation HPLC, correct?

A. Yeah, gel permeation, yes, HPLC.

Q. And another word for gel permeation HPLC is SEC-HPLC, correct?

A. Size-exclusion, yes.

Q. They are pretty much -- they are synonymous, right?

A. Yes.

Q. And a person of skill in the art reading Van Urk would have understood that plant-derived recombinant human serum products could have low levels of aggregated albumin and, with that, low levels of endotoxins too, right?

A. You would assume that plant would have?

Q. Based on the teachings that it relates to plants, that it teaches low aggregated albumin of less than 2 percent and nondetectable levels of endotoxin, right?

A. I would say that's not an assumption that you would use that to result in that from a plant system.

Q. Okay. Let's talk about Berezenko, which also, as we mentioned earlier, discloses recombinant human serum albumin derived from plants.

It also describes the contaminants or endotoxins can be removed from plant-derived recombinant human serum albumin, correct?

A. It's for recombinant human serum albumin.

Q. Okay.

MS. HOEKEL: Your Honor, sorry, just another objection. My team is telling me that we also don't have copies of these demonstratives that were supposed to be served at the beginning of cross.

I'm in another room, but I just want to make that objection for the record.

I don't know that I have an objection to this slide, it's an excerpt from Berezenko, but I just wanted to point that out.

JUDGE MCNAMARA: Okay. Can you get that sorted out, Mr. Shaffer?

MR. SHAFFER: Of course, Your Honor. I will get them a copy. I just asked Ms. Downey to do so.

MS. HOEKEL: Thank you.

Q. Doctor, you agree that Berezenko also discloses plant-derived recombinant human serum albumin is less than 2 percent aggregated albumin; is that fair? If I could have 19 --

A. I would not say I feel confident that using a plant system would result in less than 2 percent aggregate here. And I have no evidence to show that it would.

Q. Well, Berezenko tells a person skilled in the art that the albumin of the invention is at least 99.5 percent monomeric, right?

A. I see that there.

Q. Okay. And if it's 99.5 percent monomeric, as you read that, then that leaves .5 percent for everything else, right?

A. It does. And if that's claim 1, that's linked to the further claim 17 as well, yeah.

Q. Okay. I did notice that you put up claim 17. So

why don't we do that. But this is the disclosure in Berezenko, and you would agree with me that it claims at least -- or it discloses or teaches to a person of skill in the art at least 99.5 percent monomeric, right?

A. I think, if they have shown that in yeast, then they have shown that in yeast. I don't believe that that would result in that from any other system.

Q. Okay. Regardless of the platform, doctor, you agree with me that what's taught here is less than 2 percent aggregated albumin, right?

A. If there -- I mean, they don't call it out, but usually when you say monomeric, you would assume that would be the case.

Q. It says the albumin of the invention.

A. Yes.

Q. Okay. I notice that you put up claim 17 very quickly on your direct. Why don't we go there. Claim 17 is --

If we could go to JX-27, which is Berezenko, page 25, at column 36, please, Mr. Fisher.

And you pulled up claim 17. And you understand, doctor, that this is a dependent claim, right?

A. Yes.

Q. Okay. And this is -- there's multiple teachings in a patent, you understand that, right?

A. I suppose so.
Q. Okay. So you focused on one with claim 17, right? Correct?
A. Because it's linked back to claim 1, that's why I was using that in context of claim 1.
Q. Okay. But we look -- we started out talking about you look at the patent as a whole in what it teaches, right?
A. Of course, yeah.
Q. That's what we do. Okay. So let's talk about what it teaches as a whole, because you pointed out a number of different things here.
So claim 17 talks about 99 percent protein is albumin when assessed by reducing SDS-PAGE, right? Right? That's what it says.
A. Yes.
Q. And I believe your testimony on direct was, well, we don't know what that means, because -- right? We're not quite sure what that means, right?
A. What I'm saying is that that particular method they are referring to is the claim that they are making and one is related to that particular technique essentially.
Q. Okay. So is it your opinion now that this does teach less than 2 percent aggregated albumin or not?
A. I don't think they are specifying less than 2

percent. If it is based on this particular method, we could say it's potentially based on monomeric albumin, but, again, we have to look in the context of the specifications to look further, if we could, yes.

Q. Absolutely. And I agree with you. So you can't tell by looking at claim 17 in isolation whether this is telling a person skilled in the art whether it's less than 2 percent aggregated albumin; is that fair? Is that your testimony?

A. Well, it appears, right, that it says it's a certain percentage of monomeric based on -- what it's specifying is one is based on that particular technique is what that tells me.

Q. Doctor, it doesn't say monomeric here anywhere.

A. But it says according to claim 1. So the formulation is according to claim 1. That's why I was indicating --

Q. Okay. You understand that this is a dependent claim that depends from claim 1, right?

A. Yes.

Q. Okay. Well, let's look at claim 1, then, and see what that says.

JUDGE MCNAMARA: I think that's all she was saying.

MR. SHAFFER: Okay, Your Honor. The point here

is that there's multiple teachings in the patent.

JUDGE MCNAMARA: Well, I think anybody knows that. Come on. That's a fairly broad statement. Even I'm going to call you on that one. Come on.

MR. SHAFFER: Your Honor --

JUDGE MCNAMARA: She knows that. She has been testifying for two days. I'm sorry. That was a little condescending.

MR. SHAFFER: No, no, Your Honor. There's different tests that are disclosed and --

JUDGE MCNAMARA: Of course.

MR. SHAFFER: Okay. All right.

Q. You didn't point to claim 1, though, did you, doctor, where it says 99.5 percent monomeric. That's the only point I'm trying to make, right? You just pointed to claim 17.

A. No, we also -- I linked it to claim 1.

Q. All right. You didn't show claim 1, though, did you. Okay.

A. I thought we did. I thought we specified that so --

Q. Okay.

A. That's just my remembering but maybe --

Q. I understand, doctor. That's fine. We're getting close to the end.

I do want to talk a little bit about the knowledge of a person of skill in the art at the relevant time a little bit more.

And you do understand that, the state of the art before the '951 patent, that a popular example of transgenic plants was rice, correct?

A. If you think about popular, we have Ventria, so they have expressed many different products in rice. Was it popular in terms of many different entities were using rice? No.

Ventria had examples, and if you'll see those references there are linked with Ventria, because of their expression system and their ability to accumulate high levels of protein in them.

Q. Okay. Let's go to slide 20. This is your 2017 paper again.

A. Okay.

Q. And I'm quoting your own words here. It says, a popular example of transgenic plants is rice due to generally regarded status -- generally regarded as safe status, and it cites Nandi, a 2002 paper, established production infrastructure, relatively high protein content and expression level, low risk of contamination by human pathogens, low phenolic concentrations, and presence of endogenous protease inhibitors that prevents degradation of

recombinant proteins through processing.

Do you see that?

A. Yeah, that's a Ventria. Nandi is Ventria associated.

Q. Okay. And he published that in 2002. And a person of skill in the art would be aware of that paper. And you published this with your dissertation advisor, Dr. Nikolov, in 2006, right?

A. Yes. Those are some potential advantages to using rice. Those are a snapshot. There's a lot more complexities and challenges as well. These are some potential advantages to using rice, from our experience of working with transgenic rice.

Q. Understood, doctor. So a person of skill in the art would understand, in looking at all the knowledge that was available to them, that plant was a popular example -- that rice was a popular example of a transgenic plant, right?

A. It was the one -- it was one of them used. When I'm thinking popular, not saying that everyone around the world is using it, but it was one that has demonstrated the highest expression, and they have been able to express recombinant proteins.

There's a big difference between simply saying here's some benefits and actually, you know, developing a

purification process and dealing with some of those challenges associated with that.

Q. Are you done, doctor?

A. Yes.

Q. Are you done? Okay.

A. Yeah. Yeah.

Q. All right. Let's briefly talk about -- skipping a little bit -- I made a promise and I want to hold my promise that we'll be done by 6:00.

If we could have slide 21, please, of my cross-examination slides.

Dr. Wilken, do you remember talking about Yang and the Yang patent in your direct?

A. In the direct? We talked about some of his publications.

Q. Some of his publications?

A. Yeah.

Q. And you understand that Dr. Yang's work is directed to something a little bit different than removing endotoxins, right, from your review of those papers?

A. I don't remember it called out specifically here. It would be included -- I mean, it's an impurity, right, not necessarily a protein impurity.

Q. Okay. Well, you do understand that his papers don't mention endotoxin at all, that they went in a little

bit different strategic direction and really looked at host cell proteins. You understand that from a review of Dr. Yang's papers, right?

A. They discuss nontarget proteins, as any paper likely would talking about protein purification.

Q. Okay. Sure. But he hasn't mentioned endotoxin anywhere, does he.

A. I would have to go back through and look. I don't want to give a promise here that I don't a hundred percent remember.

Q. Okay. That's fine.

A. Yeah.

Q. That's fine. If we could have Dr. Wilken's direct, slide 14.

This is one of the papers that you pulled up, right? This is a 2013 paper, correct?

A. Yes.

Q. Okay. And you understand -- and I believe you used this evidences -- and you had some testimony that Dr. Yang and Healthgen had copied the '951 patent.

You understand that this publication was in 2013, right?

A. It is in 2013.

Q. Okay. And that the '951 patent application was originally published in 2011, right?

A. Yes.
Q. Okay.
A. I believe so.
Q. And that Dr. Yang is looking at something completely different than the purification steps of new versus old, as disclosed in the '951 patent, and is instead looking at host cell proteins for purification? You understand that, right, doctor?
A. He is talking about just the challenges. It's a review article talking about some of the challenges associated.
Q. Okay. And you understand that he -- you understand that he got a patent on his host cell protein research, right, a U.S. Patent?
A. He does have -- I see that he had a patent there.
Q. And yet you say that he copied the '951 patent. But you didn't provide any evidence at all that he, in fact, copied the '951 patent, did you?
A. There's pretty significant, if we look at the fact that there's two -- two people or two groups producing recombinant human serum albumin using the same platform, a lot of the same --
Q. I understand that it's your position that the Healthgen products infringe, and we've been there. We don't need to revisit that. But you understand that copying as a

secondary indicia of nonobviousness is different than that, right?

A. I know it is a part of.

Q. Okay. And, doctor, you didn't come forward with any evidence that Dr. Yang has copied the '951 patent, right?

A. We see the claim compositions from the '951 patent.

Q. Okay. Doctor, do you have an understanding one way or the other whose clinical grade product, Healthgen's or Ventria's, came to market first?

A. I don't know the exact dates for that particular --

Q. No?

A. No.

Q. Okay.

A. I don't remember.

Q. Would it surprise you to learn that Healthgen's clinical grade product came to market three years before Ventria's Optibumin?

A. I don't -- I don't have any one way or the other regarding that.

Q. All right.

MR. SHAFFER: I don't have any further questions, Dr. Wilken. Thank you.

THE WITNESS: Thank you, Mr. Shaffer.

MS. HOEKEL: Your Honor, I have -- I'm sorry.

Mr. Guarnieri, sorry.

JUDGE MCNAMARA: Mr. Guarnieri, do you have any questions?

MR. GUARNIERI: I was on mute. Your Honor, no, the Staff does not have any questions for this witness. Thank you.

JUDGE MCNAMARA: Okay. Thank you. Ms. Hoekel?

MS. HOEKEL: Yes, very brief redirect.

REDIRECT EXAMINATION

BY MS. HOEKEL:

Q. Dr. Wilken, Mr. Shaffer just asked you if there were any Yang patents that discussed endotoxin. Do you recall that?

A. Yes.

Q. Can we pull up Joint Exhibit 23, please? Who is this paper by?

A. This is Dr. Yang.

Q. And this was a book chapter that you discussed in your direct examination correct?

A. Yes.

Q. If we can look at page 4. We talked about this in your direct.

Do you see endotoxins mentioned on page 4?

If we can blow up paragraph 1.2.2, which is the paragraph we discussed on your direct.

A. Yes. Sorry. I should have remembered that. Yes, they list endotoxins specifically here.

Q. What year was this book chapter from, do you recall?

A. Was this the 2013 -- no, 2018, 2018 book chapter, I believe.

Q. Thank you. And if we can pull up Joint Exhibit 1, please.

Mr. Shaffer just asked you some questions about when Ventria's commercial product came to market, Optibumin, versus when Healthgen's clinical grade product came to market. Do you recall that?

A. Yes.

Q. What year did the 2015 patent application -- I'm sorry.

What year did the '951 patent application publish?

A. I believe that was the -- was it 2009 or 2011?

Q. Do you see it under related U.S. application data?

A. Related...

JUDGE MCNAMARA: Hard to see.

A. 2009.

Q. Sorry. 2009 is when the provisional application was filed, correct?

A. Yes.

Q. Okay. That doesn't tell us publication, though, I don't believe. I think I got -- I pulled up the wrong thing for that.

But are you aware that this patent published far before it issued in 2020?

A. Yes.

Q. And the record will reflect otherwise when it published, correct?

A. Yes.

MS. HOEKEL: No further examination, Your Honor.

JUDGE MCNAMARA: Thank you.

Mr. Shaffer, anything more?

MR. SHAFFER: No, Your Honor. I'm done.

JUDGE MCNAMARA: Wow. We beat the clock on this one.

I think, Dr. Wilken, you can step down. Thank you for coming in again.

THE WITNESS: Thank you, Your Honor.

Okay. Is there any business that we need to take care of before tomorrow morning?

MS. HOEKEL: Not that I'm aware of, Your Honor.

MR. SHAFFER: One thing from Respondents, if I

may.

JUDGE MCNAMARA: Sure.

MR. SHAFFER: It looks like we're sort of back on track on schedule, I think. We have two remaining witnesses. I know that Mr. Jackson brought up the possibility of a short closing argument tomorrow, if Your Honor would like one. We certainly would welcome that opportunity, if Your Honor would like to set some time aside.

JUDGE MCNAMARA: Sure. We're all lawyers here, so what do you mean?

MR. SHAFFER: Nothing too long, Your Honor.

JUDGE MCNAMARA: No, no, whose time are you -- you're assuming that you can just build that into the time that you've got remaining.

MR. SHAFFER: Correct.

JUDGE MCNAMARA: Okay. I just wanted to be clear about that, that you're not asking for an extra hour.

MR. SHAFFER: No. In fact, I think we can start at 9:30 tomorrow. I think we really are very much back on track.

MS. HOEKEL: Ventria agrees with that, Your Honor. I think we have time in that, in the normal day, to do the parties' closing.

JUDGE MCNAMARA: Okay. And I welcome the

closings.

MS. HOEKEL: Great.

JUDGE MCNAMARA: She's getting a check. Does your team agree, Ms. Hoekel?

MS. HOEKEL: Yes, Your Honor, our team agrees.

JUDGE MCNAMARA: Okay. So that's a good idea. I think closings are great. I really do. I think they are a great way for everybody to pull together evidence and to really think about inferences and to think about what is explicitly provided and what isn't. So I always used them.

MS. HOEKEL: Your Honor, we're thinking maybe 30 minutes. I don't know if the parties wanted to discuss that now, but I think that seems sufficient and yet within the bounds of the day.

JUDGE MCNAMARA: It's your time. However you want to use your time is really up to you.

MS. HOEKEL: Thank you, Your Honor.

MR. SHAFFER: I agree with the ground rules. I think no more than 45 minutes for certain. That way we know we're going to get it all in. So that sounds great.

JUDGE MCNAMARA: Okay. Very good. Is there anything from Staff, Mr. Guarnieri?

MR. GUARNIERI: No, Your Honor. I think, given the Staff's limited participation, I expect I will only want to make a very short closing statement.

JUDGE MCNAMARA: Very good.

MR. GUARNIERI: The proposal sounds fine.

JUDGE MCNAMARA: Very good. Then everybody have a great evening, and I will see you tomorrow morning at 9:30.

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(Whereupon, at 5:52 p.m., the proceedings adjourned, to reconvene the following day, Wednesday, November 10, 2021, at 9:30 a.m.)

C O N T E N T S

INDEX OF WITNESSES

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1053-1055

EXHIBIT LISTS PROVIDED FOR RECEIPT INTO EVIDENCE:

LIST OF EXHIBITS USED WITH

DR. WILKEN, MARCUS CURL, AND RYAN LAMOTTA

Dr. Lisa Wilken:

CDX-0001C

RDX-0004C

CX-0051

CX-0052C

CX-0053C

CX-0252

CX-0542

CX-0548

CX-0663C

CX-0710C

CX-0896

CX-0898

CX-0900

CX-0904

CX-0919

CX-0923

CX-0924

CX-0970

JX-0009C

JX-0018

JX-0019

JX-0021C

JX-0022

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JX-0090C
Ryan LaMotta:
CDX-0002C
RDX-0005C
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CX-0452
CX-0577
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CX-0786C
CX-0835
CX-0855
CX-0857
CX-0867C
JX-0052C

JX-0064C

JX-0065C

C E R T I F I C A T E

TITLE: CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME

INVESTIGATION NO.: 337-TA-1238

HEARING DATE: Tuesday, November 9, 2021

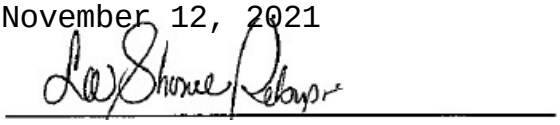
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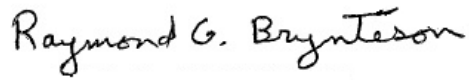
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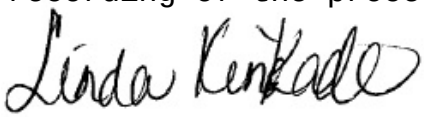
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UNITED STATES
INTERNATIONAL TRADE COMMISSION

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In the Matter of Investigation No.

CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME 337-TA-1238

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UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

Before the Honorable MaryJoan McNamara

Administrative Law Judge

In the Matter of | Investigation No.

CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME | 337-TA-1238

EVIDENTIARY HEARING

Wednesday, November 10, 2021

Volume V

The parties met via remote videoconferencing pursuant to notice of the Administrative Law Judge at 9:30 a.m. EST.

Reported by: Linda S. Kinkade RDR CRR RMR RPR CSR

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*** Index appears at end of transcript ***

P R O C E E D I N G S

(In session at 9:30 a.m.)

JUDGE MCNAMARA: Good morning, everyone. I think where we left off, Dr. Giannelli, I think you're up this morning.

Is there any business that we need to take care of?

MR. HENEGHAN: I don't think so, Your Honor.

MS. GIANNELLI: I think we can proceed.

JUDGE MCNAMARA: Okay. You're a little light. Your voice isn't coming across very loudly. Just doing a sound check.

MS. GIANNELLI: How is this?

JUDGE MCNAMARA: Better. Thank you.

MR. HENEGHAN: Judge, how is my voice? Is it okay?

JUDGE MCNAMARA: Yeah, I think it's coming across. Thank you.

I saw -- by the way, I looked at the time remaining, and I think each of you has more time remaining than we do have in the day for the trial. So I don't know that that's a good sign or not.

In any event, Dr. Giannelli, if you'd like to get started.

MS. GIANNELLI: Thank you, Your Honor. This is

Max Giannelli on behalf of Healthgen. We can begin on the public record.

LOUIS J. DEFILIPPI, Ph.D.,

having been previously duly sworn and/or affirmed on his oath, was thereafter examined and testified further as follows:

DIRECT EXAMINATION

BY MS. GIANNELLI:

Q. Can you please reintroduce yourself to the Court?

A. Yes. I'm Dr. Louis J. DeFilippi.

Q. You're back today to testify about the products at issue?

A. Yes, I am.

Q. Have you prepared demonstratives to illustrate your testimony?

A. Yes, I have.

Q. For the record, those are RDX-2C. If we could please have those demonstratives at slide 3.

Have you compared Healthgen's recombinant albumin products to the claims of the '951 patent?

A. Yes, I have.

Q. What did you conclude?

A. My conclusion is shown on the first bullet, that Healthgen's products do not infringe any claim of the '951 patent. More specifically, they do not contain less than 2

percent aggregated albumin as required by all claims.

Q. Did you also compare Ventria's products to the claims of the '951 patent?

A. Yes, I did.

Q. What did you conclude?

A. And you can see that in the second bullet where I state Ventria's Exbumin, Cellastim, and products containing Cellastim do not practice any claim of the '951 patent. And, more specifically, they do not contain less than 2 percent aggregated albumin, as required by all claims.

Q. If we could go to slide 4. I'd like to start with the meaning of aggregated albumin.

Dr. DeFilippi, what is the adopted construction of aggregated albumin?

A. You can see that on the bottom right where it says, claim term, aggregated albumin, and the adopted construction is non-monomeric albumin, e.g., albumin dimers.

Q. What is the adopted construction of less than 2 percent aggregated albumin?

A. That is less than 2 percent non-monomeric albumin by weight.

Q. If we could please go to slide 5.

Dr. DeFilippi, can you explain the difference between monomeric albumin and aggregated albumin?

A. Yes, I can.

Q. Please do so.

A. Yes. On the left you see monomeric albumin. That's the monomer. As we said a number of times, it's a polypeptide made of amino acids strung together. And then on the right is your family of aggregated albumins, which are non-monomeric albumin. So none of these are monomers in a standalone fashion.

So just quickly going from left to right, you can see two fragments together, a monomer plus a fragment would be up center, two monomers would be below that, and three monomers together to the right, all of which are non-monomeric albumin.

Q. And for clarity, can you please explain how the molecular weight of aggregated albumin compares to the molecular weight of monomeric albumin?

A. It would be larger.

MS. GIANNELLI: For the next slide we'll need to go on the Ventria confidential record, and I can confirm that there are no representatives of Healthgen participating today.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. GIANNELLI:

Q. What did Ventria's testing by reducing SDS-PAGE of Healthgen's samples show?

A. The summary is to the right where you can see the yellow highlighted numbers that correspond to the high molecular weight impurities. Each band alone is greater than the 2 percent, but, as you add it up together, I'm talking the uppermost set of data, when you add them all together, you get 9.67 percent. Similarly, on the second group of numbers, added together you have 6.82; and the third set of numbers would be 7.2 percent.

And these numbers are the aggregated -- the sum of the aggregated albumin species.

Q. Are all of the HMW, or high molecular weight, impurities identified in this table considered non-monomeric albumin?

A. They are.

Q. If we move to slide 22, I'd like to look at the third set of data.

And for this we need to go on the Healthgen confidential record.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. GIANNELLI:

Q. Dr. DeFilippi, what happens to the level of aggregated albumin when an albumin product is freeze-dried?

A. Yes. You can see on the y-axis on the left, that's percent aggregated albumin. And, as the process of lyophilization, the freeze-drying is implemented, you can see on the right, you have the lyophilized powder, there's an increase in the percent aggregated alumina -- albumin, excuse me -- percent aggregated albumin.

Q. If we go to slide 28, Dr. Wilken argued that aggregated albumin must be comprised of components that retain the biological or therapeutically beneficial activity of native mammalian albumin.

Do you agree with that argument?

A. I do not agree with that argument.

Q. Let's go to slide 29.

Under the adopted construction for aggregated albumin, is there a requirement that aggregated albumin be comprised of units that retain the full activity of native albumin?

A. There is no such requirement.

Q. If we add the adopted construction for recombinant mammalian albumin on slide 30, looking at the

adopted construction for this different term, recombinant mammalian albumin, do fragments need to retain activity to be considered recombinant mammalian albumin?

A. Well, it says in the bottom, provided the fragment retains the biological or therapeutically beneficial activity of the native mammalian albumin, but it doesn't say fully retain.

Q. Were you involved in claim construction proceedings?

A. Yes, I was.

Q. If you recall, did any party argue that aggregated albumin must be comprised of active units of albumin?

A. I don't recall that.

Q. If we go to slide 31, Dr. DeFilippi, does the patent say that aggregated albumin must be comprised of active albumin units?

A. No, it does not.

Q. Can you please read the highlighted statement, which is from JX-1, column 72, at 21-24?

A. Yes. It states there that the creation of aggregated albumin is an indicator of protein degradation, which is used as one marker for degradation or loss of stability industrywide.

Q. Are fragments potential products of albumin

degradation?

A. Yes, they are.

Q. Setting aside whether aggregated albumin would need to be comprised of active albumin units, if fragments in fact formed, would they retain activity?

A. There's a very good chance that they would retain a substantial amount of activity.

Q. If we move to slide 32, please, does the '951 patent say whether fragments could potentially retain beneficial activity?

A. Indeed it does, yes.

Q. What does it say here in the quote from JX-1 at column 37, starting at line 13 on the top left?

A. Yes. That's on the top left, as you indicated. It states, fragments of native or synthetic albumin sequences may also have the desirable functional properties of the peptide from which they derived and may be used in any of the methods of the invention.

Q. Does this passage envision that certain fragments may retain the beneficial activity of native albumin?

A. Certainly, yes.

Q. Let's look at the bottom quote, which is from the '951 patent, column 38, starting at line 14.

Can you please read the highlighted portion into the record?

A. Yes, I can. There it states, accordingly, the albumin of the invention can comprise amino acid deletions -- that means an amino acid is removed -- insertions, or mutations in any of the functional binding domains of albumin.

Q. Dr. DeFilippi, if you alter a binding domain of albumin, as suggested in the '951 patent, will you potentially alter the activity of the albumin?

A. You could potentially reduce certain facets of activity as well as increase. Sometimes, for example, the binding strength can be increased by such an event.

Q. If you altered one of the binding domains of albumin, as suggested in the '951 patent, would the resulting albumin retain at least some of the biological or therapeutically beneficial activity of native albumin?

A. Yes.

Q. If you look at the figure on the right here, do each of the domains of albumin contain these binding sites?

A. Yes, they do.

Q. Can you briefly remind us of how albumin functions in cell culture media?

A. Well, albumin is a carrier and a deliverer. It carries beneficial compounds and metals and can also bind, potentially, materials, which would in turn protect the cell, and these beneficial compounds are delivered to the

cell to aid in the cell metabolism and growth.

Q. If you cleave the albumin to form two fragments, what happens to the activity?

A. A substantial proportion of the activity will still be -- would still remain. As you recall, there are these three domains, and then each has two subdomains, so a total of six. And some of these domains might be totally independent, or it's likely they will be relatively independent of the other domains. So you cleave it or don't cleave it, they will still perform a beneficial function.

Q. If we move to slide 33, can you please summarize your conclusions regarding Healthgen's powder products?

A. Yes. The summary is on the right where the question is, do we satisfy, what's in quotes, less than 2 percent aggregated albumin, and the answer is no, using these various --

Q. Wait. We're still on the public record, so don't identify the names by specifics.

A. Various.

Q. Okay. Have you seen any data showing that Healthgen powder products contain less than 2 percent aggregated albumin?

A. No, I haven't.

Q. Now before we turn to the liquid product, I'd like to discuss the techniques for analyzing aggregated

albumin.

Of the -- starting with Native-PAGE, reducing SDS-PAGE and SEC-HPLC, which of these techniques would be the most reliable method for quantifying aggregated albumin?

A. That would be the SEC-HPLC.

Q. Why is that?

A. That's because you're not pretreating the sample in any fashion, so it's being -- you're performing your separation without altering the properties of the substance or substances being separated.

Q. What would be the next best technique shown here?

A. The next best would be the Native-PAGE. It's a similar benefit, as just mentioned, that you're not pretreating the sample in such a way that the sample will be altered. And specifically we're talking about aggregation, but, in general, you're not altering the sample.

Q. That leaves reducing SDS-PAGE. So let's advance to slide 35.

In general, Dr. DeFilippi, how are samples prepared for reducing SDS-PAGE?

A. Yes. The samples are prepared by adding both a bond-breaking agent, a disulfide-breaking agent, and also -- and that would be your reducing agent -- and also a surfactant, which would be addressing the noncovalent forces binding the various portions of the protein together.

So, as you see on the top, you would be converting -- all that can be converted by these processes from the dimers or aggregates to, as far as possible, to the monomers.

And underneath, aggregated albumin with covalent disulfide bonds, expands on that a little bit, except now we're showing a monomer and a fragment, and roughly the same process will be occurring.

Q. To be clear, how does this reducing SDS-PAGE sample treatment affect the percent of aggregated albumin in a sample?

A. It would necessarily reduce the observed level of aggregated albumin.

Q. Can reducing SDS-PAGE be used to reliably show that a product contains less than 2 percent aggregated albumin?

A. It would not be reliable, in answering that particular question.

Q. We did discuss reducing SDS-PAGE earlier, which showed that there was more than 2 percent aggregated albumin.

Can reducing SDS-PAGE be used to show more than 2 percent aggregated albumin?

A. It could if the forces were not the ones they mentioned. You don't have the -- you have other, like,

covalent linkages binding the monomer to something else, the fragment, and there are potential situations where you cannot break those. So you would still see some aggregated material, but less than what you would see if you did no treatment at all.

MS. GIANNELLI: So for the next portion we'll need to go on the Ventria confidential record. I can again confirm that no representatives from Healthgen are participating.

JUDGE MCNAMARA: Thank you, Dr. Giannelli.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. GIANNELLI:

Q. Dr. DeFilippi, could --

(Clarification by reporter.)

Q. Could SDS-PAGE potentially break up aggregated albumin even without a bond-breaking agent?

A. It would break up due to the surfactant nature of the SDS, the detergent nature. It can break up those aggregates that are held together noncovalently.

Q. Is reducing SDS-PAGE a common technique?

A. It's a very common technique, yes.

Q. How is reducing SDS-PAGE commonly used?

A. Well, we have to take the step back with the definition of purity. In effect, what you're doing now is you're looking at how pure your protein is relative to the universe of all other proteins. So with albumin you would be looking at your albumin family and how pure is that relative to all the non-albumin proteins in the universe of other proteins.

Q. Have you seen any data showing the effect of reducing SDS-PAGE on the level of aggregated albumin?

A. Yes, I have.

Q. Let's pull up RDX-2C at slide 38, please.

This is from RX-311, which is already in

evidence.

Dr. DeFilippi, what products are being addressed here?

A. You can see these are Ventria products that are being addressed. On the left side there are two runs in this analysis of Exbumin and two of Cellastim.

Q. And do those products contain recombinant human serum albumin?

A. Yes, they do.

Q. And what two techniques are you comparing here?

A. Here on the far right is the SEC-HPLC, size exclusion, and in the center you see the results from an analysis of employing reducing SDS-PAGE.

Q. Looking at the results for Exbumin in the top two rows, how does the level of aggregation using reducing SDS-PAGE compare to the level of aggregation by SEC-HPLC?

A. Well, the SEC-HPLC shows a significantly higher level, the analysis method shows a significantly higher level of aggregated albumin relative to the reducing. It's over a factor of 2, closer to a factor of 3 in some spots.

Q. What would explain these different results?

A. Well, as we already mentioned, the SEC is -- has no addition of compounds that will alter the nature, the aggregation nature, of the proteins being tested. So that number, like the 4.41 percent in the upper right, would be

the closest to an unaltered sample.

But when you have, just to the left of that, 2 percent, that's showing that, to the greatest extent possible, or to the extent possible, reducing SDS is breaking up these aggregates greater than -- by greater than a factor of 2.

Q. Looking at the results for Cellastim in the last two entries, how do the results using reducing SDS-PAGE compare to the results for SEC-HPLC?

A. Yeah, there we have a factor of 3. It's a similar situation where the SEC-HPLC is showing the unaltered material, indicating or giving a measurement of aggregated albumin of 4.6 percent; whereas when you add the bond-breaking and surfactant components, those are now driven down to smaller materials, thereby reducing the level of aggregated albumin in the sample, and you're going to, therefore, detect a smaller percentage, and here it's the 1.5 percent.

Q. Dr. DeFilippi, if you recall, do we have any other data in this case comparing the level of aggregated albumin by SEC-HPLC to reducing SDS-PAGE using the same sample at the same approximate time?

A. I don't believe so.

MS. GIANNELLI: We need to go back on the confidential record.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. GIANNELLI:

Q. Dr. DeFilippi, please -- is reducing SDS-PAGE a quantitative technique for measuring aggregated albumin?

A. As I think I already indicated, that would not be appropriate.

Q. Did any party provide reducing SDS-PAGE data on the products at issue here?

A. Yes, I believe so.

Q. Which party was that?

A. That would be Ventria.

Q. Now let's look at slide 41. I'd like to discuss how the patent analyzed aggregated albumin.

On slide 42 -- what techniques have you identified here?

A. This is the SEC-HPLC. That would be in the middle here. And on the right side you see the reducing SDS-PAGE.

Q. Remind us, are either of these quantitative techniques for measuring aggregated albumin?

A. The SEC-HPLC would be appropriate for the aggregated albumin.

Q. If we move to slide 43, I'd like to look at the results described for SEC-HPLC and reducing SDS-PAGE.

Starting with SEC-HPLC, were any albumin aggregates observed by SEC-HPLC in the '951 patent?

A. Yes. They found dimer peaks.

Q. Were any of the albumin dimers observed or detected by reducing SDS-PAGE in the '951 patent?

A. I don't believe so.

Q. Now in the section for reducing SDS-PAGE, do you see the reference to aggregates around 250 kilodalton?

A. I'm sorry. Where am I looking? Sorry.

Q. In the section for reducing SDS-PAGE --

A. Okay. I was looking at the wrong side. I'm sorry. Continue, please.

Q. In the bottom highlight, do you see the reference to aggregates at around 250 kilodalton?

A. Yes, I do.

Q. Is that species at 250 kilodalton an albumin dimer?

A. A dimer itself, it's a little too large for just a dimer.

Q. Did the patent report observing any dimeric albumin using reducing SDS-PAGE?

A. Well, they really didn't. They didn't attribute any band to albumin dimers.

Q. Did the '951 patent quantify total aggregated albumin using reducing SDS-PAGE?

A. That was their attempt, yes.
Q. Did the patent ever quantify the total amount of dimeric albumin present?
A. Well, the '951 using the reducing SDS-PAGE, they did not find any, any dimer.
Q. So did the patent ever quantify the amount of dimeric albumin aggregates present?
A. Yes.
Q. What technique did they use to quantify the level of albumin dimers?
A. That would be using the SEC-HPLC.
Q. And so in SEC-HPLC did they say the amount of the dimers that were present?
A. I don't think they reported the amount. They just mentioned it was present.
Q. Did the patent quantify the amount of dimeric albumin present using any technique?
A. No.
Q. Did the '951 patent quantify the total aggregated albumin including dimers using any technique?
A. Not quantifying, no.
Q. Now which of these techniques, if properly employed, could potentially quantify total aggregated albumin?
A. That would be the SEC-HPLC.

Q. If we move to slide 45, I'd like to move to Healthgen's clinical grade liquid product.

And for this we'll need to go on the Healthgen confidential record.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. GIANNELLI:

Q. Let's look back at the testing by Haemtech of Ventria's product.

Remind us, Dr. DeFilippi, by how much did reducing SDS-PAGE decrease the aggregated albumin in Ventria's recombinant albumin products?

A. It would be factors approaching 4, without running the numbers too quickly, in the factor of 2 to factor 4 range, more or less.

Q. If we move to slide 55, Dr. Wilken testified that aggregates -- observed aggregates could possibly be due to albumin aggregated with other impurity proteins.

Do you recall that testimony?

A. Yes, I do recall that.

MS. GIANNELLI: For this we'll need to go on the Healthgen confidential record.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

BY MS. GIANNELLI:

Q. If we move to slide 70, please.

Which products has Ventria argued meet the limitations of claim 1 of the '951 patent?

A. As presented here, the Cellastim, the Exbumin, and the Optibumin, and then the products containing Cellastim, which are listed at the left.

Q. If we move to slide 71, who provided test data on Ventria's products?

A. You can see on the left the party responsible for testing on the first line, that would be Ventria.

Q. What test method did Ventria's test lab use?

A. That is the reducing SDS-PAGE.

Q. Did any other party provide testing on Ventria's products?

A. There is also the Healthgen product -- testing by Healthgen of the products.

Q. What test method did Healthgen's test lab use?

A. These are the -- this is using the SEC-HPLC.

Q. If we move to slide 72, let's look at the first set of data, by reducing SDS-PAGE.

What were the results by reducing SDS-PAGE for Cellastim here on the top?

A. Yes. Even with the reducing SDS-PAGE, which would necessarily reduce the observed value of the aggregates, there are still a sum of 2.22 percent high molecular weight impurities found on the top for the Cellastim product.

Did you ask just for Cellastim?

Q. Just for Cellastim.

A. Thank you.

Q. How does the value for Cellastim compare to the claim limitation of less than 2 percent aggregated albumin?

A. It is certainly higher than the 2 percent limitation.

Q. Now Dr. Wilken redlined some of the entries here for Cellastim.

Do you recall that from her testimony?

A. Yes, I do recall.

Q. Now would all the high molecular weight purities that you have highlighted here for Cellastim as reported by even reducing SDS-PAGE be considered aggregated albumin?

A. Yes.

Q. And are all those high molecular weight impurities reported here even after reducing SDS-PAGE be considered non-monomeric albumin?

A. Yes.

Q. Let's look at Exbumin. What was the total

aggregated albumin in Exbumin using reducing SDS-PAGE?

A. Again, this would be the sum of those three values on the lines to the right of the high molecular weight impurities, and they add together to 2.9 percent.

Q. We may have a typo on the slide. I think those might total to 2.29 percent. I apologize for that. For the record I think the 2.9 is actually totaling 2.29 for Exbumin.

A. I believe you're right. Taking a quick look, a quick estimation, I believe you are correct.

Q. Okay. Now if the value for Exbumin totals 2.29 percent, how does that compare to the claim limitation of less than 2 percent?

A. Again, it's not satisfying that claim. The 2.29 percent is above the 2 percent aggregated albumin value required by that element of that claim.

MS. GIANNELLI: I'll note, for the record, Mr. Fisher has fixed our demonstrative to now refer to --

JUDGE MCNAMARA: He has. That was fast.

MS. GIANNELLI: Thank you, Mr. Fisher.

JUDGE MCNAMARA: That was great. That was terrific.

MR. HENEGHAN: Certainly no objection to the correction. That was very impressive.

JUDGE MCNAMARA: It really is.

Q. Now would all the high molecular weight impurities reported here by reducing SDS-PAGE for Exbumin be considered aggregated albumin?

A. Yes. You could say at a minimum, definitely yes.

Q. And would all the high molecular weight impurities reported even by reducing SDS-PAGE for Exbumin be considered non-monomeric albumin?

A. Yes.

Q. Let's look at the second set of data on slide 73. Let's look at the SEC-HPLC data and actually turn to slide 74.

Dr. DeFilippi, what was the total aggregated albumin in Exbumin by SEC-HPLC?

A. Yes. This is the SEC, which is going to be the most reliable method for answering the question of total aggregated albumin. And there were two runs, injection 1 and injection 2. And those values for the albumin, aggregated albumin, are 4.41 percent and 3.65 percent.

Q. What was the total aggregated albumin in Cellastim by SEC-HPLC?

A. They are quite similar, and they come to 4.6 percent and 3.88 percent. As you can see on the right, in the right column.

Q. Now if we move to slide 75, let's look at some of the underlying data.

What was the analytical technique used to generate the data that's actually shown here?

A. This is the SEC-HPLC, visualized on this slide.

Q. With reference to this SEC-HPLC data, where did the different sizes of the species appear?

A. Yes. With this kind of analysis, the larger components come out first. So if you go from left to right, as you're looking at this, that's time in minutes.

So the furthest left that's highlighted, those would be the largest species highlighted in yellow, and then smaller ones will come out later. Again, this is permeation, so these molecules are going in and out of the media particles. So they are retarded, just by having a greater path that they have to passage through. So that's that second one. I think it's about 14 and change minutes. And then the major peak would be your monomeric albumin. And to the right of that are the fragments.

Q. Okay. Now with reference to where the monomeric peak arises, can you identify the high molecular weight albumin aggregates?

A. Yes. Those are -- as you observe this graph, that's -- the higher molecular weight aggregates are to the left.

Q. And can we -- do you see the relative amounts of those aggregates in the data table in the upper right of the

graphic?

A. Yes, you can see -- you have four columns there. It's the fourth column where it says "percent area."

Q. Okay.

A. I'm sorry. Did you want me to read the numbers?

Q. No, that's fine.

Looking at the aggregated albumin in the data, what was the -- what were the values reported for the different aggregated albumin species observed by SEC-HPLC?

A. Yes. Two values are 0.64 and 3.77 percent. Those are the aggregates.

Q. Now if we move to slide 76, have you seen any articles analyzing SEC-HPLC data for recombinant albumin products?

A. Yes, I have.

Q. This slide is a little busy. Let's first pull up CX-1044.

Mr. Fisher, if you could zoom in on the top of the article.

Dr. DeFilippi, can you please read the title of the article into the record?

A. The title is "Determination of supplier-to-supplier and lot-to-lot variability in glycation of recombinant human serum albumin expressed in Oryza sativa."

Q. Okay. And this first author is Frahm.

Can you please read into the record where the -- actually, for the record, I'll state that the -- I'm sorry, Dr. DeFilippi --

A. I can read it, if you like.

Q. Can you identify the author affiliation on this article?

A. The author affiliation, as presented here, is the Center for Biologics Evaluation, Biologics and Genetic Therapies Directorate, Health Canada, Ottawa, Ontario, Canada.

Q. Do the authors here have any apparent connection to any of the parties in this case?

A. Not that I'm aware of.

Q. Mr. Fisher, can you please zoom into just the abstract and highlight the sentence starting with "high molecular weight aggregates" a little over halfway down.

Dr. DeFilippi, can you read this into the record?

A. Yes, I can. It states, high molecular weight aggregates in OsrHSA samples were detected with SEC and supplier-to-supplier variability and, more critically, lot-to-lot variability, and one manufacturer's supplied products were identified.

Q. What is lot-to-lot variability?

A. Lot-to-lot means when you take two different

preparations of the same product, those would be assigned different lots. So you look at how those different preparations of the same material change when you have another batch of manufacturing occurring.

Q. Okay. Mr. Fisher, if you could zoom back out, and we should identify the date on this document, which I believe is 2014, but we should show that for clarity. It's on the bottom.

Dr. DeFilippi, what is the date of this publication?

A. The date of this publication is October 2014.

Q. You're not relying on this publication to establish the level of aggregated albumin in anyone's current product, are you?

A. No, I'm not.

Q. Let's go to page 2. Mr. Fisher, please blow up the section titled "Materials and Methods."

If you could highlight the statement starting on the fourth line, "Oryza sativa," and highlight all the way through to Cellastim. Perfect.

Now, Dr. DeFilippi, do the authors here report testing Cellastim?

A. Well, these are the items reported, and indeed it does say items tested, and it indeed does mention Cellastim.

Q. Okay. And did the names assigned to the

Cellastim lots all have OsrHSA-SIG in the name?

A. Yes. It would appear so.

Q. Okay. And if you look two lines down, do you know what the S-I-G, sig, may refer to?

A. Well, the sig refers to Sigma, Sigma-Aldrich. That's the distributor or supplier.

There it is, okay. I already knew it. I've ordered from Sigma for quite a few times.

Q. Now let's go back to slide 76.

Dr. DeFilippi, which analytical technique was used to generate the data in the center of slide 76?

A. In the center we're talking about -- well, these analyses, yes, are run by the SEC-HPLC, the size exclusion, the SEC.

Q. Okay. And where are the albumin aggregates observed in these data?

A. The aggregates, as we already mentioned, would be coming out earlier in the trace, and that would be to your left as you view these scans.

Q. And where are the fragments observed?

A. The fragments would be to the right, taking those left and right relative to the main peak, which is the monomer.

Q. Okay. Mr. Fisher, could you please blow up the paragraph on the right? And highlight the sentence starting

with "peaks of high molecular weight."

Dr. DeFilippi, could you please read into the record the two highlighted sentences here?

A. Yes. "Peaks of higher molecular weight (eluting between 12 and 16 minutes postinjection were observed for pHSA, all OsrHSA samples, pprHSA and Recombumin, Recombumin (Figure 2, Table S1) OsrHSA samples generally showed a higher percentage of these dimers/oligomers."

Did you want me to read the next sentence, or is that where you want me to stop?

Q. I think that's great. Thank you, Dr. DeFilippi.

A. You're very welcome.

Q. In this passage are the authors equating the high molecular weight species in SEC-HPLC with albumin, dimers, and oligomers?

A. Yes.

Q. Now, in the passage on the right, the authors report that the Sigma-Aldrich samples could be divided into two groups.

Do you see that?

A. On the right? Where are we looking? Give me a different color.

Q. Mr. Fisher, can you highlight where it starts Sigma-Aldrich supplied?

A. There we go.

Q. Thank you.
A. Okay.
Q. And then, Dr. DeFilippi, could you please read that sentence into the record?
A. Yes. It says, Sigma-Aldrich supplied OsrHSA lots can be divided into two groups.
Q. And what was the reported level of aggregation in the first group for the Sigma-Aldrich supplied lots?
A. The first group had higher molecular weight peaks representing 16 to 20 percent.
Q. And how does that compare to the level of aggregated albumin in the second group of the Sigma-Aldrich batches of Cellastim?
A. In the second group it states, these peaks represented only 8.3 percent of the injected samples.
Q. How would you characterize that level of lot-to-lot variability?
A. How would I characterize it? Well, it's all above 2 percent. I'm not sure --
Q. Between the first group and the second group, are the results consistent?
A. Well, in the first group there's more lot-to-lot variability than in the second group.
Q. Okay. But assuming these are all Cellastim, as identified in the materials, would the range of 8.3 to 20

percent aggregated albumin -- how would you characterize that in terms of variability?

A. Well, I see 16 to 20 percent. Is that what you're referring to?

Q. And then in the second --

A. The other one is 8.3 percent.

Q. And those all have the sig identifier in them; is that right?

A. Yes, they do.

Q. Okay. And so do you understand that those are all different batches of Cellastim?

A. Yes, they are.

Q. Okay. So how would you characterize the level of variability from, say, 8.3 to 20 percent of the high molecular weight aggregates?

A. I would characterize it as very well variable.

Q. If we can -- we can hop down the paragraph and look at the actual data from 2014, on slide 76, I believe.

If we compare the data -- Dr. DeFilippi, can you identify where the Cellastim samples are in this SEC-HPLC data?

A. Yeah. The Cellastim samples are -- you can see bracketed -- the brackets aren't exactly lined up, but it's close -- where it says Sigma equals Ventria. So there will be a total of -- I believe it's four samples, from what I

can see.

Q. Okay. And then what are the -- who would be the manufacturer of the three samples on the bottom?

A. The lowest three, that bracket needs to be dropped down a hair, but the lowest three would be Healthgen samples.

Q. Okay. And how does the level of aggregation appear back in 2014 in the Healthgen samples?

A. The level is -- of the aggregates are substantial.

Q. Are they fairly consistent from lot to lot?

A. Yes, they are quite consistent from lot to lot.

Q. How does the -- were there any fragments observed back then in 2014 in the Healthgen samples?

A. It would appear not. It does not appear -- there do not appear to be fragments visualized in those Healthgen samples. And, again, those would be to your right as you look at the main peak. That's very flat to the right of the main peak. So that would be consistent with there not being fragments present.

Q. Okay. And how does the level of fragments in Ventria's Cellastim lots in the center compare to the level of the fragments in Healthgen's products?

A. Yes. The variability of the Ventria products look to be substantially greater from lot to lot than the

Healthgen samples from lot to lot.

Q. Are there any fragments observed in the Ventria samples?

A. Yes, there are quite clearly fragments present. Again, each one of those traces has a rather significant blip to the right of the main peak. Once again, the main peak being the albumin itself, the albumin monomer.

JUDGE MCNAMARA: May I interject or ask a question? Just based on what I'm seeing, all you're looking at are -- you have not yet revealed the numbers for the Ventria products, have you? These are all focused on the Healthgen OsrHSA products.

MS. GIANNELLI: Would you like me to explain or Dr. DeFilippi, Your Honor?

JUDGE MCNAMARA: Well, I know what he is doing. It's just that he just made a qualitative statement about the spikes or the visual presentation on the Ventria products, but they are not there. The values aren't there.

MS. GIANNELLI: Unfortunately, the authors called out the significant variation in the Sigma samples, but the authors didn't separately discuss the quantity.

We're not relying on this data in any way for noninfringement or lack of technical domestic industry. It's simply a comparison of the method for identifying where the aggregates are.

JUDGE MCNAMARA: Right. I understand that, but, again, as I was listening along, it just seemed to be a not accurate -- well, the comparison was not there.

MS. GIANNELLI: I see. Could we ask one follow-up question?

JUDGE MCNAMARA: Sure. This is just something I was listening to, and, as I'm separating things in my own mind, there was just no evidentiary support that I heard for the observation about the Ventria product.

MS. GIANNELLI: Okay.

MR. HENEGHAN: Judge, could I interject?

JUDGE MCNAMARA: Sure.

MR. HENEGHAN: The issue here is that the product name OsrHSA is a Healthgen brand name.

JUDGE MCNAMARA: No, I understand that. But the problem is that, again, Dr. DeFilippi called out a Ventria product that's not shown here.

MR. HENEGHAN: Exactly. He is calling an OsrHSA-branded product Ventria.

JUDGE MCNAMARA: That's right. And then he called out something for which there was no observable evidence.

MS. GIANNELLI: If we could -- I see where the confusion is.

Thank you, Mr. Heneghan.

The OsrHSA is a brand name of Healthgen, but that's not how it's being used here.

And if we could, please, Mr. Fisher, pull up again CX-1044. The authors have applied it in a more generic sense. And go to page 2.

Under Materials and Methods, the authors actually identify four different lots of Cellastim using those identifiers, and that's where the confusion comes in. Sigma is a supplier of Ventria, not of Healthgen. And they have acquired --

JUDGE MCNAMARA: Thank you for clarifying that, because that was confusing. Thank you. That's much clearer.

MS. GIANNELLI: Okay. Just so the record is clear, we're looking at the section of 1044 on page 2 where they are referring to OsrHSA sig C, OsrHSA sig G, OsrHSA sig H, and OsrHSA sig J, as Cellastim lots acquired from Sigma-Aldrich. And, for clarity, those are not Healthgen samples. However, there are additional Healthgen samples discussed further down in the paragraph.

JUDGE MCNAMARA: Right.

MS. GIANNELLI: Thank you very much for bringing this to our attention, Your Honor. We want to make a clear record.

JUDGE MCNAMARA: No, I appreciate that. I am

sorting this out.

MS. GIANNELLI: Thank you, Mr. Fisher. I think we can go back to slide 76.

MR. HENEGHAN: Your Honor, I guess not to belabor the point, but other than Ms. Giannelli's representation right now, there's nothing in the record that establishes that these particular samples from Sigma came from Ventria.

JUDGE MCNAMARA: I understand that. And also based on Dr. Giannelli's representation, this isn't used -- this isn't being used for either infringement or invalidity.

MS. GIANNELLI: Correct. We just went with the brand name of Cellastim. We weren't aware of any other manufacturer producing Cellastim apart from Ventria, as I think has been made clear.

JUDGE MCNAMARA: I understand that seems to be the case. We've got Healthgen and we've got Ventria. They are the rice-based --

Go ahead, Mr. Heneghan.

MR. HENEGHAN: That's argument, and I understand that, but it's being presented as evidence.

JUDGE MCNAMARA: It is. It's clever. I mean, I think Dr. Giannelli is going to clarify. I understand what's going on.

MR. HENEGHAN: Thank you.

JUDGE MCNAMARA: And may I say also, you did not

object, Mr. Heneghan.

MR. HENEGHAN: I did not, Judge, until it came up now and this explanation came from Dr. Giannelli.

JUDGE MCNAMARA: I understand what you're doing.

MR. HENEGHAN: I plan to address it on cross, but what I'm objecting to is this sort of argument of explanation.

JUDGE MCNAMARA: But I understand what's going on.

MR. HENEGHAN: Thank you.

MS. GIANNELLI: I believe with the clarification of the identity of the samples that clarifies the previous testimony, and given that the limited point for which this was being discussed, I believe we can move on to slide 77.

JUDGE MCNAMARA: Makes sense. Thank you.

Q. So turning back to the testing of Ventria's products by Haemtech, did you review the methodology for Haemtech, the SEC-HPLC method?

A. Yes, I did.

Q. Did Haemtech, in your view, use a reliable method?

A. Yes, they did.

Q. Based on the method used by Haemtech, can you reliably quantify a relative amount of different albumin species present?

A. Yes. One can using that information, yes.
Q. And why is that?
A. Well, this is the SEC-HPLC method, which we already know, gives the answer with the least amount of alteration, and the analyses were run at 280 nanometers, which is a particular wavelength of light at which proteins are well-known to absorb the light. And the amount absorbed -- amount of light absorbed is proportional to the amount of the protein that is present in that particular system.
Q. So using this technique, does that permit quantification of the albumin aggregates relative to the monomeric albumin?
A. Absolutely, yes.
MS. GIANNELLI: For the next point we'll need to go on the Ventria confidential record.
(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

JUDGE MCNAMARA: Sure.

MS. NIEMEYER: I spoke to my team about submitting the exhibits to box by Friday, and we have a short question, and it may depend on what's more or less feasible.

But do you want simply the exhibits uploaded to box for your use or is this also for submission to the Commission?

JUDGE MCNAMARA: It's a different process. So just submit them to box, please.

MS. NIEMEYER: But, I mean, so there's a set that goes to the judge and a set that goes to the Commission. And if it's the -- in the format that the Commission wants, it will take -- it will likely take significantly more time to put them in that format because they have to be broken down to less than 25 megabytes.

JUDGE MCNAMARA: You have to do that for us too.

MS. NIEMEYER: Okay. To be honest, we spoke to our team, and they think Friday would be extremely optimistic, because the exhibits right now, it will be one PDF and they have to be broken down.

We could potentially do it by Monday, but given that it's Wednesday and tomorrow is a holiday, getting it

done by Friday, I think, for them, would be putting a huge burden on them.

JUDGE MCNAMARA: Then Monday will do it. We'll say close of business on Monday.

MS. NIEMEYER: Great. Thank you very much, Your Honor.

JUDGE MCNAMARA: We have deadlines internally too so we -- do me a favor, or what I'm going to ask you to do, to make Ms. Muhammad's job a lot easier, please make sure, just double-check the exhibit numbers against the lists, because -- she does that anyway -- but if we know it's already been done and you can say, yes, we did that, and that we have withdrawn certain exhibits from what we previously provided, and that's also shown, that will save us a lot of time on our end, before we get them submitted. We have a process we have to do internally from our box up to the Commission. So it's just cumbersome.

MS. NIEMEYER: Understood. I appreciate that, Your Honor, and my team appreciates it. I had not appreciated how much work goes into what needs to be done to make that happen. I appreciate it.

JUDGE MCNAMARA: I didn't either until I sat in on a session with the rest of the staff and the folks doing this in Dockets. It's a lot right now.

MS. NIEMEYER: Thank you very much, Your Honor.

I'll turn it over to the closing. Thank you.

JUDGE MCNAMARA: Okay. And that would be Mr. Heneghan, you're doing it for the Respondents?

MR. HENEGHAN: I am, Your Honor. As far as the confidential record, there are one or two spots where there's some Healthgen confidential information, and my folks are ready to quickly hustle out and hustle back in so it won't cause any delay. I'm not aware of anyone from Healthgen being on the call, so it might be moot. I'll just go right through, if that's okay.

JUDGE MCNAMARA: Sure. Do you think that works across the board for everybody?

MR. SHAFFER: Your Honor, this is Rob Shaffer. Good afternoon.

There are a couple confidential Healthgen documents that we'll have, and I may be going back and forth a little bit.

JUDGE MCNAMARA: I'll tell you what. I'm sorry. I didn't mean to interrupt. Go ahead. I thought you were done. It was that pause.

MR. SHAFFER: That's quite okay. It may just disrupt the flow a little bit, so there may be some pockets where I don't necessarily come back and forth because it's a little intermixed.

MR. HENEGHAN: Judge, we rearranged our room a

little bit so Ms. Shoffstall doesn't have to run around the corner quickly.

MR. SHAFFER: That's fine.

JUDGE MCNAMARA: Okay. We'll do it.

MR. HENEGHAN: Are you ready, Judge?

JUDGE MCNAMARA: Yes. Thank you.

MR. HENEGHAN: Your Honor, over the last five days Ventria has laid out a full record of the facts in this case. On Thursday we made promises about what the evidence would show, and we have kept those promises. Ventria has been transparent about the issues in this case as well as the facts surrounding those issues.

We have more than established that Ventria has a domestic industry under both prongs, and that Healthgen's accused products infringe the asserted claims of the '951 patent.

Ventria brought both its President and CEO and Director of Product Applications as witnesses to this hearing. Scott Deeter, Ventria's President and CEO, testified about the extensive research and development efforts Ventria has made to invent and commercialize its Cellastim, Exbumin, Optibumin, OptiVERO, OptiPEAK, and ITSE + A products.

Mr. Deeter testified about the numerous challenges Ventria has faced, including targeting by various

entities to unfairly compete with Ventria.

Mr. Deeter told you about the Kansas and Colorado facilities, the personnel, the farm fields and agricultural equipment, and the millions it has spent all in the United States. The fact that all of its products and raw materials are made in the U.S. was also covered extensively by Mr. Deeter.

Ventria is the quintessential ITC domestic industry having invested many millions of dollars in the United States to launch and grow its business in which it employs a wide range of skilled workers in activities ranging from R&D, the laboratory work, the rice breeding, the farming and harvesting, and to manufacturing its rHSA products. Ventria is exactly the type of company that merits protection from the ITC.

Marcus Curl testified about Ventria's commitment to its scientific efforts and the desire to gain adoption of its novel technology to solve health inequities and other pressing challenges. Mr. Curl also testified about the confusion caused by Healthgen's aggressive marketing and the business that Ventria lost due to Healthgen's malicious pricing.

While Ventria presented two fact witnesses in its case-in-chief, including several hours of testimony from Mr. Deeter, by contrast, Healthgen brought no fact

witnesses, not even its founder, Dr. Yang. Healthgen's entire case rises and, more importantly, falls with the experts.

Healthgen wants to have its cake and eat it too. Healthgen has asked the Commission to find that its products do not infringe the claims of the '951 patent, while effectively being allowed to advertise that they do, in fact, meet those claims.

Healthgen has focused on its noninfringement arguments on the shipping of its products, specifically Healthgen argues that shipping of the accused products causes them to aggregate somehow, so much that they fall out of the claim scope.

However, the Healthgen product information specifies the storage and handling conditions that it expects the accused products to be subjected to and states the accused products are stable under those conditions for several years. That's what they tell their customers.

A bumpy plane ride in a FedEx package can't possibly be a defense to infringement.

The weight of the evidence presented shows that the accused products have less than 2 percent aggregated albumin and thereby infringe claim 1 of the '951 patent.

At this point, Judge, we're going to go into a little bit of Healthgen CBI, so I'll ask the Ventria folks

to leave the room for a moment.

JUDGE MCNAMARA: So, Ms. Shoffstall, I think you don't have to worry about it.

MS. SHOFFSTALL: I'm stationed here.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

JUDGE MCNAMARA: Good. Thank you.

MR. HENEGHAN: The evidence in this case falls far short of the clear and convincing evidence standard required to find the '951 patent invalid. As we saw, the art relied upon by Healthgen in this case is largely directed to yeast production systems.

As Dr. Wilken testified extensively, the host from which albumin is derived matters. It's important to the analysis, and based upon her extensive experience in the field where she works hands-on with plant-derived recombinant human serum albumin every day in her lab, where the albumin is derived from matters.

Dr. DeFilippi admitted he has not worked as a consultant or in an academic capacity with albumin generally and, more specifically, recombinant albumin since 1972.

Dr. DeFilippi asserts that processes not developed for plants can be applied to recombinant protein derived from plants. He said the ligands bound to the albumin are not coming from the host. He said the method of removing endotoxin does not matter if the host is different.

Each of these opinions were directly contradicted by the literature, by Healthgen's own publication, and by Dr. Wilken's testimony.

Dr. Wilken, who has spent her career in this technology, testified that the host absolutely matters, and she explained why it matters. Dr. DeFilippi's explanation was more along the lines of, because I said so.

As we discuss Healthgen's anticipatory references, their primary references, Van Urk and Berezenko, are both yeast-based systems. And because the references are essentially the same, the substance of Berezenko and Van Urk were both before the Patent Office, were both examined during the prosecution of the '951 patent.

In fact, even Dr. DeFilippi confirmed that the Van Urk disclosure that he relies on is identical to the disclosure the USPTO examined in Berezenko.

The Patent Office granted the '951 patent over Berezenko, and, therefore, over Van Urk, over Deeter, and over Huang. All those references were considered and the '951 patent issued and has the -- enjoys the presumption of administrative correctness and can overly be overcome by clear and convincing evidence.

Dr. DeFilippi's invalidity arguments have been rejected by the Patent Office and they should be rejected here.

Healthgen has simply not met its burden of proof and the Court should find the patent valid.

Let's move on to domestic industry. Healthgen

concedes in this case that Optibumin meets the limitations of claim 1 of the '951 patent in all respects. Healthgen concedes that Cellastim and Exbumin meet all the limitations other than the 2 percent aggregated albumin.

Ventria's regular marketing materials and Certificates of Analysis do not report aggregated albumin. Therefore, Ventria had to turn to testing by a reputable third-party lab, in this case SGS, to test for aggregates to analyze this claim limitation.

Ventria's testing of this element shows that Cellastim and Exbumin have less than 2 percent aggregated albumin.

In addition, the weight, the greater weight of the Healthgen testing, shows that Cellastim and Exbumin have less than 2 percent aggregated albumin.

As far as the economic prong, you heard from Ventria's expert, Mr. LaMotta, that Ventria more than satisfies the economic prong of domestic industry. Between Ventria's investments in plant and equipment, labor capital, and research and development, and the fact that all of its activities and investments take place in the United States, it is hardly controversial that Ventria has submitted substantial evidence of a domestic industry in this investigation.

Indeed, Healthgen does not have a legitimate or

reasonable basis to dispute this. Healthgen's economic expert, Mr. Reed, confirmed only moments ago that he has not expressed any opinion on satisfaction of the economic prong of domestic industry. It is a settled issue.

You also heard from Mr. LaMotta about the appropriate amount of bond and remedy in this case should a violation be found. Mr. LaMotta testified as to the price differences between Ventria and Healthgen's powder product. This large difference with Healthgen's product being sold for a significantly lower price justifies at least a 100 percent bond.

You also heard from Mr. LaMotta that a limited exclusion order would not be a sufficient remedy in this case should a violation be found.

Healthgen has a variety of aliases that would help it avoid a limited exclusion order. Therefore, a general exclusion order is called for and is the appropriate remedy in this case.

In sum, Ventria has demonstrated that the accused products infringe the claims of the '951 patent, and that the Ventria DI products satisfy the requirements of domestic industry.

Before I conclude, I just want to note again, this is the slide that ended my opening on Thursday, and it's a summary of Healthgen's admissions and concessions in

this case.

For claim 1, a cell culture media supplement or complete media composition for improving the growth of a cell in cell culture comprising, Healthgen has admitted that that limitation, as far as its own product, and has conceded that the Ventria product is a DI product under the limitation.

Recombinant mammalian albumin, again, Healthgen admits its product meets that limitation and concedes that Ventria's product meets that limitation.

Wherein said albumin is, one, produced in a transgenic plant, that's admitted as far as Healthgen's own product and conceded as far as Ventria's product.

Two, has less than 1 EU of endotoxin per milligram of albumin, again, admitted by Healthgen in the response to request for admissions formally sent in this case, and they have conceded that in their arguments about the DI products.

And then we go to the dependent claims, claim 11, there's no dispute here, claim 11 is the composition of claim 1, wherein said albumin is recombinant human serum albumin, admitted by Healthgen in relation to its own products and conceded by Healthgen in relation to the Ventria DI products.

Claim 12, the composition of claim 1 wherein said

transgenic plant is a transgenic grain, admitted by Healthgen in relation to their products, conceded by Healthgen in relation to the Ventria DI products.

And, finally, the last dependent claim, claim 13, the composition of claim 12, wherein the transgenic grain is transgenic rice, admitted by Healthgen in response to request for admissions and conceded by Healthgen in their arguments and lack of evidence at this hearing.

Healthgen has posed great problems for Ventria, which is why we are here today. Both its infringing activity and improper and aggressive marketing practices have given Ventria no choice. Ventria must protect its intellectual property.

Over these five hearing days we have appreciated your time, Your Honor, your attention, and your fairness.

We're thankful for Mr. Guarnieri and Staff.

We're thankful for Ms. Kinkade and the hard work she has done, probably the most hard work of anybody here.

And we also thank Ms. Lee, Ms. Goalwin, and Ms. Muhammad for all of their assistance.

We hope to come out of this investigation with justice for Ventria and for all those who will benefit from Ventria's lifesaving innovations.

Thank you, Your Honor.

JUDGE MCNAMARA: Thank you, Mr. Heneghan.

Mr. Shaffer?

MR. SHAFFER: Yes. Thank you, Your Honor. Good afternoon. This is Rob Shaffer for the record.

Your Honor, I'd like to start where Mr. Heneghan left off, and that is, on behalf of our entire team, both parties, we thank you for your close attention, not only through the five days of hearing, but also throughout this entire case. Of course Ms. Kinkade, the entire Court staff, and OUII, thank you. I know everyone has been paying close attention as well.

Your Honor, I'd like to start on the technical side of the case where we began and ended, and that's on issues of infringement.

I promised Your Honor during opening that, even though it is not our burden to prove, that we would show Healthgen's products do not infringe. And I think our presentation of the evidence focused the Court's attention rightfully so on one required limitation for all the asserted claims, and that is a recombinant human serum albumin product containing less than 2 percent aggregated albumin.

We saw a lot of evidence come in with different measuring techniques or test methods of recombinant human serum albumin products using these different techniques. And I want to be clear. They are all acceptable techniques.

They are all important. And they are all used in the industry by both parties.

And I think the parties agree on that, but here is where the parties diverge, Your Honor. Different test methods answer different questions about albumin makeup of the rHSA product.

And in view of the less than 2 percent aggregated albumin claim limitation that we're talking about, the question for the Court is what is the most appropriate test to measure that, how to best quantify aggregated albumin as a percent.

Now size-exclusion chromatography or SEC-HPLC as we have been abbreviating it all along, along with SDS-PAGE, both reducing and nonreducing, they are both test methods that we have talked a lot about.

SEC-HPLC is a robust and specific prominent test method known by those of skill in the art and used in the ordinary course of Healthgen's business for their Certificate of Analysis.

SDS-PAGE we know is another popular technique used by Healthgen. It's a little bit more qualitative in nature, and it's used to differentiate between the different bonds in the protein aggregates, whether disulfide bonds or noncovalent bonds.

And as Mr. Heneghan said, and this is an

important point, and he said it very specifically, and he said it right, that SDS-PAGE measures monomer content, albumin monomer content. And that's what it measures, Your Honor. It measures total albumin purity, all of the albumin in the product.

And I'm going to go briefly into some Healthgen confidential information.

(Whereupon, the trial proceeded in confidential session.)

O P E N S E S S I O N

MR. SHAFFER: Everyone can come back and we can go back on the public record.

JUDGE MCNAMARA: Okay.

MR. SHAFFER: Thank you.

I think you heard substantial evidence that SEC-HPLC, unlike reducing SDS-PAGE, does not use detergents and reducing agents. SDS-PAGE uses these agents like TCEP and DTT that break apart those strong disulfide bonds that form the dimers and polymers and aggregated albumin.

Both experts agree that SDS use of a bond-breaking agent is critical to this case, Your Honor, because, as the evidence amply showed, it decreases the percent of aggregated albumin in the product that is being tested.

And the person from Ventria who explained this best did not appear at trial, Your Honor, and that was Dr. Randall Alfano. He is a Ventria scientist who was familiar with the different test methods and he gave meaningful answers at his deposition.

He corroborates Dr. DeFilippi's testimony regarding how SDS-PAGE, whether reducing or not, artificially lowers the percent of aggregated albumin due to these bond-breaking features of the reducing agents, like

DTT and TCEP.

And I'd like to play a clip of his testimony, rule 30(b)(6) testimony, which is in evidence, Your Honor. This is testimony from May 27th, 2021, at pages 29-38. It is in evidence and it's dispositive on this issue, Your Honor.

MR. HENEGHAN: Your Honor --

JUDGE MCNAMARA: Hold on just a minute, please. I'm sorry.

Mr. Heneghan, what's your objection?

MR. HENEGHAN: My objection is just to the characterization of the testimony. He was not a 30(b)(6) witness on these testing topics. He was identified as a corporate rep on other topics and he did offer his own personal deposition, but he was not a 30(b)(6) witness on these topics.

JUDGE MCNAMARA: Okay. So clarified. Go ahead, Mr. Heneghan. I mean Mr. Shaffer. I'm sorry. Go ahead.

MR. SHAFFER: Okay.

(The following video clip was played:)

Q. Does purity indicate anything about --

MR. SHAFFER: Hold on one second.

Q. -- and 99.3 percent is albumin.

Does purity indicate anything about the level of dimerization or aggregation of the albumin?

A. With SDS-PAGE, no.
Q. Under what circumstances would dimers and aggregates of albumin be broken up using SDS-PAGE?
A. With essentially the right sample prep.
Q. And what kind of sample prep would break up the dimers and aggregates?
A. Addition of agents that may break covalent bonds between those -- between the molecules.
Q. And what types of agents would break up the covalent bonds between the albumin molecules?
A. Heat, B-ME, DTT.
Q. And how is the sample preparation different for Native-PAGE than SDS-PAGE?
A. It does not involve any of the addition of bond-breaking agents that I mentioned previously.
(Conclusion of video clip.)
MR. SHAFFER: Your Honor, I think I would like to put that on confidential for Ventria. I believe it --
JUDGE MCNAMARA: That was -- I'm going to say something -- I don't want to interrupt your flow.
That's just general information. That's scientific information.
MR. SHAFFER: I agree, Your Honor. Thank you. It was out of an abundance of caution.
JUDGE MCNAMARA: I know. Everybody is being

careful. I appreciate that.

MR. SHAFFER: Thank you, Your Honor.

If we could have slide 4, please, Mr. Fisher.

And while Dr. Wilken admitted that her lab, while she may work with plant-derived rHSA, she doesn't perform quantitative test methods on aggregated albumin as part of her work.

She did acknowledge and she did confirm what Dr. Alfano told us, that SDS-PAGE will turn aggregated albumin, like dimers and trimers, into monomers, whether under reducing conditions, with a bond-breaking agent like DTT, or under nonreducing conditions, as her testimony is reflected on the right of slide 5 here of my closing argument slides, Your Honor.

And the result here is really uncontroverted. When SDS-PAGE is used, the percent of aggregated albumin in the sample will be artificially lowered. As Dr. DeFilippi explained, the tester will not get an accurate percentage of the aggregated albumin. It's just not the appropriate test method to use for the question that is before the Court based on the claim limitation in Ventria's '951 patent.

Your Honor, here's a depiction of this. What we have here is just a sample of a product on the left. This is -- the single molecules are monomeric -- represent monomeric albumins. You see below that some dimers. Those

are aggregated albumin, as well as polymers, which are below that, Your Honor.

When the SDS-PAGE with a reducing agent is used, like TCEP or -- that should be DTT -- it breaks the bonds, as we just heard. It takes those dimers and trimers and polymers and breaks them into monomer units.

And what is the result? The result is that the monomeric percentage of the sample will go up, the monomer percentage will go up, and at the same time what comes down in percentage is the aggregated albumin.

So it artificially decreases the percent of aggregated albumin while at the same time it's actually artificially increasing the percent of monomeric albumin. So it has a 2x difference or a delta, Your Honor, in terms of how it reacts.

MR. HENEGHAN: Your Honor, I would like to point out for clarification that the drawing above was not presented to Dr. Wilken with her testimony below. She did, in fact, testify to whatever she said she said, but this was not -- they were not connected during the course of trial. That's all I'm saying.

JUDGE MCNAMARA: Fair enough. It's a closing.

MR. HENEGHAN: I understand.

JUDGE MCNAMARA: I understand. Thank you.

MR. SHAFFER: Thank you, Your Honor.

And if we could go to slide 6, please.

And the parties both point to peer-reviewed literature in this area. And both experts rely on it. And it's really telling, Your Honor.

We have Mahler, JX-60, shown here on slide 7, and den Engelsman, JX-32, also shown here, which will be on the next page. And they both inform a person skilled in the art -- if we could go to slide 7; thank you -- that a person skilled in the art, that SEC-HPLC is a robust, sensitive, and precise test for quantifying aggregated albumin; whereas, quantification of aggregated proteins like albumin, with SDS-PAGE, is difficult.

And that is the exact question before Your Honor, appropriately surveying the evidence to determine the quantification of percent of aggregated albumin upon importation into the United States.

And, with that, Your Honor, I want to turn to the evidence that shows unequivocally that Healthgen's powder products do not infringe.

We just heard from Dr. DeFilippi this morning explain that the data that was generated by Ventria before this litigation started, in view of the '951 patent claims, they purchased Healthgen's product that had been shipped to the United States and they used a test method that they knew would accurately quantify the percent of aggregated albumin,

as the '951 patent requires.

They used a test called Native-PAGE. They did not use SDS-PAGE. And Native-PAGE, much like SEC-HPLC, does not use a bond-breaking agent or detergent that reduces the aggregated albumin.

And the tests here are dispositive and uncontroverted, Your Honor, so much so that Dr. Wilken completely ignored Ventria's own test data completely. And it begs the question: How did Ventria even have a good-faith basis to accuse the Healthgen products in the first place.

So what did they do? During this investigation they obtained a sample from Healthgen that had been imported into the U.S. and they hired a third-party lab, SGS Life Science, which Dr. Wilken admitted was reputable, to test Healthgen's powder product again.

But instead of using the appropriate test method or technique to the independent lab to use, Ventria instructed the lab to use reducing SDS-PAGE, with the knowledge that Healthgen's products did not meet the claims under nonreducing conditions, and with the hope that the aggregated albumin percent, under this new test method, one that uses bond-breaking agents, would result in a percentage of aggregated albumin less than 2 percent.

Well, it didn't. As shown here in slide -- if we

go to slide 11, please -- I'm sorry. Back to 10.

In each of the Healthgen powder products tested, the aggregated albumin was greater than 2 percent, not infringing.

And Dr. Wilken admitted that she did not address this data at all. Ventria simply ignored it like it didn't happen.

And, Your Honor, on slide 11, this is Healthgen's intermediate stock that Dr. DeFilippi explained this morning. Healthgen's powder products tested under SEC-HPLC also show that Healthgen's powder products do not infringe.

So what does Healthgen point to to try to show that -- I'm sorry -- Ventria point to to try to show that Healthgen's cell culture products infringe. Internal Healthgen Certificates of Analysis that were analyzed the day of or the -- the day of manufacture, the day after, and before importation.

And they rely on these Certificates of Analysis that use reducing SDS-PAGE that measure total albumin purity. There is no data that quantitates the aggregated albumin percent as a standalone quantitative measurement that they point to. It's all SDS-PAGE data.

And 99 percent purity, as measured by reducing SDS-PAGE conditions, as we have discussed, only shows the total albumin, monomer plus all the aggregates. It doesn't

parse out and separately quantify the percent of the aggregated albumin as required by the claims.

That remaining 1 percent from the 99 percent is not aggregated albumin. It's host cell proteins and other impurities. It's not evidence of infringement at all. Healthgen's cell culture product does not infringe.

So let's turn to the clinical grade product.

Ventria asserts that Healthgen's SEC-HPLC testing that was performed the day after manufacture demonstrates infringement here. It does not. Importation, shipment, storage, and other environmental factors will affect the percent of aggregated albumin, and that is why, as Dr. Wilken explained on cross-examination, that there is an acceptance criteria built into this product for the product. And the documents show that. As the experts agree, there's up to a 4 percent allowance or acceptance range for the aggregated albumin. That could mean that under some conditions it infringes and others it would not.

So, realizing this, Ventria obtained a sample during discovery from the same exact batch that was analyzed in China months earlier and tested it in the United States to try to show infringement. And they sent that sample to the SGS lab for testing, and they instructed SGS to use reducing SDS-PAGE.

It is right here in the summary of the test

results, this is from the independent lab, Your Honor, there's two of them, CX-094 and JX-129, right under the Summary of Test Results, and they state, this is SGS saying this, that they performed the assay instructed by the sponsor, which we know is Ventria.

Now I want to pause here, Your Honor, because it's very interesting, because if Ventria wanted to show in a scientifically valid comparison, that they would have told SGS to test Healthgen's clinical grade products under the same test methods that were performed in China, SEC-HPLC, but they didn't do that.

More notable is the fact that SGS, as part of their aggregation analysis on their website, and as part of their validated procedures, uses SEC-HPLC as their validated method to test aggregated proteins. It's right here on their website, Your Honor. And shown on the left of slide 13, SGS uses SEC-HPLC. There's no mention of using reducing SDS-PAGE for testing aggregated proteins.

But Ventria told them to use reducing SDS-PAGE, and, with that, we know that the strong bond-breaking agent TCEP would break apart the aggregated albumin that was going to be measured.

And the result is not surprising. There was very little aggregated albumin in the test that came from it. And that's the data that they are pointing to, Your Honor.

Frankly, it's misleading. So Dr. Wilken admitted that she did not rely on all of the SGS test data.

SGS performed another test a month later on the same exact liquid product, the same exact sample, as the report that she did testify to. I asked her about that on cross. And she really didn't have a good answer when faced with the disparity in the test results on that same exact sample tested a month later but using a different reducing agent than what was used before.

In one test, and it's right there in the documents, they used TCEP. That's the one that she relied on. And the second test that she ignored, Your Honor, SGS used DTT, and that's shown here on slide 14.

And the results were astounding, Your Honor. The same sample tested one month later with the different reducing agent showed a three times higher percent of aggregated albumin over the test that she relies on. .64 compared to 1.81 in 30 days. This is the prime example of Ventria picking and choosing, not only the test methods, but also the results that they want to rely on.

Even more notably, Your Honor, Ventria or its test lab did not test and what we submit they needed to do to quantify the aggregated albumin was to test the sample with SEC-HPLC. That evidence is what Ventria needs. They do not have it to show Your Honor because they did not ask

for it. And because of that, any test that they do point to is, frankly, insufficient to support their infringement claim against the liquid product.

And we know, this isn't about a company knowing that it shipped and all that, as Mr. Heneghan was alluding to earlier, we know from Mahler and from den Engelsman that shipment, storage, shaking, temperature change, exposure to light, could induce albumin aggregate formation and increase the percent of aggregated albumin in the product. Ventria's statements during Mr. Heneghan's close missed that point.

Your Honor, at bottom, that's why the testing needed to be done. Ventria has failed to meet its burden that the Healthgen's clinical grade product infringes upon importation.

If I could have the next slide, please, Mr. Fisher.

Turning to the DI products, Your Honor, there are six of them, five of them are the medium-grade cell culture products. And they, like Healthgen's cell culture products, do not come close to meeting the less than 2 percent aggregated albumin claim limitation.

I submit, Your Honor, that, based on the independent testing alone, no matter who's doing the testing, whether Ventria's or Healthgen's, it's not a close call, and it's not surprising because of the results found

in Healthgen's powder products as well.

Healthgen, through an independent lab, conducted an apples-to-apples comparison, and we tested all the products with SEC-HPLC, SDS-PAGE under reducing agents, and SDS-PAGE under nonreducing agents. And those tests revealed, under SEC-HPLC, and under SDS nonreducing conditions, that the DI products did not meet the limitations.

On your left, Your Honor, we have the results from the SEC-HPLC of aggregated albumin as a percent, all above 2. And to make the point, how the same sample tested at the same time under different reducing conditions yields dramatically different results, we show what happened when reducing SDS-PAGE was used on the same sample using DTT. We didn't even use the more harsh example of TCEP as the reducing agent.

If we go to slide 18, please, Mr. Fisher.

The testing was revealing on another level, and that's what I just explained, the disparity in the results. And it shows, indisputably, Your Honor, that when you measure aggregated albumin under reducing conditions, you're going to see lower levels of aggregated albumin due to the bond-breaking nature of the reducing agent.

And next slide, please, Mr. Fisher.

Even Ventria's own test data, slide 19, shows

that their products do not meet the claim limitation and are not covered.

So what is Ventria's answer to all this third-party testing? Well, Dr. Wilken strikes through certain albumin data, without any analysis or biological testing or activity that she says is the aggregated, because it's not a pure dimer or pure polymer should not count.

Your Honor, that is problematic on many levels. First, the independent tests provided the results on what they were asked to quantitate -- aggregated albumin. And those were the results. Dr. Wilken admitted that she, not the independent lab, then took those results and struck through what they had measured as aggregated albumin under the Court's construction, which is simply non-monomeric albumin.

What she did is not right. Dr. Wilken admitted that she did not test for or measure any biological activity of anything before she redlined those lab results.

The other problem, Your Honor, is that she is basing her opinion on a claim construction understanding that is not only new to this case but is also wrong as a matter of law.

Ventria's arguments, frankly, invite legal error by improperly conflating and importing the construction of two different claim terms that have different meanings.

We're going to brief that, Your Honor.

If we could -- we're on slide 21.

And that's exactly right, Your Honor. The Court's construction does not require fully formed. There's a lot of testimony she said on that. It does not require retention of full function. Certainly not. And it does not require native biological activity, as she says, she misses the or in the construction of native mammalian albumin.

If we can go to 22. Let's move to invalidity, Your Honor.

Dr. DeFilippi walked through the disclosures in the two anticipatory references that we have, Van Urk and Berezenko, in detail, and he pointed out where each and every claim limitation is found in the references.

Dr. Wilken didn't do that. She didn't point really to any reference and say that there was a specific disclosure or teaching that wasn't present in one or the other reference. She attempted to diminish the references by saying that the '951 patent claim limitation mentioned plant-derived rHSA a few times, or it mentioned endotoxin once or twice, but that's not a defense to anticipation, Your Honor.

And there really is no dispute that all the limitations are present in each of these references, and Dr. Wilken, in fact, admitted during redirect, Your Honor,

that they are all there. But they are not present in the manner claimed. Those were her words. The claim elements for which they have been presented are not arranged in the reference in the manner claimed.

Your Honor, it's black letter Federal Circuit law that the order combination of elements is not a defense to an anticipatory reference. All the elements are there.

Her second defense is that the references are not enabling. They wouldn't need to present this defense, Your Honor, if the references were really truly missing a claim limitation.

So they have to present this enabling argument. She didn't meet the burden. It's presumptively enabled. She didn't present evidence on why it's not enabled. They did not meet their burden there either, Your Honor.

We move to slide 26.

And here Dr. Wilken ignored the teaching in the patent itself that unequivocally acknowledges what was known to a person skilled in the art and how it relates to the present invention.

The '951 patent includes a discussion on purification of rHSA derived from rice for use in this invention using any, any recognized methods listed in the patents above. This is for yeast, this is for other plants, and that's what the '951 patent is telling a person skilled

in the art, that there's nothing unique about rice when it comes to downstream purification.

Dr. Wilken also ignored the knowledge of a person skilled in the art, which included the Deeter patent. The Deeter patent had everything that the '951 patent had but for two downstream processing steps for purifying endotoxins.

That was made very clear. We went through that on cross yesterday. We put up Dr. Jordan's, Ventria's employee's, declaration that explained the difference between B000, the old process in Deeter, and B0000C, the new process in the '951 patent. There were two steps they dealt with: a detergent and a rinse. These were all steps that were known to persons of skill in the art based on rinsing and purifying and filtrating other types of rHSA-derived proteins. The '951 patent tells a person of skill in the art that purification techniques can be used for the claimed invention.

And, moreover, Your Honor, the simple fact of the matter is that purification steps are not claimed. So any purification that they point to as being different, they were disclosed, and they are in the patent, but Dr. Wilken spent a lot of time going through the data, looking at the old data versus the new data, showing that there's fewer endotoxins in the '951 specification than there were in

Deeter, but it's not claimed, Your Honor. It's only claimed as a matter of 1 EU. There are no steps, no methods, no processes in the claim itself.

Dr. Wilken focused on the improved biological activity, as was disclosed in a couple of the tables that I just mentioned. I believe they were E4 and E5, Your Honor.

But that too is irrelevant. There is no dispute that Ventria amended its claims during prosecution. And, with that, they disclaimed any improved biological activity in the cell culture.

Under relevant Federal Circuit authority, Ventria cannot now through the testimony of Dr. Wilken or Mr. Heneghan's arguments try to recapture any improvement of activity to differentiate the claims of less than 1 EU from this patent to the prior art based on its processes. The claim is strictly limited to the number. That's it.

And a person skilled in the art with the expression system of derived plant rHSA from Deeter would know how to get there, would know how to purify the endotoxins in rice, not only based on Deeter, but what -- also based on what the inventors of the '951 patent told a person skilled in the art, to come to the understanding of nondetectable levels of endotoxins at 0 as taught and disclosed in both Van Urk and Berezenko.

The '951 patent is invalid under 102, Your Honor.

And this is disclosed in Van Urk and Berezenko. Dr. DeFilippi explained it in detail, the testimony of what a person of skill in the art would understand based on the profound disclosures on purification. That testimony was unrebutted.

Finally, Your Honor, we have the domestic industry, and the evidence shows that Optibumin cannot -- are not significant or substantial. Only Optibumin counts. That's their clinical grade liquid product.

As we stated in our pretrial brief, Your Honor, and I made clear in opening, and I think I was chastised by someone on the Ventria side for saying it in opening, I made clear that Optibumin has less than 2 percent aggregates, and the reason why I made that clear during opening, Your Honor, is because it was tested under the right and appropriate method for testing the 2 percent aggregated claim limitation.

Optibumin, unlike any of the other five products, was tested using SEC-HPLC, and it showed, based on the granularity of the data, specific line entries, we added those up, and it was less than 2 percent.

We're consistent with our data, Your Honor. We look to SEC-HPLC. Optibumin met it. We don't dispute it.

But Ventria's economic prong on domestic industry is simple. Only Ventria's Optibumin product can meet the

claims of the '951 patent, which means that only the investments that Ventria tied to Optibumin can be considered, and those numbers are small, too small to meet the statutory requirement of significant or substantial.

Ventria started this action claiming millions of investments relating to six different products they claimed practiced the '951 patent. They were wrong. They did not account for the fact that its clinical grade product, relatively new to the market, would be the only product at issue.

And, with almost no sales, they can't carry their burden, Your Honor. The sales are de minimis. Ventria could have conducted a different analysis, but they chose to use a sales-based apportionment for allocation. When they realized that only Optibumin may be at issue, they tried to inflate their investments. That evidence should be given little weight, little to no weight, as the sales and investments are minuscule.

Bottom line, Your Honor, the investments of Optibumin are small. They just aren't enough. There's no numerical minimum, we understand that, but there must be a bottom, and Ventria's numbers are below that bottom.

Thank you, Your Honor. We appreciate the opportunity to close before Your Honor and thank you.

JUDGE MCNAMARA: Thank you, Mr. Shaffer.

I have to say that this has been -- this has been -- this is maybe the wrong word to use -- this has been a really enjoyable trial. I think it's been hard on you-all.

Mr. Guarnieri, I know you're up next, but I just want to say, this has been really excellent lawyering here, something I enjoy so much. It's just one of the benefits of doing this, I think, is just watching people's techniques and watching how they present really complicated issues. It's been done very well here on both sides.

MR. SHAFFER: On behalf of our team, Your Honor, thank you. And I hope Ms. Kinkade has all that on the record.

JUDGE MCNAMARA: Yeah, I think she does.

No, I think this was -- again, I learned a lot. This is really a very, very good trial. It was smooth. It was well-presented. It was pretty seamless. And I just really wanted to let you know how much I appreciated that.

MR. SHAFFER: Thank you, Your Honor.

JUDGE MCNAMARA: I appreciate great lawyering, I always have.

MR. HENEGHAN: We really appreciate that, and especially for the folks who are not on the screen right now, it is really nice to hear that from you. So thank you.

JUDGE MCNAMARA: Your teams are really good.

I'm sorry, Mr. Guarnieri, and I include you, I include Staff. I think you know what I think about Staff in general and the cumulative knowledge and wisdom.

MR. GUARNIERI: Well, we appreciate that a great deal, Your Honor. It is always a pleasure and honor to appear in front of you for all of us on Staff. I will echo your sentiment that a very high level of professionalism was shown by counsel on both sides.

JUDGE MCNAMARA: Yeah, really good.

MR. GUARNIERI: I obviously came in a little bit late in this case and counsel on both sides and their staff have been incredibly helpful in getting me up to speed and providing things.

I would like to call out by name Ms. Downey of Finnegan and Ms. Hitchens at Husch Blackwell, and the support team have really been valuable helping me get my hands on lists and documents. So I do thank the parties for all the help and the phone calls and all that. It makes a huge difference, I think, in the work that we do at the Commission.

JUDGE MCNAMARA: It really does. It really does. And I thank you, Mr. Guarnieri. So go ahead. It's your floor.

MR. GUARNIERI: Thank you. On behalf of the Staff, thank you, Your Honor, and the court. I think both

private parties said this, but I will echo it. The court staff is incredibly important. I think this hearing went very smoothly, Ms. Lee, Ms. Muhammad, and obviously, Ms. Kinkade and her hard work. So certainly OUII appreciates that all the time. We are grateful for all the hard work that we know goes on behind the scenes.

I also share Your Honor's sentiment. It's a really interesting case. The Staff learned a great deal. But for better or for worse, I'm only here to comment on the remedy.

JUDGE MCNAMARA: This is one of the downsides of limited participation, isn't it.

MR. GUARNIERI: That's right. I'm sure there's a lot I'd love to say, but --

JUDGE MCNAMARA: Yeah.

MR. GUARNIERI: As with my opening, I make clear that all my comments on remedy, of course, assume that Mr. Heneghan gets his way and that a violation is found. So I don't mean to say, I'm not meaning to take a position one way or the other on the merits here, just speaking of what happens if a violation is found.

So, with that, I think would just like to briefly summarize I think the more interesting evidence that I thought came in about the remedy, starting with the general exclusion order.

And I will say too, if Your Honor has any questions about anything that comes up, please feel free to interrupt, I would be happy to answer them.

Just for context, of course, sort of putting this where we need to be for a general exclusion order question, we're looking at whether it's necessary to prevent the circumvention of a limiting exclusion order, or whether there's a pattern of violation and difficulty identifying the source.

I think the Staff's view of the evidence that we heard at the hearing, along with some of the evidence I think both parties alluded to that's going to come in through designations and such, did not show that either of those prongs have been met.

I think it's actually easiest to deal with the sections in reverse, talk about the pattern of violation and difficulty of identifying source.

It's pretty clear that it's easy to identify the source. That's Healthgen. There's only one source of the accused products here; that's Healthgen. We heard from Mr. Deeter, from Mr. Curl, and Mr. LaMotta as well, that the only companies that make rice-derived rHSA products are Ventria, obviously the Complainant, and Healthgen, the Respondent here.

And then we also heard from Mr. Deeter, Mr. Curl,

and Mr. LaMotta that Healthgen is the only company that sells or, I'm sorry, I should say makes products branded as Oryzogen and OsrHSA. Those are the brand names the product is sold under.

So I think, from that, we can conclude that the products that are the accused products that are being imported here, that are accused of violating section 337, these are products that unquestionably come from Healthgen and are branded with Healthgen trademarks.

And so I think it's not going to be -- the CBP will be able to identify these goods and there's not going -- there's not a pattern, a number of actors that are all acting separately. There's just Healthgen. And I think a limited exclusion order against Healthgen would allow the products to be excluded.

The other prong is a little bit more interesting, I think, whether or not conditions are ripe for circumvention.

Here, and I think Mr. Heneghan really highlighted this in his closing remarks, here it's really the primary evidence is really about the aliases, the different names, I think is really the strongest point that Ventria was able to raise.

As a general matter, I think the same evidence that I just discussed about pattern of violation, I think

that same evidence shows that a GEO is probably not necessary here.

We have a single source of the goods sold under a brand name that's widely recognized as being from this single source. And that CBP can enforce a limited exclusion order against those goods and keep the products out.

Just as sort of a marker, we don't need to put it up, but I thought Mr. LaMotta had a very nice slide at CDX-2, slide 57, that I think lays out the names that, at least from Ventria's perspective, is one of the primary supports for why a GEO is necessary here.

The Staff views that that's really not -- it's not enough to show that a GEO is necessary. The names are all very similar. Your Honor will remember many had the name Healthgen in them. This isn't a case where the names are completely different. I'll get to one in a second that was a little bit different.

Second, I think I heard Mr. Deeter and Mr. Curl both testify that they were aware that all these different names were all associated with Healthgen. So these are two sophisticated industry participants. Obviously they both know their business really well. And I think the fact that they understood that these names were coming from the same source suggested that this is more akin -- these names are more akin to the same evidence we heard about Ventria, which

is that Ventria was originally, I think Mr. Deeter said it was Applied Phytogenics, it changed its name to Ventria Bioscience, and then it added Ventria Bioscience Inc. And, of course, there's nothing sinister about that. They do business under InVitria, I understand, as well. Again, nothing sinister about that. This is just the normal course of business where companies will brand themselves different things in order to sell their products, and that's acceptable.

I don't think the evidence that we've seen about the Healthgen name suggests anything here beyond that normal slight variations of names that is common in business.

But before I proceed any further, I think we're about to go under the -- in the interest of caution -- I think this might be third-party CBI. So if there are any Healthgen or Ventria witnesses, we should probably have them exit at this point.

(Whereupon, the trial proceeded in confidential session.)

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Dr. DeFilippi:

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CX-1065

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Ryan LaMotta:

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Dr. Lisa Wilken:

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RX-0050

RX-0206

RX-0374

C E R T I F I C A T E

TITLE: CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME

INVESTIGATION NO.: 337-TA-1238

HEARING DATE: November 12 2021

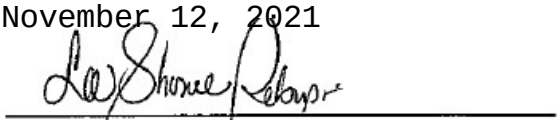
LOCATION: Washington, D.C. - Remote

NATURE OF HEARING: Evidentiary Hearing

I hereby certify that the foregoing/attached transcript is a true, correct and complete record of the above-referenced proceedings of the U.S. International Trade Commission.

Date: November 12, 2021

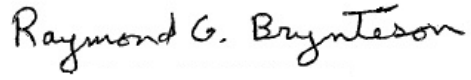
Signed:

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Signature of the Contractor or the Authorized Contractor's Representative

I hereby certify that I am not the court reporter and that I have proofread the above-referenced transcript of the proceedings of the U.S. International Trade Commission against the aforementioned court reporter's notes and recordings for accuracy in transcription in the spelling, hyphenation, punctuation and speaker identification and did not make any changes of a substantive nature. The foregoing/attached transcript is a true, correct and complete transcription of the proceedings.

Signed:

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I hereby certify that I reported the above-referenced proceedings of the U.S. International Trade Commission and caused to be prepared from my record media and notes of the proceedings a true, correct and complete verbatim recording of the proceedings.

Signed:

ss// 