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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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EXELA PHARMA SCIENCES, LLC,)
) VOLUME 3
Plaintiff,)
) C.A. No. 20-365 (MN)
v.)
)
ETON PHARMACEUTICALS, INC.,)
)
Defendant.)

Wednesday, March 16, 2022
08:30 a.m.
Bench Trial

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE MARYELLEN NOREIKA
United States District Court Judge

APPEARANCES:

FISH & RICHARDSON
BY: CORRIN N. DRAKULICH, ESQ.
BY: ELIZABETH FLANGAN, ESQ.

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Counsel for the Defendant

Jenke - direct

10:15:57 1 we will turn to obviousness. It might be a good time to
10:16:00 2 break for Your Honor as well.

10:16:01 3 THE COURT: That sound great. Let's break and
10:16:04 4 then -- hold on a second.

10:16:14 5 So let's come back around noon.

10:16:19 6 COURT CLERK: All rise.

10:16:21 7 (A brief recess was taken.)

11:57:43 8 THE COURT: All right. Everyone be seated.
12:07:21 9 Let's continue.

12:07:21 10 MS. FLANAGAN: Thank you, Your Honor.

12:07:23 11 BY MS. FLANAGAN:

12:07:24 12 Q. Dr. Jenke, can you hear me okay?

12:07:26 13 A. Yes, I can.

12:07:27 14 Q. I'm loud enough?

12:07:28 15 A. Yes, I can. Thank you.

12:07:29 16 Q. We're going to turn now from anticipation to
12:07:31 17 obviousness. All right?

12:07:31 18 A. Yes, ma'am.

12:07:31 19 Q. And can we please have up PDX 527. In conducting
12:07:32 20 your obviousness analysis, Dr. Jenke, what legal standard
12:07:41 21 did you apply?

12:07:42 22 A. I used the legal standard of would a person of
12:07:42 23 ordinary skill in the art had a reason to combine the prior
12:07:51 24 art to arrive at the claimed invention and a reasonable
12:07:52 25 expectation of success in achieving the claimed invention.

12:08:00 1 Q. Now, you heard Dr. Baertschi address obviousness for
12:08:03 2 claims in the '155, '795, and '713 patent; correct?

12:08:10 3 A. Yes, I did.

12:08:11 4 Q. Let's briefly take a look at the claims of those
12:08:14 5 patents. We already looked at claim 27 of the '155. So
12:08:18 6 let's look at PDX 561 which has '795 patent, claim 1. Did
12:08:31 7 you consider this claim in forming your opinions?

12:08:34 8 A. Yes, I did.

12:08:37 9 Q. If we can go to PDX 562 which has the '795 patent,
12:08:43 10 claims 19 and 27. Did you consider these claims in forming
12:08:46 11 your opinions?

12:08:46 12 A. Yes, I did.

12:08:47 13 Q. If we can go to PDX 563, did you consider this claim,
12:08:53 14 claim 1 of the '713 patent, in forming your opinion?

12:08:57 15 A. Yes, I did.

12:08:58 16 Q. And can we also please have up the '713 patent, which
12:09:03 17 is JTX 4, I believe, Mr. Doyle, with the blow out of claim 1
12:09:09 18 and 8 through 10. And Dr. Jenke, did you consider these
12:09:21 19 claims of the '713 patent?

12:09:24 20 A. Yes, I did.

12:09:26 21 Q. Now, we can take that down, please.

12:09:30 22 Having done all this work in this case, what do
12:09:33 23 you understand to be a core feature of the inventions of the
12:09:37 24 asserted claims?

12:09:39 25 A. I consider the -- a core feature, perhaps the core

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12:09:44 1 feature of the asserted claims is to meet the specifications
12:09:49 2 over a specified period of time.

12:09:52 3 Q. And in particular, the specifications in the claims
12:09:55 4 that you are talking about, is one of them no more than
12:10:01 5 150 parts per billion of aluminum?

12:10:02 6 A. Yes, it is.

12:10:03 7 Q. Is another one of them related to cystine?

12:10:06 8 A. It is.

12:10:07 9 Q. And in the claims we looked at, do you recall which
12:10:10 10 claim limitations you tied to the cystine concept? We can
12:10:16 11 pull those up.

12:10:17 12 A. Please do that. I don't remember.

12:10:19 13 Q. Let's go to PDX 563, please. This has the '713
12:10:32 14 patent, which claim elements, Dr. Jenke?

12:10:36 15 A. The third one, a pharmaceutically acceptable amount
12:10:40 16 of cystine for at least 12 months from the time of
12:10:44 17 manufacture.

12:10:44 18 Q. In analyzing that claim, did you use the plain and
12:10:47 19 ordinary meaning of the pharmaceutically acceptable amount
12:10:50 20 of cystine?

12:10:52 21 A. Yes, I did.

12:10:53 22 Q. If could go to PDX 561 which has claim 1 of the '795
12:10:58 23 patent. Which claim limitation there relates to the concept
12:11:04 24 of cystine?

12:11:05 25 A. Substantially free from visible detectable

12:11:09 1 particulate matter.

12:11:10 2 Q. And Dr. Jenke, what opinion did you reach as to
12:11:14 3 whether claim 27 of the '155 patent and claims 19 and 27 of
12:11:20 4 the '795 patent, and claims 1, and 8 through 10 of the '713
12:11:26 5 patent are obvious?

12:11:28 6 A. I came to the conclusion that they were not obvious.

12:11:31 7 Q. Now, in your view, what are the fundamental problems
12:11:35 8 with Dr. Baertschi's obviousness opinion analysis?

12:11:40 9 A. I would offer two points. Point number one is I
12:11:45 10 believe the -- I believe in certain key aspects, the
12:11:49 11 analysis was superficial, focusing on sound bites instead of
12:11:54 12 the substance. And I believe again in key points it
12:12:00 13 demonstrated a focus on one dimension when, in fact, the
12:12:04 14 problem of developing a stable L-cysteine formulation is a
12:12:10 15 multidimensional problem where several of the dimensions are
12:12:16 16 interconnected.

12:12:20 17 Q. Now, is one of the things you considered in your
12:12:25 18 obviousness analysis whether a skilled artisan would have
12:12:29 19 been motivated to come up with a low aluminum cysteine
12:12:33 20 composition described in the claims?

12:12:35 21 A. Yes.

12:12:35 22 Q. And do you agree such a motivation existed?

12:12:38 23 A. I do agree that such a motivation existed.

12:12:41 24 Q. How long did that motivation exist before Exela's
12:12:45 25 patent filing in January of 2019?

12:12:48 1 A. Decades.

12:12:50 2 Q. Did you understand Dr. Baertschi's obviousness
12:12:56 3 opinion to be in a nutshell to take the Sandoz product and
12:12:59 4 put it in a Schott Type 1 Plus vial?

12:13:03 5 A. I understood that to be his argument in a nutshell.

12:13:08 6 Q. And so when he suggests using the Sandoz product kind
12:13:12 7 of as a starting place to put it in a Schott vial, in your
12:13:16 8 opinion what exactly would a skilled artisan be starting
12:13:21 9 with?

12:13:21 10 A. Well, I think you need to understand and I believe a
12:13:25 11 skilled artisan would understand that the term Sandoz
12:13:30 12 product is not the same as the term Sandoz solution. The
12:13:35 13 term Sandoz product is the Sandoz solution in a product, in
12:13:40 14 a container, manufactured by a process, and it is those
12:13:45 15 three things that define the Sandoz product.

12:13:49 16 Q. And would a skilled artisan have known how the Sandoz
12:13:53 17 product was manufactured in any detail?

12:13:56 18 A. No.

12:13:58 19 Q. Did you hear any testimony throughout the course of
12:14:01 20 this trial or read any testimony suggesting otherwise?

12:14:02 21 A. No.

12:14:07 22 Q. And what's the significance of a skilled artisan not
12:14:12 23 knowing how the Sandoz product was made in terms of using it
12:14:15 24 as a starting point?

12:14:22 25 A. So in essence, you know, there are two issues to

address with the development of the Sandoz product. It's controlling aluminum, and controlling the formation of a particulate, in this case a particulate that forms because of oxidation. The manufacturing process is arguably the most significant aspect of controlling oxygen, and that's why it is important.

Q. And so how straightforward would it have been for a skilled artisan to come up with the low aluminum cysteine product of the asserted claims by starting with what was actually known about the Sandoz product?

A. In my opinion it is not obvious to be able to do that.

Q. Now, I want to turn your attention to the information available to a skilled artisan about the process by which aluminum could have possibly gotten into the Sandoz product. What would a skilled artisan have understood about that process, big picture?

A. Big picture the skilled artisan would have understood that that -- that the phenomenon causing that issue was the leaching.

Q. You told us what the phenomenon was earlier this morning.

A. Yes, I did.

Q. In this circumstance for the Sandoz product, what solid and liquid are relevant to the leaching issue?

12:15:47 1 A. Well, so the packaging, which is the solid, is
12:15:52 2 relevant because it's the source. The product is relevant
12:15:58 3 because A, it's where the leachable ends up in what gets
12:16:05 4 dosed to the patient, and B, because it's the entity that's
12:16:09 5 doing the leaching.

12:16:10 6 Q. And when you -- in your answer there, you used the
12:16:13 7 product as being --

12:16:15 8 A. Excuse me, the solution. Solution. Thank you.

12:16:17 9 Q. The solution?

12:16:18 10 A. Yeah.

12:16:19 11 Q. So the container is the solid, and the solution being
12:16:21 12 the mixture of cysteine and water is the solution?

12:16:25 13 A. Yes, that's correct.

12:16:27 14 Q. Now, big picture, what factors influence a drug
12:16:31 15 product's ability to leach aluminum from its container
12:16:35 16 closure system?

12:16:36 17 A. Big picture, it's the composition.

12:16:39 18 Q. All right. And what do you mean by that?

12:16:41 19 A. Well, for example, the pH, the pH is going to impact
12:16:50 20 the magnitude of leaching. Whether the pharmaceutical
12:16:54 21 solution contains an agent that has an affinity for aluminum
12:16:58 22 is going to impact the amount of leaching.

12:17:02 23 Q. Is there anything about the container closure system
12:17:05 24 that would influence leaching?

12:17:08 25 A. Well, again, big picture, the substance that we are

12:17:11 1 talking about has to be in the container closure system to
12:17:15 2 begin with.

12:17:15 3 Q. And what about considerations of time and/or
12:17:18 4 temperature?

12:17:19 5 A. Both time and temperature will influence the rate and
12:17:22 6 amount of leaching.

12:17:23 7 Q. And do those factors that you just identified as
12:17:27 8 influencing aluminum leaching, do they operate independently
12:17:32 9 of one another?

12:17:32 10 A. They do.

12:17:34 11 Q. They operate independently of one another?

12:17:37 12 A. Well, so the impact or the mechanism by which time
12:17:41 13 and temperature influences leaching is different than the
12:17:44 14 mechanism by which the solution impacts leaching, but the
12:17:51 15 combined effect, the effect that dictates how much aluminum
12:18:01 16 is actually in the product is caused by the interacting
12:18:11 17 phenomenon of both the solution and time and temperature.

12:18:14 18 Q. Now, did the prior art provide information about how
12:18:19 19 those factors you identified impact the leaching of aluminum
12:18:24 20 by cysteine composition?

12:18:27 21 A. No, it did not.

12:18:29 22 Q. Did the prior art provide any information about how
12:18:34 23 those factors impact the leaching of aluminum by cysteine?

12:18:40 24 A. No, it did not.

12:18:50 25 Q. And in forming your opinions, did you look at a body

12:18:54 1 of work by Dr. Bohrer?

12:18:59 2 A. Yes.

12:18:59 3 Q. What did her body of work contribute to the state of
12:19:02 4 the art?

12:19:03 5 A. What her work contributed to the state of the art was
12:19:08 6 an understanding of the affinity of cysteine and cystine for
12:19:14 7 aluminum as well as the effect of temperature on the
12:19:20 8 leaching of aluminum.

12:19:21 9 Q. Let's take a look at that and we can take those in
12:19:28 10 turn.

12:19:29 11 You can look in your binder or we can call it
12:19:32 12 up, we have PTX 227, an article by Bohrer dated 2001. It
12:19:40 13 should be towards the front of your binder, I believe. PTX
12:19:45 14 227. Do you have that?

12:19:51 15 A. Well, let's see what comes up on the screen.

12:20:00 16 Q. Okay. Let's go to PDX 528. Do you recognize this as
12:20:05 17 the Bohrer article that you considered in forming your
12:20:08 18 opinion?

12:20:10 19 A. I'm sorry.

12:20:12 20 Q. That's okay. Referring to the title of the Bohrer
12:20:14 21 article at PTX 227, what did Bohrer study in this paper?

12:20:21 22 A. Bohrer studied the influence of amino acids on the
12:20:24 23 leaching of aluminum from glass containers.

12:20:26 24 Q. Let's take a look. PDX 525, PTX 227.4, which has the
12:20:32 25 Figure 2 of Bohrer. What does Figure 2 convey about

12:20:39 1 cysteine relative to other amino acids?

12:20:43 2 A. Figure 2, which is a plot of aluminum leached as a
12:20:47 3 function of time, establishes that of the amino acids
12:20:51 4 examined in this study, cysteine has a strong affinity for
12:20:57 5 aluminum.

12:20:59 6 Q. What does Figure 2 teach about cystine's affinity for
12:21:04 7 aluminum?

12:21:04 8 A. Similarly it establishes that cystine has a strong
12:21:09 9 affinity for aluminum.

12:21:14 10 Q. And in terms of time, does Figure 2 show that the
12:21:18 11 cysteine and cystine solutions studied are done with
12:21:22 12 leaching of aluminum over the time period studied in
12:21:27 13 Figure 2?

12:21:27 14 A. No, over the time period studied in this figure which
12:21:31 15 is roughly 350 days, we see that the plots for both cysteine
12:21:36 16 and cystine are still increasing.

12:21:41 17 Q. And in his testimony, Dr. Baertschi talked about a
12:21:47 18 reference called the '337 patent. Do you remember that?

12:21:50 19 A. I do remember that.

12:21:51 20 Q. And what pharmaceutical composition is the subject of
12:21:56 21 the '337 patent?

12:21:58 22 A. Ibuprofen lysine.

12:22:01 23 Q. Does that have any connection to the information
12:22:04 24 disclosed here in Figure 2?

12:22:05 25 A. It does.

12:22:06 1 Q. Please explain?

12:22:07 2 A. One of the amino acids represented in this figure is
12:22:13 3 lysine, it's represented by this symbol, LYS.

12:22:17 4 Q. What does Figure 2 teach about lysine affinity for
12:22:22 5 aluminum?

12:22:23 6 A. That lysine's affinity for aluminum is quite small.

12:22:28 7 Q. And do you understand Bohrer to have drawn any
12:22:32 8 conclusions about lysine's affinity for aluminum based on
12:22:36 9 her data? If we go to PDX 530, looking at PTX 227.5. What
12:22:44 10 is she telling the skilled artisan here?

12:22:48 11 A. What she is telling the skilled artisan here is that
12:22:55 12 four of the amino acids, cysteine, cystine, aspartic acid
12:23:00 13 and glutamic acid had an affinity for aluminum, were able to
12:23:05 14 release aluminum from the glass vial, whereas the other
12:23:09 15 amino acid studies did not.

12:23:11 16 Q. So for a skilled artisan who is trying to make
12:23:16 17 aluminum cysteine compositions of the claims, what are some
12:23:19 18 of the key takeaways from the Bohrer paper at PTX 227?

12:23:24 19 A. Very simply that the presence of the cysteine as the
12:23:29 20 major ingredient and cystine as the major degradation
12:23:32 21 product is going to make my job a lot harder.

12:23:37 22 Q. All right. We've looked at affinity, let's talk
12:23:40 23 about -- and time. Let's talk about temperature. Can we
12:23:44 24 please have up PDX 531, which shows up in the title from PTX
12:23:52 25 228, which is another article by Bohrer and her colleagues

12:23:56 1 dating from 2003. Do you recognize this as an article that
12:24:00 2 you considered in forming your opinions?

12:24:02 3 A. I do.

12:24:02 4 Q. And what factor did Bohrer study in PTX 228?

12:24:07 5 A. In this particular study she studied the effect of
12:24:13 6 heating by sterilization on the leaching of aluminum from
12:24:17 7 glass.

12:24:18 8 Q. If we can go to PDX 532 which shows us PTX 228.5
12:24:25 9 which is Figure 2, what information does Figure 2 convey to
12:24:30 10 the skilled artisan?

12:24:31 11 A. Well, first and foremost, the information that's
12:24:36 12 conveyed to the skilled artisan is that the amount of
12:24:39 13 aluminum leached after sterilization is dramatically higher
12:24:44 14 than the amount of aluminum released before sterilization.

12:24:49 15 Q. And that's true for cysteine and cystine in this
12:24:53 16 figure?

12:24:53 17 A. That is true for both cysteine and cystine.

12:24:56 18 Q. And so the takeaway is what?

12:24:59 19 A. The takeaway is that temperature impacts leaching.

12:25:02 20 Q. All right. Now, let's turn to pH. Does pH affect
12:25:11 21 leaching of aluminum from glass?

12:25:12 22 A. Yes, pH does affect the leaching of aluminum by
12:25:17 23 glass.

12:25:17 24 Q. Can you explain the impact of the difference in pH on
12:25:22 25 aluminum leaching?

12:25:23 1 A. It's actually no more difficult than at low pH the
12:25:29 2 mechanism by which aluminum is leached is ion exchange, and
12:25:33 3 the mechanism by which aluminum is released at higher pH is
12:25:39 4 by actual decomposition of the glass.

12:25:42 5 Q. What is the significance of that different mechanism?

12:25:46 6 A. Well, the significance of the different mechanism is
12:25:50 7 that the different mechanism will impact the magnitude of
12:25:56 8 aluminum leaching.

12:25:56 9 Q. Is that information about the differential in
12:26:01 10 leaching associated with pH, was that known in the
12:26:04 11 literature?

12:26:05 12 A. It was indeed.

12:26:08 13 Q. Can we go to PDX 547, please. This has an excerpt
12:26:17 14 from DTX 409.2 which is the Hernandez-Sanchez reference.
12:26:23 15 And it's not highlighted in here, but right in the middle
12:26:26 16 there is a sentence that starts "low pH." Do you see that,
12:26:33 17 Dr. Jenke?

12:26:33 18 A. Yes, low pH favors exchange of metal ions from glass
12:26:38 19 whereas high pH solutions promote the dissolution of the
12:26:42 20 glass surface itself.

12:26:44 21 Q. And that is what you're talking about?

12:26:47 22 A. Yes, that is what I said.

12:26:48 23 Q. Now, the prior art talks about aluminum leaching in a
12:26:51 24 solution at a pH of 7 and you're asked to extrapolate that
12:26:52 25 to a solution of a pH of 1 to 2-and-a-half like the pH of a

12:27:00 1 cysteine solution, could you do that?

12:27:03 2 A. I would not, no.

12:27:05 3 Q. Did you see that happen yesterday?

12:27:11 4 A. I did.

12:27:11 5 Q. With respect to what?

12:27:12 6 A. With respect to the observation that this patent

12:27:17 7 somehow makes the claims obvious.

12:27:21 8 Q. And when you say this patent somehow makes the claims

12:27:25 9 obvious, do you remember which one you're talking about?

12:27:27 10 A. Which patent?

12:27:29 11 Q. Yes.

12:27:30 12 A. This patent, '337. The existence of '337 makes the

12:27:34 13 claims that we are discussing here obvious.

12:27:37 14 Q. And we had Hernandez-Sanchez up on the screen, so I

12:27:41 15 just wanted to clarify that for the record.

12:27:43 16 A. I'm sorry.

12:27:43 17 Q. That's okay. What is it about the solution of the --

12:27:46 18 excuse me, the composition that is the subject of the '337

12:27:51 19 patent that you saw that relates to this issue of

12:27:52 20 differences in pH?

12:27:52 21 A. That the pH of the Ibuprofen lysine solution is

12:28:00 22 adjusted to approximately seven.

12:28:00 23 Q. We talked about the impact of pH on leaching. Did

12:28:12 24 you see anything in the prior art about oxygen having an

12:28:15 25 impact on the aluminum leaching from Bohrer?

12:28:18 1

A. I did.

12:28:19 2

Q. All right. Let's go to PDX 534, which has an excerpt from PTX 271.4. Do you recognize the graph?

12:28:32 4

A. I do.

12:28:32 5

Q. And is this excerpted from a publication by Bohrer that you reviewed in forming your opinion?

12:28:39 7

A. It is.

12:28:40 8

Q. All right. Figure 2 has two graphs, one labeled A showing the presence of oxygen and one labeled B showing the absence of oxygen. Can you explain to us in simpler terms how these -- what these figures show about the behavior of aluminum leaching by cysteine solutions with or without oxygen?

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12:29:03 13

12:29:04 14

A. Yeah. So the behavior of cysteine in these figures is the symbol CYS. That's cysteine. In the absence of oxygen, you see that, again, I'm ballparking that it must be 30 days, the leaching of aluminum has reached an asymptote, it's essentially stopped. On the other hand, in the presence of oxygen, the leaching of aluminum by cystine is not stopped. In fact it continues to increase.

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Q. So now considering all of this research by Bohrer that you have just shown us that touches on the factors related to aluminum leaching, what does all of this

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12:29:57 23

12:30:00 24

information tell a skilled artisan about the complexity of preparing the low aluminum cysteine compositions of the

12:30:04 25

12:30:08 1

asserted claims?

12:30:09 2

A. That it is a complex process.

12:30:11 3

Q. We can take that down, please, Mr. Doyle.

12:30:14 4

Did you see any real world examples of that

12:30:18 5

complexity bearing out during the development of low

12:30:23 6

aluminum cysteine product in forming your opinion?

12:30:25 7

A. Yes, I did.

12:30:25 8

Q. Where did you see that?

12:30:27 9

A. This was in a regulatory document from a company

12:30:31 10

called Avadel.

12:30:33 11

Q. And big picture, what did you see in that

12:30:36 12

documentation that demonstrated the complexity you're

12:30:39 13

talking about?

12:30:40 14

A. Avadel essentially did two studies, and the

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difference in the design of those two studies allowed me to

12:30:49 16

be able to see the phenomenon we're talking about now, the

12:30:51 17

complexity.

12:30:56 18

Q. And can you just briefly explain before we go to the

12:30:59 19

documents what the difference was between the experiments

12:31:01 20

and what the complexity or the phenomenon you saw?

12:31:05 21

A. So, again, in a nutshell, and I do hope we get the

12:31:09 22

opportunity to go into the details because they are

12:31:12 23

important. But in a nutshell, Avadel did two experiments

12:31:20 24

where the only difference between those two experiments is a

12:31:25 25

solution was filled in an unlined Type 1 vial, and the same

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12:31:33 1 solution was filled in a Type 1 Plus lined vial.

12:31:39 2 Q. And what was the difference that gives rise to this
12:31:43 3 complexity?

12:31:44 4 A. The fact that the solution stored in the lined vial
12:31:52 5 produced the precipitate.

12:31:55 6 Q. Now, let's take a look at the cysteine compositions
12:32:04 7 Avadel made in these two different experiments starting with
12:32:08 8 the cysteine composition having the lowest aluminum content.
12:32:12 9 If we can go to PDX 535. On the left-hand side of this
12:32:21 10 slide, Dr. Jenke, we have a cover page from a pharmaceutical
12:32:27 11 development document. Did you review this document in
12:32:30 12 forming your opinions?

12:32:31 13 A. I did.

12:32:32 14 Q. Did you understand it to relate to Avadel's NDA
12:32:36 15 submission?

12:32:36 16 A. I did.

12:32:38 17 Q. So up here we have PTX 1B at 1663 and there is a
12:32:41 18 heading for lined-vial primary stability/registration
12:32:51 19 batches. What do you understand stability/registration
12:32:52 20 batches to refer to?

12:32:52 21 A. Stability/registration batches, honestly there is no
12:33:10 22 mystery. They are stability batches designed to support a
12:33:13 23 product registration.

12:33:14 24 Q. How many batches were made?

12:33:15 25 A. Three batches were made.

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12:33:16 1 Q. And they were assigned batch or lot numbers C1800029,
12:33:23 2 30, and 31?

12:33:24 3 A. Yes, that's correct.

12:33:25 4 Q. And what process in terms of the descriptor used in
12:33:31 5 Section 3.8 was used to make those batches?

12:33:34 6 A. So it is a process that is described in detail in
12:33:39 7 this document as Figure 1 left.

12:33:42 8 Q. And you looked at that process?

12:33:44 9 A. I did.

12:33:45 10 Q. Can we call these three lots made in this way the
12:33:50 11 lined-vial registration batches?

12:33:53 12 A. Yes.

12:33:53 13 Q. Just for short hand.

12:33:55 14 A. That's fine.

12:33:55 15 Q. Did you look at the aluminum content of these
12:33:58 16 batches?

12:33:58 17 A. I did.

12:34:00 18 Q. Let's go to PDX 536 which has a blow out of PTX 1A at
12:34:00 19 1489.

12:34:10 20 Dr. Jenke, did you consider the tables of
12:34:12 21 stability information associated with these batches?

12:34:15 22 A. I did.

12:34:16 23 Q. Is that contained in this document?

12:34:18 24 A. It is.

12:34:19 25 Q. How much aluminum were in the lined vial registration

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12:34:22 1 batches in the first few months after manufacture?

12:34:27 2 A. Less than five parts per billion.

12:34:31 3 Q. For the record you're looking at Table 2 and the

12:34:34 4 results for lot C1800029?

12:34:37 5 A. Yes, that's correct.

12:34:39 6 Q. All right. Now let's turn to the cysteine batches

12:34:42 7 with the higher aluminum level. Let's go to PDX 537 which

12:34:47 8 contains PTX 1B at .1661. There is a heading there for 3.7

12:34:54 9 unlined vial supportive GMP batches. What do you understand

12:34:59 10 that label, supportive GMP batches based on your review of

12:35:05 11 these documents?

12:35:09 12 A. It was a -- it was a batch used to establish good

12:35:18 13 manufacturing practices for the drug product.

12:35:21 14 Q. And was it -- let's talk about the lots. There were

12:35:26 15 again, three lots made?

12:35:27 16 A. Yes, there were three lots.

12:35:29 17 Q. Batch numbers C1700195, 196, and 197?

12:35:35 18 A. That is correct.

12:35:39 19 Q. And was the process used to make this set of batches

12:35:40 20 the same or different than the process used to make the

12:35:42 21 lined-vial registration batches?

12:35:42 22 A. It was the same process, Figure 1 left.

12:35:43 23 Q. What type of vials were these batches put into?

12:35:52 24 A. These were unlined Type 1 vials.

12:35:52 25 Q. And do you have an understanding based on the

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12:35:58 1 documents as to why they used unlined vials?

12:36:02 2 A. The Type 1 Plus vials were not available.

12:36:06 3 Q. And so could we call these three batches the
12:36:11 4 unlined-vial supportive GMP batches?

12:36:14 5 A. Yes.

12:36:14 6 Q. Let's go to PDX 538 which has PTX 1A at 1505. How
12:36:22 7 much aluminum was in the unlined vial supportive batches in
12:36:27 8 the first few months after manufacture?

12:36:32 9 A. 45 to 221 parts per billion.

12:36:37 10 Q. 45 to 102 parts per billion at three months?

12:36:43 11 A. Yes, at three months.

12:36:46 12 Q. Okay.

12:36:46 13 A. The 221 comes in at 12 months.

12:36:50 14 Q. Let's go to PDX 539 which has PTX 1B.1656. What does
12:37:00 15 Avadel's documentation say about the expected differences
12:37:03 16 between cysteine batches in lined versus unlined vials?

12:37:08 17 A. They expected I think what any skilled artisan would
12:37:14 18 expect, and that's the aluminum levels would be higher in
12:37:19 19 the unlined vials versus the lined vials. And it was their
12:37:25 20 expectation that they would actually exceed recommended
12:37:28 21 levels.

12:37:28 22 Q. Did they expect anything else to be different?

12:37:32 23 A. No. As a matter of fact they very clearly
12:37:36 24 communicated that they expected the other parameters to be
12:37:39 25 identical.

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12:37:40 1 Q. Now, you have described two batches, the only
12:37:42 2 expected difference between aluminum levels and shown the
12:37:46 3 aluminum levels were different in the first few months after
12:37:49 4 manufacture?

12:37:49 5 A. Yes.

12:37:50 6 Q. Did the lined vial registration batches and the
12:37:55 7 unlined supportive batches behave the same?

12:37:57 8 A. No, they did not.

12:37:58 9 Q. What happened?

12:38:00 10 A. A visual inspection of the batches from the lined
12:38:08 11 vials indicated the formation of particulate.

12:38:10 12 Q. Did Avadel determine what the particulate was?

12:38:17 13 A. Yes, they determined that it was cysteine related --
12:38:21 14 cystine related, excuse me.

12:38:23 15 Q. What does that appearance of the cystine precipitate
12:38:26 16 mean in terms of the stability of the lined vial
12:38:30 17 registration batches?

12:38:33 18 A. The presence of visible particulate means that those
12:38:39 19 units were not stable.

12:38:42 20 Q. Let's go to Table 23. We'll pull up PDX 540, please,
12:38:49 21 Mr. Doyle. Is that PTX 1B.1683.

12:38:52 22 Looking at Table 23, about how prevalent was the
12:38:59 23 cystine particulate problem in the lined vial registration
12:39:04 24 batches?

12:39:06 25 A. In the three batches that were studied, the

12:39:11 1 percentage of units that were rejected because they
12:39:16 2 exhibited visible particles was anywhere from 22 to
12:39:21 3 53 percent.

12:39:21 4 Q. How does that compare as to the rejection rate for
12:39:25 5 the unlined vial batches?

12:39:29 6 A. The rejection rates in the unlined vial batches was
12:39:33 7 on the order of .1 to .2 percent.

12:39:37 8 Q. So, Dr. Jenke, to review the only difference between
12:39:39 9 the lined vial registration batches and unlined vial
12:39:43 10 supportive batches was the aluminum level?

12:39:46 11 A. Yes, that is correct.

12:39:47 12 Q. And the cystine precipitates formed only in lined
12:39:54 13 vial registration batches?

12:39:55 14 A. Yes.

12:39:57 15 Q. Dr. Jenke, could you see a relationship between lower
12:40:00 16 aluminum levels and generation of cystine particulate?

12:40:03 17 A. I do see there is a link between the two.

12:40:04 18 Q. And that link is?

12:40:07 19 A. When the aluminum levels were high, the particulate
12:40:11 20 didn't form.

12:40:12 21 Q. Did the prior art connect reducing the aluminum
12:40:16 22 levels with the formation of cystine particulate in cysteine
12:40:20 23 product as Avadel observed with the lined vial batches?

12:40:25 24 A. Yes, it did. No, I'm sorry, I'm confused, no, it did
12:40:32 25 not. I'm sorry.

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12:40:35 1 Q. Now, thank you for that correction of the record.

12:40:39 2 Now, ultimately was Avadel able to fix the
12:40:42 3 cystine particulate problem?

12:40:45 4 A. Yes, they did.

12:40:46 5 Q. And just big picture, how did they do that?

12:40:49 6 A. They changed their manufacturing process.

12:40:52 7 Q. All right. Let's take a look at that. If we can
12:40:54 8 call up PDX 541 which has PTX 1B at .1640, this is that
12:41:03 9 Figure 1 that you were talking about, Dr. Jenke?

12:41:05 10 A. Yes, that figure on the left was Figure 1 left in the
12:41:08 11 previous conversation.

12:41:09 12 Q. And we're focusing on that one in this demonstrative
12:41:13 13 exhibit, correct?

12:41:14 14 A. Yes.

12:41:14 15 Q. What oxygen controls were employed in that Figure 1
12:41:18 16 left-hand process?

12:41:19 17 A. They used the nitrogen overlay and the nitrogen
12:41:23 18 flush.

12:41:25 19 Q. Did they use nitrogen sparging?

12:41:26 20 A. They did not.

12:41:27 21 Q. Do Avadel's documents say why nitrogen sparging was
12:41:31 22 not employed in this process?

12:41:32 23 A. They indicated that nitrogen sparging had been taken
12:41:36 24 out of the process.

12:41:37 25 Q. Let's go to PDX 542, which has PTX 1B at .1657. Is

12:41:45 1 that what's indicated here, sir?

12:41:47 2 A. Yes. Again, they had experimental evidence that
12:41:51 3 suggested to them that sparging had no impact on cystine
12:41:57 4 levels.

12:41:57 5 Q. And you're reading from the nitrogen sparging of the
12:42:01 6 WFI was not carried out bullet point, correct?

12:42:04 7 A. Yes, that is correct.

12:42:05 8 Q. Let's look at the updated process implemented by
12:42:08 9 Avadel to fix the problem. We'll go to PDX 543 which has
12:42:14 10 PTX 1B.1640 again. What changed between the two processes
12:42:19 11 in Figure 1 in terms of oxygen control?

12:42:22 12 A. They reintroduced sparging with nitrogen.

12:42:26 13 Q. Is nitrogen sparging a type of dissolved oxygen
12:42:29 14 control?

12:42:29 15 A. Yes, it is.

12:42:31 16 Q. And did Avadel's documents say anything about the
12:42:37 17 reason for using nitrogen sparging for its cysteine
12:42:43 18 solution? If we can go to PDX 544. This has PTX 1B.1675.
12:42:51 19 You got some highlighting here, Dr. Jenke. Can you explain
12:42:56 20 the takeaway?

12:42:56 21 A. The takeaway is that the use of insert gas sparging
12:43:01 22 was expected to improve the stability of the drug over time.

12:43:04 23 Q. Now, there is also a bullet point here for addition
12:43:08 24 of hydrochloric acid. Does that relate to another process
12:43:12 25 change Avadel made?

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12:43:13 1 A. That is correct.

12:43:13 2 Q. Now, did the Avadel documents comment on the issues
12:43:18 3 they faced working on their cysteine formulation?

12:43:20 4 A. Yes, they made a comment.

12:43:22 5 Q. Let's go to PDX 545, which has PTX 1B at 1674 to 75.

12:43:32 6 What is Avadel saying here, Dr. Jenke?

12:43:35 7 A. Avadel is saying that the -- those aspects that
12:43:43 8 control the chemistry of cystine and cysteine, in other
12:43:48 9 words, the kinetics and equilibrium are complicated and not
12:43:51 10 always predictable in a practical study.

12:43:51 11 Q. Does what they wrote make sense to you?

12:43:51 12 A. Absolutely.

12:43:51 13 Q. So what do you take away from this failed attempt by
12:44:01 14 Avadel of making reduced aluminum cysteine product in the
12:44:01 15 lined vials?

12:44:01 16 A. That it is a complicated process.

12:44:01 17 Q. Is that consistent or inconsistent with all the
12:44:11 18 literature that you have presented in your testimony?

12:44:11 19 A. It is completely consistent.

12:44:11 20 Q. Do you remember Dr. Baertschi talking about two
12:44:21 21 references relating to oxygen control, the Butler and the
12:44:21 22 Waterman references?

12:44:21 23 A. I do remember both.

12:44:30 24 Q. And you reviewed both of those in forming your
12:44:30 25 opinions in this case; right?

12:44:34 1 A. I did.

12:44:35 2 Q. Let's focus on Butler. Do you remember what the
12:44:38 3 Butler one was about?

12:44:40 4 A. Yes, I do. The Butler manuscript dealt with the
12:44:48 5 sparging of water under -- with nitrogen under laboratory
12:44:54 6 conditions.

12:44:54 7 Q. So it discloses a technique?

12:44:57 8 A. I'm sorry?

12:44:58 9 Q. It discloses a technique for removing oxygen?

12:45:01 10 A. Yes.

12:45:02 11 Q. Does it provide any specific details about removing
12:45:04 12 oxygen from cysteine formulations or any other kind of drug
12:45:11 13 formulation to achieve any specific purpose?

12:45:13 14 A. No, it did not.

12:45:15 15 Q. And are the lab conditions disclosed in Butler
12:45:18 16 similar to the conditions used for making drug formulations
12:45:21 17 like cysteine formulations at a pharmaceutical company?

12:45:24 18 A. No, they are not.

12:45:31 19 Q. And in your opinion, would a skilled artisan look at
12:45:34 20 Butler in trying to solve the problems of high aluminum in
12:45:37 21 cysteine injection products?

12:45:40 22 A. Yes.

12:45:42 23 Q. For what purpose?

12:45:44 24 A. I'm sorry?

12:45:46 25 Q. What would they -- if they looked at Butler, what

12:45:51 1 would they get out of it?

12:45:52 2 A. Well, what they would get out of it is sparging with
12:45:58 3 nitrogen as a potential means of controlling dissolved
12:46:01 4 oxygen.

12:46:02 5 Q. All right. Let's talk about Waterman. And you heard
12:46:06 6 Dr. Baertschi talk about Waterman teaching the use of
12:46:09 7 headspace oxygen and dissolved oxygen controlled techniques,
12:46:14 8 is that fair?

12:46:14 9 A. Yes.

12:46:15 10 Q. And do you agree or disagree that it does disclose
12:46:19 11 those general techniques?

12:46:20 12 A. I certainly agree.

12:46:21 13 Q. And does Waterman teach anything about the details
12:46:25 14 about how to employ oxygen control techniques to generate a
12:46:29 15 low aluminum cysteine composition like the ones in the
12:46:33 16 asserted claims?

12:46:34 17 A. No.

12:46:35 18 Q. Now, Waterman does mention cysteine, we heard that
12:46:39 19 from Dr. Baertschi, correct?

12:46:40 20 A. It does.

12:46:42 21 Q. In what context?

12:46:42 22 A. Waterman mentions cysteine in the context of a
12:46:47 23 protein formulation.

12:46:49 24 Q. Does the Sandoz product contain a protein
12:46:52 25 formulation?

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12:46:53 1 A. It does not.

12:46:54 2 Q. Now, does Waterman characterize the oxygen control
12:47:00 3 technique discussion as broadly applicable to all drugs? If
12:47:07 4 we can have up PDX 557 -- excuse me, PDX 559. What did
12:47:20 5 Waterman say, Dr. Jenke?

12:47:23 6 A. Well, Waterman said with regard to all his
12:47:28 7 recommendations, and specifically applicable to the
12:47:31 8 recommendations that we're discussing, that in the end every
12:47:36 9 drug represents a unique situation.

12:47:38 10 Q. Do you agree with that?

12:47:39 11 A. I do.

12:47:40 12 Q. All right. So now we're going to turn to the
12:47:50 13 references Dr. Baertschi discussed in combination with the
12:47:54 14 Sandoz product to suggest the claim inventions were obvious,
12:47:58 15 those were Hernandez-Sanchez, the '337, and the Schott
12:48:02 16 brochure. Did you review all of those in forming your
12:48:04 17 opinion?

12:48:05 18 A. I did review all three.

12:48:07 19 Q. In your review of Hernandez-Sanchez, did you see
12:48:12 20 anything in there that would motivate or teach one of skill
12:48:16 21 in the art to use a Schott Type 1 Plus vial or any other
12:48:20 22 coated vial in attempting to prepare a reduced aluminum
12:48:24 23 cysteine combination?

12:48:26 24 A. No, I did not.

12:48:28 25 Q. Did Hernandez-Sanchez suggest anything for attempting

12:48:31 1 to prepare a reduced aluminum cystine composition?

12:48:35 2 A. No, it did not.

12:48:37 3 Q. Did Hernandez-Sanchez disclose aluminum levels in any

12:48:41 4 parenteral product had been successfully reduced?

12:48:45 5 A. Yes.

12:48:45 6 Q. Can we go to PDX 475. While we're bringing that up,

12:48:51 7 in what parenteral product was that?

12:48:53 8 A. A gluconate containing parenteral product.

12:48:57 9 Q. I'm sorry, PDX 547. Quite the transcription of

12:49:13 10 numbers, my apologies. So we have PDX 547 which is DTX

12:49:21 11 409.02. Is this what you're talking about from the

12:49:25 12 Hernandez-Sanchez reference?

12:49:26 13 A. Yes.

12:49:27 14 Q. What does it say specifically about calcium

12:49:30 15 gluconate?

12:49:30 16 A. It says that repackaging of calcium gluconate from

12:49:35 17 glass into polyethylene vials reduced the mean aluminum

12:49:39 18 concentration by 96 percent.

12:49:43 19 Q. Let's go now to '337 patent and that's the one about

12:49:52 20 the Ibuprofen lysine composition you already touched on

12:50:00 21 briefly?

12:50:01 22 A. Yes.

12:50:02 23 Q. Do you recall Dr. Baertschi using that as an example

12:50:04 24 of a way to fix or solve the problem of aluminum levels in

12:50:08 25 cysteine compositions?

12:50:10 1 A. Yes, I remember that.

12:50:11 2 Q. And do you agree that that provides an example of

12:50:17 3 solving the problem of aluminum levels in cysteine

12:50:21 4 compositions?

12:50:22 5 A. No, I do not.

12:50:23 6 Q. And why is that?

12:50:26 7 A. It's because the specific product dealt with in the

12:50:32 8 '337 patent is not as potent a leacher as is the L-cysteine

12:50:41 9 hydrochloride solution.

12:50:42 10 Q. Is there a difference in pH between the two products?

12:50:45 11 A. There is a difference between the pH.

12:50:48 12 Q. What significance could a skilled artisan give to

12:50:51 13 those differences between the two compositions, Ibuprofen

12:50:55 14 lysine on the one hand and cysteine on the other?

12:50:57 15 A. That aluminum leaching would not be the same.

12:51:00 16 Q. Now, the '337 patent does discuss some kind of an

12:51:05 17 issue with aluminum, is that right?

12:51:07 18 A. That is correct.

12:51:08 19 Q. What was that issue?

12:51:10 20 A. The issue in the '337 patent is that aluminum and the

12:51:12 21 lysine combine to perform a precipitate.

12:51:22 22 Q. If we can go to PDX 552. We have DTX 523 at the '337

12:51:23 23 patent at column 1, lines 48 to 58. Does that describe that

12:51:32 24 aluminum problem you just mentioned?

12:51:35 25 A. Yes, that is correct.

12:51:36 1 Q. Is precipitation of aluminum the issue with cysteine
12:51:39 2 solutions?

12:51:40 3 A. It is not.

12:51:51 4 Q. So what, if anything, in your opinion does a '337
12:51:56 5 patent teach to a skilled artisan about making or achieving
12:51:59 6 the low aluminum cysteine solutions of the claimed
12:52:02 7 inventions?

12:52:03 8 A. It teaches me nothing with respect to that.

12:52:06 9 Q. Now, let's turn to the Schott brochure.

12:52:14 10 Dr. Baertschi I think suggested that the coating was
12:52:21 11 projected to be stable for ten years. That's something that
12:52:23 12 he took away from the Schott brochure. Do you remember
12:52:26 13 that?

12:52:26 14 A. I do remember that.

12:52:27 15 Q. Let's look at something else the Schott brochure
12:52:31 16 says. Can we please have PDX 550 at DTX -- excuse me, PDX
12:52:34 17 550, and this is at JTX 13N.11806. What did the Schott
12:52:52 18 brochure say and what is the teaching to the skilled artisan
12:53:00 19 that results from it?

12:53:00 20 A. What the Schott brochure is saying at this particular
12:53:02 21 point is if you want to know how good this vial is with your
12:53:02 22 drug product, you better test the drug product in the vial.

12:53:12 23 Q. Is there anything in this brochure that would have
12:53:14 24 inform a skilled artisan that the Schott Type 1 Plus vial
12:53:17 25 was likely to be effective for use in cysteine products to

12:53:21 1 keep aluminum levels below 150 parts per billion for a time
12:53:26 2 frame of say 12, 18 or 24 months?

12:53:30 3 A. No.

12:53:30 4 Q. And also not produce cystine particulates during that
12:53:35 5 time period?

12:53:36 6 A. And also not produce cystine particulates during that
12:53:40 7 period.

12:53:44 8 Q. Okay. You have covered all the references. Before
12:53:48 9 we get to your ultimate opinions on obviousness, just one
12:53:54 10 more topic. Did you consider any objective factors that may
12:54:02 11 support a finding of nonobviousness?

12:54:04 12 A. Yes.

12:54:05 13 Q. In particular did you consider long felt need?

12:54:07 14 A. I did.

12:54:08 15 Q. Did you hear Dr. Kuhn testify about the need for a
12:54:11 16 low aluminum cysteine formulation for use in clinical
12:54:14 17 practice?

12:54:15 18 A. I did.

12:54:15 19 Q. And did you rely on that opinion?

12:54:17 20 A. I did.

12:54:18 21 Q. And what else did you -- and you relied on his
12:54:22 22 opinion that ELCYS fulfilled that long felt need; correct?

12:54:27 23 A. Yes.

12:54:27 24 Q. Now, what else did you rely on for long felt need
12:54:32 25 besides just Dr. Kuhn in terms of the literature and

12:54:35 1 disclosures about --

12:54:36 2 A. Well, in terms of the literature, it's well
12:54:41 3 documented by many authors, many authors use phrases like a
12:54:46 4 decade old unresolved problem.

12:54:49 5 Q. So did you see anyone else in the prior art before
12:54:55 6 Exela ever take the Sandoz product and put it in a Schott
12:55:00 7 Type 1 Plus vial as Dr. Baertschi suggest was such an
12:55:03 8 obvious solution?

12:55:05 9 A. I did not see anyone do that.

12:55:06 10 Q. Even though there was a motivation to do so?

12:55:07 11 A. Even though there was a strong motivation to do so.

12:55:13 12 Q. To clarify, a motivation to achieve a reduced
12:55:17 13 aluminum cysteine composition for clinical use?

12:55:20 14 A. To be specific, yes.

12:55:22 15 Q. And what does that suggest to you about whether or
12:55:26 16 not the asserted claims are obvious?

12:55:28 17 A. It suggest to me that the asserted claims were not
12:55:32 18 obvious.

12:55:33 19 Q. All right. So now you have addressed the Sandoz
12:55:37 20 product, the Hernandez-Sanchez reference, the '337 patent,
12:55:41 21 the Schott brochure, and you considered the state of the art
12:55:45 22 including what it taught about oxygen controlled by Butler
12:55:50 23 and Waterman, and leaching as taught by Bohrer, right?

12:55:52 24 A. That is correct.

12:55:54 25 Q. Now, in listening to Dr. Baertschi's testimony, did

12:55:59 1 you hear Dr. Baertschi ever explain why the combination of
12:56:03 2 the Sandoz product, Hernandez-Sanchez, the '337 patent, and
12:56:08 3 the Schott brochure would have given a skilled artisan a
12:56:12 4 reasonable expectation of success in achieving the claimed
12:56:19 5 cysteine compositions?

12:56:20 6 A. No, I did not.

12:56:21 7 Q. Did you even hear him address a reasonable
12:56:25 8 expectation of success on that issue as to even three months
12:56:28 9 after the time of manufacture?

12:56:29 10 A. No, I did not.

12:56:31 11 Q. Now, I'm going to turn to your opinion for each of
12:56:34 12 the patents. Based on the evidence you testified about,
12:56:41 13 what is your conclusion about whether a person of ordinary
12:56:44 14 skill in the art would have combined the Sandoz product with
12:56:51 15 Hernandez-Sanchez, the '337 patent, and the Schott brochure
12:56:54 16 to achieve the cysteine composition required by claim 12 of
12:56:57 17 the '155 patent with any reasonable expectation of success?

12:57:01 18 A. My conclusion is that the skilled artisan would not
12:57:04 19 have a reasonable expectation of success.

12:57:10 20 Q. And if we can call up PDX 561. This now has claim 1
12:57:21 21 of the '795 patent. Based on the evidence you testified
12:57:24 22 about, what is your conclusion about whether a person of
12:57:27 23 skill in the art would have combined the Sandoz product with
12:57:30 24 Hernandez-Sanchez, the '337 patent, and the Schott brochure
12:57:33 25 to achieve the cysteine composition of claim 1 of the '795

12:57:42 1 patent with a reasonable expectation of success?

12:57:46 2 A. I do not believe the skilled artisan would have had a
12:57:51 3 reasonable expectation for success.

12:57:52 4 Q. Let's go to PDX 562 which was the '795 patent, claims
12:57:59 5 19 and 27. These claims differ from claim 1 by increasing
12:58:04 6 the time period for how long the composition has to remain
12:58:09 7 at a certain state after manufacture. Is that right?

12:58:13 8 A. Yes, that's correct.

12:58:14 9 Q. And what's your conclusion about whether a person of
12:58:19 10 skill in the art would have combined the Sandoz product with
12:58:23 11 Hernandez-Sanchez and the '337 patent to achieved the claim
12:58:27 12 composition of claims 19 and 27 as described in those claims
12:58:31 13 with a reasonable expectation of success?

12:58:34 14 A. A skilled artisan would not have had a reasonable
12:58:39 15 expectation of success.

12:58:40 16 Q. Let's pull up PDX 563, which is claim 1 of the '713
12:58:47 17 patent. Same question, Dr. Baertschi --

12:58:52 18 A. Dr. Jenke, please.

12:58:53 19 Q. My apologies. Let me start that over then for sure.

12:58:58 20 THE COURT: At least we know he's listening.

12:59:02 21 Q. Dr. Jenke, based on the evidence you testified about,
12:59:06 22 what is your conclusion about whether a person of skill in
12:59:09 23 the art would have combined the Sandoz product with
12:59:12 24 Hernandez-Sanchez, the '337 patent, and the Schott brochure
12:59:16 25 to achieve the cysteine composition of claim 1 of the '713

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12:59:21 1 patent with any reasonable expectation of success?

12:59:24 2 A. My conclusion is that an expert would not have had a
12:59:31 3 reasonable expectation of success.

12:59:34 4 Q. And if we could briefly bring up claims 8 through 10
12:59:40 5 of the '713 patent, which I believe is the JTX 4 blow out,
12:59:48 6 Mr. Doyle, that we made earlier. There we go.

12:59:51 7 Dr. Jenke, you see claims 8 and 9 both recite a
12:59:57 8 solution of claim 1?

13:00:00 9 A. Yes.

13:00:00 10 Q. And you see claim 10 recites the solution of claim 9;
13:00:05 11 right?

13:00:05 12 A. Yes, it does.

13:00:06 13 Q. And thereby indirectly recites back to claim 1,
13:00:11 14 correct?

13:00:11 15 A. I understand that, yes.

13:00:13 16 Q. What is your opinion as to whether or not claims 8
13:00:17 17 through 10 of the '713 patent would have been combined with
13:00:21 18 the Sandoz product, Hernandez-Sanchez, the '337 patent and
13:00:24 19 Schott brochure by a skilled artisan with a reasonable
13:00:31 20 expectation of success in achieving the composition of those
13:00:32 21 claims?

13:00:34 22 THE COURT: I think you want to restate that.
13:00:36 23 You said would have been combined instead of would have been
13:00:38 24 obvious.

13:00:40 25 MS. FLANAGAN: Thank you.

Jenke - direct

13:00:44 1 THE COURT: Everyone is getting a little tired.

13:00:46 2 MS. FLANAGAN: That's very true. I appreciate
13:00:48 3 the leeway, Your Honor.

13:00:50 4 Q. Claims 8 through 10 require a solution of claim 1;
13:00:54 5 correct?

13:00:55 6 A. Yes, that is correct.

13:00:56 7 Q. And you believe that solution of claim 1 to be
13:01:00 8 nonobvious, correct?

13:01:00 9 A. That is correct.

13:01:01 10 Q. Is there anything in claims 8 through 10 that change
13:01:07 11 that opinion as to whether or not the solution of claim 1
13:01:10 12 would be obvious?

13:01:14 13 A. No, 8, 9 and 10 do not change the opinion that I made
13:01:23 14 several times.

13:01:24 15 Q. And so do you think that claims 8, 9 and 10 which all
13:01:28 16 require the same basic cysteine composition as recited in
13:01:32 17 claim 1 are also obvious?

13:01:47 18 MS. FLANAGAN: Let me just take a breath.

13:01:50 19 Q. What is your opinion as to whether or not the
13:01:52 20 asserted claims of claims 8 through 10 are obvious?

13:01:52 21 A. My opinion is that they are not obvious.

13:01:52 22 Q. Thank you, Dr. Jenke.

13:01:52 23 And what are your opinions as to whether or not
13:02:02 24 all of the asserted claims are obvious?

13:02:02 25 A. My opinion is that an individual skilled in the art

13:02:09 1 would not have a reasonable expectation for success.

13:02:14 2 Q. And therefore the claims would or would not be
13:02:17 3 obvious?

13:02:17 4 A. And therefore, the claims were not obvious.

13:02:21 5 MS. FLANAGAN: Thank you, Dr. Jenke. Let me
13:02:23 6 just check with my colleague.

13:02:28 7 We're good. Thank you.

13:02:31 8 THE COURT: All right. How about we take a
13:02:33 9 break and come back in let's say about forty-five minutes.

13:02:40 10 (A luncheon recess was taken.)

13:48:37 11 THE COURT: All right. Please be seated.

13:50:11 12 Mr. Devlin.

13:50:13 13 MR. DEVLIN: May it please the Court.

13:50:15 14 CROSS-EXAMINATION

13:50:15 15 BY MR. DEVLIN:

13:50:17 16 Q. Good afternoon, Dr. Jenke. How are you?

13:50:19 17 A. I'm fine. Thank you.

13:50:20 18 Q. Can you hear me okay? Am I loud enough for you?

13:50:21 19 A. You're terrific. I'll let you know if I'm not.

13:50:22 20 Q. I'm just going to warn you and warn everyone, I hoped
13:50:23 21 to get this done in an hour or ninety minutes. There is a
13:50:24 22 lot of volume. I may be a little longer, but I'll work as
13:50:25 23 efficiently as I can.

13:50:26 24 A. I'll do my best to help you.

13:50:27 25 Q. Thank you. We'll work as a team.

THE COURT: Just say yes, yes, yes.

Q. You looked at the issues of validity here through the lens of a person of ordinary skill in the art; right?

A. Yes, that is correct.

Q. And you understand that a person of ordinary skill in the art is presumed to know all of the prior art that was out there; right?

A. Yes, I do.

Q. Okay. Now, you also agree, then, that the person of ordinary skill in the art would be aware of the Sandoz product; right?

A. Yes.

Q. Okay. And I don't mean just the label for the product, I mean the actual product and what was in it; right?

A. They would be aware that a product existed.

Q. And they would be aware I have that product and its properties, not just what was on the label; correct?

A. I don't know how they would be aware of that.

Q. Okay. Got it. You didn't consider in your opinions of validity that a person of ordinary skill in the art would be aware of the Sandoz product and its properties, you didn't consider that?

A. I considered it from the perspective that the Sandoz product properties would be revealed from information that

13:52:00 1 would be available to the skilled artisan.

13:52:03 2 Q. Okay. So your view was what the skilled artisan, the
13:52:06 3 POSA would know about the Sandoz product was what was
13:52:10 4 available publicly about that product, did I understand you
13:52:15 5 right?

13:52:15 6 A. Yes, that is correct.

13:52:16 7 Q. All right. Thank you so much.

13:52:18 8 Now, you do understand that the Sandoz product
13:52:24 9 is different, it's a different prior art reference
13:52:28 10 technically than any single document that may describe it or
13:52:34 11 its properties; right?

13:52:37 12 A. I'm sorry, could you say that a different way?

13:52:41 13 Q. Sure. There are documents in the universe that
13:52:45 14 describe the Sandoz product, its properties, whatever,
13:52:49 15 right, there is stuff out there, documents, you understand
13:52:52 16 that?

13:52:52 17 A. Yes, I understand that in the universe of literature
13:52:57 18 there could be information on the Sandoz product.

13:53:00 19 Q. Great.

13:53:01 20 And to be clear, I was just talking about the
13:53:04 21 universe as a whole. It doesn't matter, we're on the same
13:53:07 22 page. There are documents that talk about the Sandoz
13:53:10 23 product; fair?

13:53:11 24 A. Yes.

13:53:12 25 Q. Okay. And what I'm saying is that the Sandoz product

13:53:15 1 as a prior art reference is different than any single one of
13:53:21 2 those individual documents treated as a prior art reference.

13:53:25 3 You understand that, right?

13:53:27 4 A. I will accept that, yes.

13:53:30 5 Q. But did you understand it when you did your analysis
13:53:33 6 in this case that the product is a different prior art
13:53:38 7 reference than any individual document that describes it?

13:53:47 8 A. I believe my consideration of the prior art took that
13:53:56 9 into account.

13:53:56 10 Q. It took it into account the way we talked about a
13:53:56 11 minute ago, you looked at all the publicly available
13:54:02 12 documents and used those as the basis for the knowledge of
13:54:05 13 the person of skill in the art about the Sandoz product, do
13:54:09 14 I have you right?

13:54:10 15 A. You have me right, yes.

13:54:13 16 Q. Thank you. Great.

13:54:15 17 Now, in your opinion -- let me ask you this.
13:54:19 18 The Certificates of Analysis, some of which we looked at
13:54:21 19 here, for example, DTX 123, 124, and 125, do you remember
13:54:31 20 those?

13:54:32 21 A. I do remember those.

13:54:32 22 Q. Those Certificates of Analysis of the Sandoz product,
13:54:35 23 in your view those are confidential documents; right?

13:54:37 24 A. Yes, they are.

13:54:38 25 Q. And so based on what you just told me as I'm

13:54:42 1 understanding it, the person of ordinary skill in the art
13:54:45 2 would not know about the information on those documents with
13:54:49 3 respect to their knowledge, the POSA's knowledge of the
13:54:53 4 Sandoz product. Do I have you right?

13:54:54 5 A. You have me right.

13:54:56 6 Q. Thank you.

13:54:56 7 You talked about batches of, testing of
13:55:13 8 documents, right -- I'm sorry. You were looking at the
13:55:17 9 Certificates of Analysis and in doing that, you -- in doing
13:55:24 10 that you mentioned that the batches that -- sorry, the
13:55:29 11 actual vials that had been tested could not have been sold.
13:55:31 12 Do you remember that?

13:55:34 13 A. Yes, I do.

13:55:35 14 Q. Okay. Now, those test samples could have been taken
13:55:40 15 from batches that were sold commercially; right?

13:55:41 16 A. Those vials are representative of a batch, and it is
13:55:51 17 possible that that batch could have been sold.

13:55:51 18 Q. Okay. Did you hear Mr. Hofstetter's testimony, I
13:56:01 19 think it was, where he said that every batch of the Sandoz
13:56:02 20 product that Allergy Labs made was for commercial use. Do
13:56:10 21 you remember that?

13:56:11 22 A. I do not remember that.

13:56:12 23 Q. Okay. Do you remember your testimony about -- I
13:56:30 24 think you were looking at the '719 patent, it's one that has
13:56:32 25 12 months -- no, I'm sorry, I know what it was. Thank you.

13:56:43 1 It was the '155 patent, and you were looking at the aluminum
13:56:47 2 content over time. You were talking about anticipation of
13:56:50 3 the '155 patent, you were talking about aluminum over time,
13:56:54 4 and you noted that although those C of As the aluminum
13:57:01 5 started below 150, it went above 150 later in time at the
13:57:07 6 24-month period. Do you remember that?

13:57:09 7 A. Yes, I do remember that.

13:57:11 8 Q. Okay. And your point was there is nothing that
13:57:14 9 demonstrates that any of those Sandoz batches would have had
13:57:19 10 an aluminum content below 150 during the period of
13:57:25 11 stability, so at least three months, that was the issue for
13:57:28 12 the '155, do you remember that?

13:57:32 13 A. I do remember that.

13:57:34 14 Q. Okay. Let's take a look at DTX 486, if we can. And
13:57:45 15 here we have another Certificate of Analysis for the Sandoz
13:57:49 16 product. It's on the screen if you want, sir. We'll expand
13:57:53 17 it out for you. If we can just have that top box. And you
13:58:00 18 see that's the Sandoz Certificate of Analysis for the Sandoz
13:58:08 19 product, right?

13:58:09 20 A. Yes, that's correct.

13:58:10 21 Q. And this is a 10 mL?

13:58:12 22 A. It is.

13:58:13 23 Q. Okay. And if we could look at -- just pop that off.
13:58:16 24 Thanks.

13:58:18 25 If we could look at the manufacturing date

13:58:23 1 there, that same box, I'm sorry, same box you had,
13:58:27 2 Mr. Patterson. Thanks. Manufacturing date bottom right on
13:58:30 3 the screen, December 2015. Do you see that?
13:58:36 4 A. I do see that.
13:58:38 5 Q. Okay. Thanks. If we could turn to the next page of
13:58:41 6 this same document and let's go to the very bottom, that
13:58:52 7 bold text first just to get the date. Do you see the date
13:58:55 8 here? Now we're July 2016. Do you see that?
13:58:59 9 A. I do see that.
13:59:00 10 Q. So about seven months later from that December 2015
13:59:03 11 date of manufacture.
13:59:06 12 A. It is.
13:59:07 13 Q. Easy math. Let's look at the aluminum results for
13:59:12 14 this particular sample. You see that's 150 parts per
13:59:20 15 billion; right?
13:59:21 16 A. It is.
13:59:21 17 Q. So that's at seven months. Right?
13:59:24 18 A. Yes, that's correct.
13:59:25 19 Q. Okay. Let me just try to ask this simply. At three
13:59:29 20 months, it would have been lower; right?
13:59:32 21 A. At three months I would estimate that it could have
13:59:42 22 been lower.
13:59:43 23 Q. All right. The reason you say that -- let me try it
13:59:47 24 a little differently. I asked it would be lower. You were
13:59:50 25 confident given what we know about how aluminum gets into

13:59:54 1 the product that at the three-month date it's going to be
13:59:59 2 lower than 150. That's fair, isn't it?

14:00:02 3 A. I'm sorry?

14:00:03 4 Q. We are confident given how aluminum makes its way
14:00:08 5 into the product over time that at the three-month date,
14:00:14 6 four months earlier than this, the aluminum content is going
14:00:17 7 to be lower; right?

14:00:23 8 A. I am not confident of that.

14:00:26 9 Q. Okay. Well, let me ask you -- let me break it down a
14:00:29 10 little for you. The way that aluminum gets in once it's in
14:00:31 11 the vial is leaching; right?

14:00:37 12 A. Yes, that is correct.

14:00:38 13 Q. Let me be a little more clear. There is aluminum
14:00:41 14 that gets in from the ingredient, the starting ingredients,
14:00:45 15 right?

14:00:45 16 A. Yes.

14:00:46 17 Q. So right at the time it's manufactured it's got some
14:00:48 18 aluminum in there; fair?

14:00:51 19 A. That amount of aluminum will not change.

14:00:52 20 Q. The amount that came from the starting materials?

14:00:56 21 A. Yes, that is correct.

14:00:57 22 Q. And the reason it won't change is because aluminum is
14:00:59 23 not a degradedant, correct?

14:01:01 24 A. No, it is not.

14:01:02 25 Q. Exactly. It's there, it's a metal, it's a metal

14:01:06 1 impurity, right?

14:01:07 2 A. Yes.

14:01:09 3 Q. Okay. So any aluminum that comes in that is
14:01:12 4 increasing within the solution is coming from leaching;
14:01:16 5 right?

14:01:16 6 A. Yes, that is correct.

14:01:18 7 Q. And that leaching happens over time; right?

14:01:20 8 A. It does.

14:01:22 9 Q. Okay. And so if you're leaching over time, unless
14:01:26 10 all of the leaching occurred in this seven-month period at
14:01:30 11 the three-month stage to get you to 150, and then no more
14:01:34 12 leaching occurred in the three to seven-month stage to stay
14:01:38 13 at 150, unless that happens, then it's going to be lower at
14:01:42 14 the three-month stage, right?

14:01:46 15 A. I agree with that.

14:01:49 16 Q. All right. Thank you.

14:01:53 17 How likely do you think it would be that all of
14:01:57 18 the leaching would happen at the three-month stage and then
14:02:01 19 no leaching will happen from three to seven? Pretty
14:02:05 20 unlikely; right?

14:02:09 21 A. No, I would not make that -- I would not make that
14:02:13 22 presumption.

14:02:17 23 Q. Okay. You think it's just as likely that it happens
14:02:21 24 all at three and none from three to seven, then the leaching
14:02:25 25 happens more gradually from time zero through month seven,

14:02:21 1 you think it's just as likely it's all in the first three
14:02:24 2 months?

14:02:29 3 A. No, but I think that it is a possibility that at some
14:02:34 4 point before three months the rate at which aluminum is
14:02:39 5 leaching is dramatically decreased.

14:02:42 6 Q. So in other words --

14:02:43 7 A. There is more to the aluminum curve than here and
14:02:46 8 here, there is a period of time when it begins to plateau,
14:02:51 9 plateau out, and that's the period of time that I'm
14:02:55 10 considering here.

14:02:56 11 Q. I hear you. So the curve flattens over time?

14:02:59 12 A. It does.

14:02:59 13 Q. Exactly. But when it flattens, that means it's still
14:03:03 14 going up a little bit?

14:03:04 15 A. That is correct.

14:03:05 16 Q. So it's still going up a little bit over time?

14:03:08 17 A. Yes.

14:03:08 18 Q. Even if it's relatively flat, it's still going down a
14:03:12 19 little bit as you go back in time?

14:03:14 20 A. It is.

14:03:15 21 Q. If you go down a little bit as you go back in time,
14:03:17 22 you get under 150, even just a little bit, fair?

14:03:20 23 A. Yes.

14:03:21 24 Q. All right. Thank you.

14:03:24 25 Now let's talk a little bit about something

14:03:38 1 different, different topic. The relationship between the
14:03:42 2 Eton ANDA product that's accused of infringement and the
14:03:46 3 prior art Sandoz product, that's our topic. Okay? Are you
14:03:50 4 with me?

14:03:52 5 A. I'm with you on that's the topic. I'm not exactly
14:03:57 6 sure I understand what that has to do with anticipation or
14:04:04 7 obviousness.

14:04:05 8 Q. I wasn't trying to stump you. I'll ask you some
14:04:08 9 questions, how is that?

14:04:09 10 A. Okay. Thank you.

14:04:11 11 Q. I was just telling you what we were going to be
14:04:13 12 talking about.

14:04:14 13 A. Terrific.

14:04:15 14 Q. Thank you.

14:04:16 15 Let me ask you. First in coming to your
14:04:21 16 validity opinions or invalidity or validity -- by the way, I
14:04:25 17 may use those words interchangeably. I'm not trying to put
14:04:30 18 words in your mouth. If I say invalidity, I know you're not
14:04:33 19 agreeing with that. Are you with me?

14:04:35 20 As part of your opinions in the case on the
14:04:38 21 question of validity, did you consider at all that there
14:04:42 22 might be a relationship between the Eton ANDA product and
14:04:45 23 how it's manufactured versus the prior art Sandoz product?

14:04:50 24 A. No, I did not.

14:04:52 25 Q. Okay. Did you factor in at all the possibility that

14:05:01 1 the two products could have the exact same starting
14:05:04 2 ingredient, the same API and the same excipient?

14:05:11 3 A. I'm sorry, would you repeat that?

14:05:14 4 Q. Sure.

14:05:15 5 Did you factor in at all, did you consider at
14:05:20 6 all the notions that the Eton proposed ANDA product and the
14:05:25 7 prior art Sandoz product could have the same set of
14:05:29 8 ingredients, the same API, and all the other ingredients,
14:05:33 9 did you consider that as part of your validity opinion?

14:05:35 10 A. No, I did not.

14:05:36 11 Q. Did you consider the fact that the two might have
14:05:41 12 been made using the exact same manufacturing process other
14:05:46 13 than a terminal sterilization step, did you consider that
14:05:51 14 potential connection between Eton's ANDA product and the
14:05:55 15 prior art Sandoz product?

14:05:57 16 A. No, I did not.

14:05:59 17 Q. Okay. Now, have you been watching all the testimony
14:06:04 18 during the trial? Did you get a chance -- I know you were
14:06:10 19 outside the courtroom for a couple of days, but were you
14:06:14 20 able to see all the testimony?

14:06:16 21 A. Yes, to the extent the audio/visual shortcomings
14:06:20 22 allowed me.

14:06:22 23 Q. So I'll just ask you some questions and we'll see if
14:06:26 24 hopefully we're good. Did you see that there has been
14:06:29 25 testimony during this trial that -- about the connection and

14:06:33 1 relationship between the Eton ANDA product and the prior art
14:06:37 2 Sandoz product?

14:06:37 3 A. I saw such testimony.

14:06:39 4 Q. And you have seen evidence put on contending that the
14:06:44 5 Eton ANDA product and the prior art Sandoz product were made
14:06:48 6 using the same ingredients, right, you have seen that?

14:06:51 7 A. I saw testimony to that extent.

14:06:53 8 Q. And you have seen evidence or testimony put on
14:06:56 9 contending that the Eton ANDA product and the prior art
14:07:01 10 Sandoz product are made using the same manufacturing process
14:07:03 11 other than the terminal sterilization step added to the Eton
14:07:10 12 process, did you see that testimony?

14:07:11 13 A. I did see that.

14:07:12 14 Q. Now, if it's found that that testimony is correct,
14:07:19 15 then you haven't considered that situation, in other words,
14:07:23 16 you didn't ever consider the situation where the Eton ANDA
14:07:27 17 product has the same ingredients and the same manufacturing
14:07:32 18 process, other than a terminal sterilization step, as the
14:07:38 19 prior art Sandoz product, you never did that, right?

14:07:41 20 A. No, I did not because to me it's more important what
14:07:45 21 the Sandoz manufacture -- or the Eton manufacturing
14:07:49 22 equipment was and not the manufacturing process.

14:08:18 23 Q. Let me talk about the issue of stability for a
14:08:21 24 second. Now, let me make a couple of things clear so you
14:08:25 25 and I are on the same page. Can we have the '155 patent,

14:08:29 1 claim 27. While it's coming up, let me just ask you the
14:08:39 2 question so you know it's coming. The word stable, that
14:08:44 3 claim term, that only appears in the '155 patent, claim 27,
14:08:50 4 among the asserted claims here; right?

14:08:53 5 A. Yes, that is correct.

14:08:54 6 Q. Okay. Thanks.

14:08:55 7 And that claim doesn't have any recitation about
14:08:58 8 lead or Mercury, right?

14:09:01 9 A. That claim has no reference to lead or Mercury.

14:09:05 10 Q. In the '713 patent, that's claims 8, 9 and 10 where
14:09:11 11 lead and Mercury come in, right, they're recited as
14:09:14 12 elements. Do you remember that? We can put it up if you
14:09:17 13 want, but do you remember it?

14:09:18 14 A. It would be nice to see it, but that is my memory.

14:09:21 15 Q. Sure.

14:09:22 16 A. Thank you.

14:09:23 17 Q. Here we are. We got 8, 9, 10, lead/Mercury, do you
14:09:28 18 see that?

14:09:28 19 A. I confirm that is my memory.

14:09:30 20 Q. And confirm that none of the claim language at issue
14:09:32 21 throughout claim 1 or 8, 9, 10 uses the word "stable,"
14:09:42 22 right?

14:09:43 23 A. The word stable is not used in those claims.

14:09:44 24 Q. Thanks.

14:09:45 25 And we can agree that the word stable is not in

14:09:49 1 the '795 patent asserted claims, either, right?

14:09:54 2 A. I would like to see it up, but I believe that is
14:09:57 3 correct.

14:09:57 4 Q. Let's work off that assumption. Now, the Sandoz
14:10:09 5 product was -- that was administered to patients, there is
14:10:12 6 no real dispute about that, that is throughout the time it
14:10:15 7 was made and sold the Sandoz product was administered to
14:10:19 8 patients?

14:10:19 9 A. Yes, I agree.

14:10:20 10 Q. Thanks.

14:10:21 11 And that Sandoz product had a shelf life of two
14:10:24 12 years, that's what the label says?

14:10:27 13 A. Yes, that is correct. Yes.

14:10:29 14 Q. All right. And so it could be administered to
14:10:32 15 patients for up to two years from the date of manufacture,
14:10:35 16 right, that's what that means?

14:10:36 17 A. Not roughly, exactly.

14:10:38 18 Q. Thank you. Let me say that more clearly.

14:10:40 19 A. I'm sorry.

14:10:42 20 Q. No, no, I appreciate it. Precision is good.

14:10:44 21 What that means, shelf life, is that the product
14:10:47 22 can be administered to patients for up to two years after
14:10:50 23 manufacture date.

14:10:52 24 A. Yes, that is correct.

14:10:54 25 Q. Thanks. Okay.

14:10:58 1 Now, you've heard -- let me confirm something.

14:11:06 2 You have heard during the course of this trial that the Eton

14:11:10 3 ANDA product in its manufacture has a terminal sterilization

14:11:15 4 step, you have heard that, right?

14:11:17 5 A. Yes, I have heard that.

14:11:19 6 Q. Did you know that before the trial?

14:11:20 7 A. No, I did not.

14:11:22 8 Q. A terminal sterilization step, that's after the

14:11:26 9 product is in the vial, it's capped and then you heat it up

14:11:30 10 for a while; right?

14:11:31 11 A. It is essentially the last step in the manufacturing

14:11:35 12 process.

14:11:35 13 Q. I'm just confirming, the product is there in the

14:11:39 14 vial, it's capped?

14:11:40 15 A. Yeah. Yes, it's everything.

14:11:42 16 Q. It's sealed. And that heating for a while is going

14:11:45 17 to increase the rate, generally, generally, heating things

14:11:50 18 increases the rate of chemical reaction, basic chemistry,

14:11:53 19 right?

14:11:54 20 A. Yes, heating generally increases the rate of chemical

14:11:58 21 reaction.

14:11:58 22 Q. And that -- for example, that's why you can mimic

14:12:02 23 long-term stability studies by using higher heat for a

14:12:07 24 shorter term, just as one example of how heat can be used

14:12:12 25 that way?

14:12:11 1 A. That is the reason for the principle of using
14:12:15 2 accelerated testing.

14:12:17 3 Q. That's why Dr. Hofstetter when he was on the stand
14:12:20 4 during Eton's case that he said that the degradedants might
14:12:24 5 increase in the Eton product when you do the terminal
14:12:28 6 sterilization relative to right before you have done it. Do
14:12:32 7 you remember that testimony?

14:12:33 8 A. I do remember that testimony.

14:12:36 9 Q. Okay. And just so we're clear, cystine is a
14:12:40 10 degradation product in this case; right?

14:12:51 11 A. It is.

14:12:52 12 Q. Okay. It degrades from cysteine; right?

14:12:55 13 A. It degrades from cysteine, yes.

14:12:58 14 Q. Thanks.

14:12:58 15 And now you know there is an issue with pyruvic
14:13:01 16 acid in the case, so let me just ask this question
14:13:04 17 carefully.

14:13:04 18 There is a dispute about whether pyruvic acid is
14:13:09 19 in these products at all, but if it is formed, it's formed
14:13:12 20 by degradation from cysteine; right?

14:13:20 21 A. Degradation from which compound?

14:13:24 22 Q. From cysteine.

14:13:25 23 A. From cysteine?

14:13:27 24 Q. Yes.

14:13:27 25 A. Yes.

14:13:28 1 Q. Thanks.

14:13:35 2 Lead and Mercury like aluminum are not

14:13:42 3 degradation products; right?

14:13:44 4 A. No, they are not.

14:13:46 5 Q. They are metals again; right?

14:13:49 6 A. Yes.

14:13:50 7 Q. Okay. Now, one difference, aluminum is an actual

14:13:56 8 ingredient in Type 1 glass used for pharmaceuticals; right?

14:14:02 9 A. Yes, that is correct.

14:14:03 10 Q. And Mercury and lead are not ingredients of Type 1

14:14:08 11 glass, they may be there as some impurity in the glass at

14:14:14 12 some level?

14:14:14 13 A. Yes, Mercury and lead are not intentional

14:14:17 14 ingredients.

14:14:18 15 Q. Thank you.

14:14:19 16 Type 1 glass is a USP listed material; right?

14:14:24 17 A. Yes.

14:14:25 18 Q. And that means that all Type 1 glass no matter who

14:14:30 19 manufactures it has to follow certain levels of quality and

14:14:32 20 consistency; fair?

14:14:32 21 A. In order for a glass to be labeled Type 1 it has to

14:14:42 22 meet the requirements of the USP.

14:14:42 23 Q. Which involves certain levels of quality and various

14:14:51 24 aspects, correct?

14:14:52 25 A. Yes.

14:14:54 1 Q. Thank you.

14:14:55 2 And both Eton in its proposed ANDA product and
14:14:59 3 Sandoz's prior art product, they both use Type 1 glass
14:15:04 4 vials; right?

14:15:05 5 A. Yes.

14:15:05 6 Q. Thanks.

14:15:06 7 Let's talk a little bit more about aluminum
14:15:30 8 leaching because you talked about that for a bit. So you
14:15:35 9 were pointing to a couple of articles that talk about impact
14:15:41 10 of certain factors on aluminum leaching. Right?

14:15:41 11 A. Yes, that is correct.

14:15:48 12 Q. Okay. Let's take a look at some of the articles that
14:15:51 13 you pointed to. You pointed to the Bohrer article. It was
14:16:00 14 PTX 227. If you could pull that up. We're going to go to
14:16:07 15 .4, the fourth page. And you had this, I think it was this
14:16:25 16 chart that has -- it's the second chart down on the left.
14:16:30 17 It's like a graph down on the left. Pardon me as I'm
14:16:34 18 pulling up my copy of this.

14:16:51 19 All right. So what's going on here is you're
14:17:00 20 looking at the ability of cysteine and cystine to leach
14:17:08 21 aluminum from glass; right?

14:17:11 22 A. Among other amino acids, yes.

14:17:14 23 Q. Got it. What you were pointing to is that cysteine
14:17:17 24 and cystine do it high and lysine is low, right?

14:17:22 25 A. Yes, that is correct.

14:17:23 1 Q. And the whole purpose of that bit of testimony was to
14:17:27 2 say that the '337 patent which used lysine is not a big
14:17:32 3 deal, right, it's not leaching the aluminum as much as
14:17:35 4 cysteine or cystine, I take it, is that what you were trying
14:17:38 5 to say?

14:17:39 6 A. That is correct.

14:17:41 7 Q. Okay. But the '337 patent itself -- let me just deal
14:17:44 8 with this now. The '337 patent itself says leaching was a
14:17:48 9 problem; right?

14:17:50 10 A. Yes, it does.

14:17:51 11 Q. Because what was happening was aluminum was reacting
14:17:54 12 with something in the solution and that was causing issues,
14:17:58 13 right?

14:17:59 14 A. Aluminum was reacting with something in solution to
14:18:03 15 produce a particulate.

14:18:05 16 Q. Got it. And so therefore the reason that was
14:18:08 17 happening is because the aluminum wasn't appearing out of
14:18:11 18 nowhere, it was leaching from the glass, the Type 1 glass
14:18:14 19 that they were using; right?

14:18:15 20 A. Yes.

14:18:16 21 Q. And so the solution to the leaching problem according
14:18:21 22 to the '337 patent was what? What did they do?

14:18:22 23 A. I'm sorry?

14:18:24 24 Q. What was their solution that we've all seen?

14:18:25 25 A. Their solution was using a Schott Type 1 glass vial.

14:18:33 1 Q. Type 1 Plus, right?

14:18:35 2 A. Excuse me, among their solutions was using a Schott
14:18:40 3 Type 1 Plus glass vial.

14:18:40 4 Q. I wasn't going through it all again. They got a
14:18:44 5 couple of ideas. They call out the Schott Type 1 Plus
14:18:48 6 coated vial and they have data on that that shows how it
14:18:51 7 stops the leaching, leaching problem; right?

14:18:56 8 A. I guess I would object to your use of the word
14:19:01 9 "stop." I would agree that it reduced the leaching.

14:19:05 10 Q. I can try to change my word in the question. Let's
14:19:08 11 see if we agree.

14:19:09 12 The Schott Type 1 Plus vial reduced the
14:19:12 13 leaching --

14:19:12 14 A. Yes.

14:19:13 15 Q. -- of aluminum from the glass, and there is data in
14:19:18 16 the patent that supports that. Do you remember that?

14:19:20 17 A. Yes.

14:19:21 18 Q. Okay. Now, you looked at another article, another
14:19:24 19 Bohrer article -- do you know Dr. Bohrer?

14:19:30 20 A. I do not.

14:19:32 21 Q. And that's PTX 228. Do we have that? And let's go
14:19:38 22 to what I have is .5. And here again you're talking about
14:19:43 23 the -- so if we pull up that middle block and you're talking
14:20:00 24 about how cysteine, which is the CYS, and cystine, those
14:20:05 25 under whatever conditions they're talking about in this

14:20:19 1 article, they're strong extractors or leachers of aluminum;
14:20:24 2 right?

14:20:25 3 A. Yes.

14:20:26 4 Q. Okay. Got it. Now, you know, there was a highlight
14:20:32 5 on one of your slides, and it went by fast and I don't think
14:20:37 6 you picked it up. Let me try to remind you of it. I'm
14:20:41 7 looking for it right now. Just give me half a second and
14:20:45 8 see if I can find it. No, I can't. But I think we'll get
14:20:54 9 through it.

14:20:55 10 Do you remember there was a quote in one of
14:21:03 11 these articles that says that under -- you were talking
14:21:07 12 about acids and bases, do you remember that, pH and how that
14:21:13 13 affects the leaching. Do you remember that?

14:21:15 14 A. I remember talking about that, yes.

14:21:16 15 Q. There was a quote that you had highlighted that says
14:21:19 16 what happens is that under acidic conditions, what happens
14:21:25 17 is the solvent, the ions in the glass get attacked, the ions
14:21:32 18 in the glass, like aluminum; right?

14:21:34 19 A. Yes, so the name of the process is ion exchange.

14:21:40 20 Q. Okay.

14:21:42 21 A. What it means is that ions in the solution, in this
14:21:45 22 particular case hydrogen ions, the ions that produce the
14:21:52 23 acidity are exchanging with aluminum ions in the glass.

14:21:54 24 Q. That means they're changing because the hydrogen --

14:21:57 25 A. The aluminum goes into the solution and the hydrogen

14:22:00 1 takes it place.

14:22:01 2 Q. Let me get that question out because we spoke over
14:22:04 3 each other. I'm sorry.

14:22:05 4 A. I'm sorry.

14:22:05 5 Q. That's okay. I'll try again.

14:22:07 6 When you said ion exchange, the hydrogen ion is
14:22:12 7 in the glass and in exchange the aluminum solution goes into
14:22:14 8 the glass out of solution?

14:22:16 9 A. Correct.

14:22:17 10 Q. And that tends to happen in acidic conditions, right?

14:22:20 11 A. Yes.

14:22:20 12 Q. Like those here, pH, the cysteine solutions here?

14:22:21 13 A. Yes. Yes. When you say that's what you mean by
14:22:24 14 here, yes, the answer is yes.

14:22:31 15 Q. Got you. Thank you.

14:22:32 16 And then in -- by the way, do you remember where
14:22:34 17 that sentence was? I would love to look at it, but if we
14:22:38 18 can't, I think we can find it later.

14:22:40 19 A. It was in Hernandez-Sanchez.

14:22:42 20 Q. Thanks.

14:22:45 21 A. I'm sorry.

14:22:46 22 Q. No, my fault.

14:22:52 23 And that is something that I can't find. We're
14:23:00 24 going to find it.

14:23:02 25 A. It also shows up in Bohrer as well, but I can't

14:23:10 1 remember where that is.

14:23:12 2 Q. All right. I think it's okay. Let me try to keep
14:23:14 3 working without it. I'll have somebody find that for me,
14:23:18 4 the Hernandez-Sanchez document, we'll go from there.

14:23:21 5 But that sentence continued, there was a second
14:23:24 6 sentence that said under basic conditions, high pH, not
14:23:27 7 what's involved with L-cysteine solutions, what happens
14:23:31 8 instead is that the solution attacks the silicone, or
14:23:37 9 silica, I mean, matrix of the glass. Did I get that right?

14:23:41 10 A. So -- you're right, it attacks the matrix of the
14:23:47 11 glass.

14:23:47 12 Q. All right.

14:23:48 13 A. Glass decomposes.

14:23:50 14 Q. That's basic conditions, and a person of ordinary
14:23:52 15 skill in the art would know that because they know this
14:23:55 16 stuff; right?

14:23:55 17 A. I'm sorry?

14:23:56 18 Q. A person of ordinary skill in the art would know what
14:23:59 19 we have just been talking about?

14:24:00 20 A. They would read it in multiple places in the
14:24:04 21 literature.

14:24:05 22 Q. Thanks.

14:24:06 23 Let's talk about what that means here for this
14:24:09 24 case. Okay? You have a solution that is acidic, right?

14:24:13 25 A. Yes.

14:24:14 1 Q. And it has cysteine and cystine in it, right?

14:24:18 2 A. That is correct.

14:24:19 3 Q. All of which is going to encourage ion exchange or

14:24:24 4 from whatever other mechanism leaching of aluminum from the

14:24:28 5 vial, right, from the glass, right?

14:24:31 6 A. It is.

14:24:31 7 Q. And the way that happens is the solvent is touching

14:24:35 8 the surface of the glass, right, and that's where the

14:24:39 9 leaching happens, right at that surface, correct?

14:24:42 10 A. Yes, leaching cannot happen until there is contact.

14:24:45 11 Q. Right. Exactly. And so if you put between the part

14:24:51 12 of the glass that has aluminum in it and the solution,

14:24:56 13 something that doesn't have aluminum at all, that's going to

14:25:01 14 prevent or reduce the leaching, right, you put a barrier in

14:25:08 15 there, that's how coated vials work, correct?

14:25:11 16 A. That is correct.

14:25:11 17 Q. And it turns out that the coated vial, the Schott

14:25:18 18 Type 1 Plus, that is a pure silicon dioxide coating, right?

14:25:21 19 A. Yes, that is correct.

14:25:23 20 Q. And because if this were basic conditions, the basic

14:25:27 21 solvent might attack that silicon dioxide matrix, right?

14:25:30 22 A. It's not outside the possibility.

14:25:40 23 Q. Okay. According to the article that we're

14:25:44 24 referencing, that could happen; right? The basic conditions

14:25:48 25 could attack the glass matrix, right, silicon dioxide?

14:25:53 1 A. No, the article specifically says that the basic
14:25:56 2 conditions attack the glass, not the coating. It doesn't
14:26:02 3 speak to the coating.

14:26:03 4 Q. That's my point. But when they attack the glasses,
14:26:08 5 they're not leaching the ions out there, they're attaching
14:26:12 6 the glass matrix itself, correct?

14:26:15 7 A. I think you need to ask that a different way.

14:26:21 8 Q. I have the article. I need the quote. My point is
14:26:28 9 this, the issue of leaching in the article was associated
14:26:32 10 with low pH acidic conditions, right?

14:26:36 11 A. That is correct.

14:26:37 12 Q. And the issue of not leaching but of attacking the
14:26:43 13 matrix itself, that was basic conditions; right?

14:26:47 14 A. Yes.

14:26:48 15 Q. So if you put a coating between the solvent and the
14:26:57 16 aluminum including glass, you put a coating in between that
14:27:03 17 just has -- that's just similar to glass, silicon dioxide
14:27:08 18 then the acidic --

14:27:09 19 A. But it's not, it's not similar to glass because it
14:27:12 20 doesn't have the aluminum and the boron in it.

14:27:14 21 Q. It's a quartz is what it is, right?

14:27:17 22 A. Quartz is another name for silicon dioxide, yes.

14:27:21 23 Q. Thanks.

14:27:21 24 But there is nothing in the article that suggest
14:27:23 25 that the acidic conditions are going to attack the quartz,

14:27:28 1 what the acidic conditions do is they extract the ions,
14:27:32 2 right?

14:27:33 3 A. There is nothing in the article that speaks to
14:27:35 4 whether the quartz is broken down by acidic conditions.

14:27:41 5 Q. Okay. Thank you.

14:28:27 6 After all that, I found it. So let me just note
14:28:34 7 for the record, I don't think we need to go through this,
14:28:36 8 but for the record the article was the Hernandez-Sanchez
14:28:42 9 reference that's PTX 152, good memory by you, and it's on
14:28:48 10 152.2. And if you're looking at the page, it's on the
14:28:51 11 right-hand column right at the top. It's really the first
14:28:54 12 full sentence there. So I'm just saying that for the
14:28:58 13 record. We can pull it up. We may as well confirm now that
14:29:01 14 we're looking at it. So the sentence starting with low pH
14:29:04 15 right at the top.

14:29:06 16 A. That is the sentence we have been talking about.

14:29:09 17 Q. Great. Thank you.

14:29:21 18 Now, in the course of your work on this case,
14:29:31 19 you looked at other references about aluminum and glass and
14:29:34 20 so forth; right, not just the ones you saw in your direct
14:29:41 21 testimony, you looked at lots of other information; correct?

14:29:44 22 A. Yes.

14:29:47 23 Q. Okay. And one of the things you looked at was an
14:29:51 24 article by Alberto Biavanti and others, is that right? Do
14:29:54 25 you remember that one?

14:29:59 1 A. I don't recognize the name. I'm sorry.

14:30:01 2 Q. Let me see if we can put it on the screen for you,
14:30:04 3 PTX 267, Plaintiff's Exhibit 267. Does that ring a bell,
14:30:11 4 this article, complex agents and pH influence on chemical
14:30:16 5 durability of Type 1 molded glass containers?

14:30:23 6 A. I am aware of this article, yes.

14:30:25 7 Q. When we look in this article, if we can go to 267.5.
14:30:50 8 Let me pull up this chart on the bottom. Okay. And do you
14:30:57 9 see that this is looking at silicon, really silica release.
14:31:03 10 That SI at the bottom is silicon, right?

14:31:06 11 A. It's elemental silicon.

14:31:09 12 Q. What is actually being measured there is the silica
14:31:12 13 that's being pulled from the glass; right?

14:31:15 14 A. Yes, it is.

14:31:16 15 Q. Okay. And so this article is looking at how certain
14:31:23 16 solvents, certain liquids under certain pHs pull the silica,
14:31:27 17 the silica dioxide out of the glass; right?

14:31:31 18 A. Yes, that is correct.

14:31:32 19 Q. All right. What we see is that the lower the pH, the
14:31:37 20 less silicon -- silicon dioxide extraction there is; right?

14:31:40 21 A. Yes.

14:31:42 22 Q. Okay. Great. And silicon dioxide is the coating on
14:31:50 23 the Schott Type 1 Plus glass?

14:31:52 24 A. Again, I'm sorry, I don't want to correct you always
14:31:55 25 on science. It's silicon, elemental silicon.

14:32:01 1 Q. Thank you. It's measuring, the machine is measuring
14:32:05 2 elemental silicon, right?

14:32:07 3 A. Yes.

14:32:07 4 Q. But what's really coming off the glass is silicon
14:32:10 5 dioxide, right, or silicon dioxide?

14:32:16 6 A. The silicon is released because the glass is
14:32:20 7 decomposing.

14:32:21 8 Q. Thanks. Okay. And the glass, the silicon dioxide is
14:32:25 9 the glass?

14:32:25 10 A. I'm just not willing to go necessarily as far as
14:32:29 11 saying that the actual species in solution is silicon
14:32:33 12 dioxide.

14:32:34 13 Q. Got it. But what's being attacked is silicon
14:32:39 14 dioxide?

14:32:39 15 A. Yes. I'm sorry, I'm answering your question before
14:32:42 16 you ask it.

14:32:43 17 Q. What is being attacked is the silicon dioxide and
14:32:47 18 silicon as a result is in solution?

14:32:48 19 A. Yes.

14:32:50 20 Q. And the point is that as you go lower pH, it happens
14:32:52 21 less and less, right?

14:32:54 22 A. It does.

14:32:55 23 Q. And silicon dioxide is the coating that's the Schott
14:33:01 24 Type 1 Plus vial coating, right?

14:33:02 25 A. It is.

14:33:03 1 Q. And this is something a person of ordinary skill in
14:33:06 2 the art would be familiar with because this is a published
14:33:11 3 article, right?

14:33:12 4 A. But this -- but I'm sorry, again, on an issue of
14:33:15 5 science, this is not silicon leaching from silicon dioxide,
14:33:24 6 it's leaching silicon from glass, which is silicon dioxide
14:33:34 7 amalgamated if you will with both aluminum oxide and boron
14:33:39 8 oxide.

14:33:39 9 Q. That's being attacked to pull the silicon ion?

14:33:42 10 A. Yes, I don't disagree with that.

14:33:44 11 Q. That's silicon dioxide?

14:33:46 12 A. I agree with that.

14:33:47 13 Q. And the lower pH, the less attack on the silicon
14:33:50 14 dioxide, right, according to this chart here in the article?

14:33:53 15 A. Yes, but the chart cut off at pH five-and-a-half.

14:33:56 16 Q. It may goes higher at real low pHs, is that what
14:34:01 17 you're saying?

14:34:01 18 A. It may go higher.

14:34:02 19 Q. But what we can see, the lower pH, the lower -- on
14:34:06 20 this chart, lower pH less attacking of the silicon dioxide?

14:34:12 21 A. Yes, sir. Yes.

14:34:12 22 Q. Now as a legal matter, this is a document that would
14:34:15 23 be known by a person of ordinary skill in the art?

14:34:18 24 A. I'm sorry?

14:34:19 25 Q. This is a document that would be known to a person of

14:34:22 1 ordinary skill in the art?

14:34:24 2 A. Yes.

14:34:25 3 Q. Thank you.

14:35:09 4 I'm not sure if I asked these questions, but I
14:35:19 5 don't think I did, so I'll ask them again. You certainly
14:35:22 6 presumed in this case that a person of ordinary skill in the
14:35:24 7 art would be aware of the Schott Type 1 Plus vial; right?

14:35:32 8 A. No, I do not agree with that.

14:35:34 9 Q. You don't -- you didn't -- you don't think it's a
14:35:38 10 reasonable presumption that a person skilled in the art
14:35:41 11 could become aware of the Schott Type 1 Plus vial?

14:35:45 12 A. Well, that's not exactly the question that you asked.
14:35:49 13 The question you asked, would an expert be aware, and my
14:35:53 14 answer to that is no, because the way that you've -- the way
14:35:57 15 that we've defined an expert doesn't presume that this
14:36:01 16 expert has worked in a situation before where leaching of
14:36:05 17 glass has been important.

14:36:10 18 Q. Let me try again. First of all, you say expert, but
14:36:15 19 what you mean there is a person of ordinary skill in the
14:36:17 20 art?

14:36:18 21 A. Person of ordinary skill in the art, yes. Thank you
14:36:20 22 for correcting me.

14:36:22 23 Q. Thank you. We're a team. Let me ask this again.

14:36:25 24 When you conducted your analysis and put that
14:36:30 25 analysis in your expert report, you presumed that a person

14:36:34 1 skilled in the art would be aware of the Schott Type 1 Plus
14:36:39 2 vials; right?

14:36:44 3 A. No, I did not.

14:36:46 4 Q. Let's take a look at your deposition. Remember I
14:36:49 5 deposed you and did it all under oath? Page 67, lines 1 to
14:36:54 6 9. Full question:

14:37:08 7 "QUESTION: I am asking a more specific
14:37:10 8 question. So if the answer is no or you don't know, that's
14:37:13 9 fine. But I'm asking a more specific question, which is:
14:37:16 10 When you conducted your analysis and put that analysis in
14:37:19 11 your expert report, did you presume that a person of
14:37:22 12 ordinary skill in the art would be aware of the Schott
14:37:25 13 Type 1 Plus vials?

14:37:28 14 "ANSWER: Yes, I presumed that a person skilled
14:37:31 15 in the art would be aware of Schott Type 1 Plus vials."

14:37:34 16 Did I read that right?

14:37:37 17 A. That is my testimony.

14:37:40 18 Q. And you maybe just forgot that here, is that fair?

14:37:43 19 A. Yes.

14:37:46 20 Q. A few more questions on the '337 patent. You agree
14:38:00 21 the drug product that's disclosed in there is a liquid drug
14:38:03 22 product; right?

14:38:06 23 A. I do agree.

14:38:09 24 Q. And aqueous or nonaqueous solvent among other things,
14:38:12 25 right?

14:38:15 1

A. Yes.

14:38:40 2

Q. Let me take a look at this, of the Certificate of Analysis. If we can start with DTX 123. We were talking about this in your direct testimony.

14:38:53 4

14:38:58 5

A. I'm sorry?

14:39:00 6

Q. I'm sorry?

14:39:00 7

A. I'm looking at the certificate, I didn't hear your question.

14:39:03 8

14:39:03 9

Q. I was talking facing away from you. My apologies.

14:39:07 10

You remember looking at this document during your direct testimony?

14:39:09 11

14:39:10 12

A. I do.

14:39:11 13

Q. And when we look at this, this is on the front page that we're looking at now, this is the one month time period in the stability testing?

14:39:14 14

14:39:17 15

14:39:19 16

A. Yes.

14:39:21 17

Q. And at one month, if we look at the appearance of the product, at the top line in the data there, you can just -- thank you. It's clear colorless solution free from visible particulate matter; right?

14:39:24 18

14:39:31 19

14:39:32 20

14:39:32 21

A. That is correct.

14:39:37 22

Q. Okay. And then the next two must be some sort of test, there is no leakage, the next two after that is black or bluish gray precipitate and a red color, those are some testing that are being done?

14:39:42 23

14:39:42 24

14:39:52 25

14:39:54 1 A. Yes.

14:39:54 2 Q. Below that is pH, 1.3, correct?

14:39:57 3 A. That is correct.

14:39:58 4 Q. And then there is upper limit on heavy metals that's

14:40:02 5 there below something. And then -- and that's now that I'm

14:40:07 6 talking about two parts per million, but it's below that,

14:40:10 7 right?

14:40:12 8 A. Yes, the report of heavy metal result is less than

14:40:16 9 two parts per million.

14:40:18 10 Q. When you see it listed like that, less than two parts

14:40:21 11 per million, that's the result, that's the sensitivity of

14:40:24 12 the machine, correct?

14:40:27 13 A. When a result is reported as less than a value, that

14:40:31 14 value usually speaks to the capability of the test.

14:40:34 15 Q. Thank you. Okay. And now down to aluminum content,

14:40:40 16 61 parts per billion. And on the other side, I forget the

14:40:45 17 number, but on the next page -- let's not go there -- is the

14:40:48 18 20 -- let's not go there -- next page is the 24-month study

14:40:51 19 and it has gone higher than the 150 parts per billion limit;

14:41:00 20 correct?

14:41:02 21 A. Yes, the level is higher and it is higher than

14:41:06 22 150 parts per billion.

14:41:09 23 Q. We may as well just get the number. Next page.

14:41:12 24 Okay. It's 296. Okay. Hold that thought. And that's

14:41:15 25 after 24 months of leaching; right?

14:41:20 1 A. That's after 24 months of storage.

14:41:22 2 Q. Storage. And the reason that the aluminum increases

14:41:27 3 over time during storage once the product is in the vial is

14:41:31 4 because of leaching; right?

14:41:32 5 A. It is because of the leaching, yes.

14:41:34 6 Q. At that point, whatever was in from the starting

14:41:37 7 ingredient was already there when it got placed in the vial

14:41:41 8 minute one, right?

14:41:42 9 A. Absolutely. Anything that came in with the drug

14:41:47 10 solution will not increase with time.

14:41:50 11 Q. Okay. Thanks. Let's go back to the first page. We

14:41:55 12 don't need to do anything with it. We're looking at that

14:41:59 13 61 parts per billion number, are you with me?

14:42:00 14 A. Yes.

14:42:01 15 Q. That's below 150, right?

14:42:03 16 A. It is below 150.

14:42:04 17 Q. Less than half, fair?

14:42:07 18 A. It is less than half.

14:42:08 19 Q. Thanks. Okay.

14:42:09 20 And did you ever consider what would happen if

14:42:12 21 instead of putting that same sample in an uncoated Type 1

14:42:20 22 glass vial like Sandoz did, they put it in a coated Schott

14:42:30 23 Type 1 Plus vial, did you ever consider that?

14:42:34 24 A. I can consider that now.

14:42:37 25 Q. We agree that it would decrease the leaching?

14:42:45 1 A. We can agree that it would decrease the leaching.

14:42:48 2 Q. Okay. You probably don't want to try to quantify
14:42:51 3 that, fair?

14:42:52 4 A. I do not.

14:42:53 5 Q. Okay. But what we know is that the way leaching
14:42:57 6 occurs is the solvent, the liquid has to contact where the
14:43:02 7 aluminum ions are, it has to contact that surface, right?

14:43:06 8 A. That is correct.

14:43:06 9 Q. So if you put a barrier in between, it's going to
14:43:10 10 make that difficult, right?

14:43:11 11 A. Yes, it would make it more difficult, that's the
14:43:14 12 purpose of the barrier.

14:43:15 13 Q. Thanks.

14:43:16 14 And you remember the data from the Avadel
14:43:18 15 studies between the Schott Type 1 glass, not coated, and the
14:43:21 16 Type 1 Plus glass which was coated, do you remember looking
14:43:24 17 at that?

14:43:26 18 A. Yes.

14:43:29 19 Q. And the difference over time was substantial;
14:43:32 20 correct?

14:43:33 21 A. The difference between less than five and several
14:43:36 22 hundred.

14:43:37 23 Q. Right. And that's -- it started out less than five
14:43:40 24 in the coated vials for Avadel; right?

14:43:42 25 A. Yes.

14:43:44 1 Q. And it basically stayed there for like six months or
14:43:48 2 even 12 months if I recall, does that sound right?

14:43:51 3 A. Yes.

14:43:52 4 Q. And the uncoated went from whatever it started at up
14:43:56 5 to in the hundreds; right?

14:43:57 6 A. Into the hundreds, yes.

14:43:59 7 Q. So did you ever think about those numbers and what
14:44:04 8 that would do if, for this sample, if it started at 61, did
14:44:10 9 you ever think about that?

14:44:14 10 A. It would not change my opinion that I wouldn't
14:44:19 11 project what would happen to that 61.

14:44:23 12 Q. In other words, you still would not want to quantify
14:44:27 13 anything is what you're saying, right? Is that what I just
14:44:31 14 understood you to say?

14:44:31 15 A. That is correct. I'm sorry if I didn't say that as
14:44:35 16 clearly.

14:44:35 17 Q. That's all right. But my point is you haven't
14:44:39 18 thought about that, you haven't thought about what that
14:44:41 19 number would look like if it had gone into a Schott Type 1
14:44:42 20 Plus glass before right now?

14:44:42 21 A. Before right now.

14:44:52 22 Q. We saw other results in DTX -- ready to go to it,
14:44:52 23 Mr. Patterson, do not need to go to it, DTX 124 and DTX 125
14:45:02 24 were also Certificates of Analysis, do you remember that?

14:45:02 25 A. Yes, I do.

14:45:07 1 Q. And they started below 150 and went up to above 150
14:45:11 2 after 24 months. Do you remember that?

14:45:13 3 A. That is correct.

14:45:13 4 Q. And you hadn't thought about whether putting any of
14:45:16 5 those samples, what would happen if Sandoz had put it in a
14:45:21 6 Schott Type 1 Plus vial instead of a regular Type 1 vial,
14:45:24 7 that's not something you thought about?

14:45:26 8 A. No.

14:45:26 9 Q. You had an exhibit, PTX 194. I wrote the 194 down.
14:45:31 10 I didn't write the P, I'm pretty sure it was PTX 194. This
14:45:31 11 is where you collected a bunch of data?

14:45:41 12 A. Yes, I recognize the exhibit.

14:45:41 13 Q. Okay. And you didn't consider whether if any of
14:45:47 14 those samples had been placed into a Schott Type 1 Plus vial
14:45:51 15 instead of a regular Schott Type 1 vial, that's not
14:45:51 16 something you thought about?

14:45:51 17 A. No.

14:45:51 18 Q. Thanks.

14:46:01 19 Let's talk about vials generally for
14:46:22 20 pharmaceutical products like this if you're going to put
14:46:22 21 something in a vial. Are you with me?

14:46:22 22 A. I am.

14:46:22 23 Q. You heard -- did you hear Mr. Brynjelsen's testimony
14:46:32 24 about that, about how many different types of vials there
14:46:32 25 are, do you remember hearing that?

14:46:37 1 A. Yes.

14:46:39 2 Q. Okay. He's got plenty of experience using vials, you

14:46:42 3 would agree?

14:46:42 4 A. I would agree.

14:46:44 5 Q. All right. And so there are plastic vials and there

14:46:49 6 are glass vials, right?

14:46:50 7 A. Yes.

14:46:51 8 Q. And those constitute the vials that are used in the

14:46:56 9 vast majority of situations for pharmaceutical products like

14:47:00 10 these, right?

14:47:00 11 A. All that I would add to your statement is that among

14:47:03 12 glass vials and among plastic vials there are different

14:47:07 13 types.

14:47:07 14 Q. Thanks. Got it. They all --

14:47:10 15 A. So again, I don't want to appear argumentative, but

14:47:14 16 from a scientific perspective I want to be very clear, the

14:47:20 17 characterization that there are glass and plastic vials is

14:47:23 18 not a hundred percent accurate. There are many types of

14:47:26 19 plastic vials. There are many types of glass vials.

14:47:29 20 Q. Thanks. Understood. And I appreciate that. And I

14:47:32 21 don't think you have been argumentative at all, so I

14:47:35 22 appreciate the clarification.

14:47:38 23 But they fall into those two categories, is that

14:47:42 24 a fair way to put it?

14:47:45 25 A. Yes.

14:47:44 1 Q. Glass can also be divided into two categories,
14:47:48 2 uncoated and coated, is that fair?

14:47:51 3 A. Yes.

14:47:52 4 Q. Okay.

14:47:54 5 A. Glass can also be categorized in terms of type,
14:47:58 6 Type 1 is not the only type of glass, Type 2 glass.

14:48:02 7 Q. How many types are there used for pharmaceutical
14:48:05 8 products like these?

14:48:06 9 A. Used for pharmaceutical products, probably
14:48:11 10 99 percent, 90 percent -- let me back off of that, about
14:48:14 11 90 percent are in Type 1 or Type 2 glass.

14:48:16 12 Q. The vast majority are Type 1?

14:48:19 13 A. Vast majority, yes.

14:48:32 14 Q. And a person of ordinary skill in the art would
14:48:35 15 understand that those are different categories of vials,
14:48:38 16 plastic and glass?

14:48:39 17 A. Yes.

14:48:39 18 Q. And coated and uncoated glass, right, categories?

14:48:45 19 A. As categories, yes.

14:48:49 20 Q. And then there is options underneath each of those
14:48:52 21 categories; right?

14:48:52 22 A. Yes.

14:48:54 23 Q. Thanks.

14:48:55 24 I am going to...

14:49:30 25 THE COURT: Are you just going to leave us

14:49:33 1 hanging there? You are going to?

14:49:36 2 MR. DEVLIN: Thank you, Your Honor. I'm sorry.

14:49:38 3 Thank you for bearing with me.

14:49:43 4 Q. So let me talk about a document that you spoke of.

14:49:52 5 Two documents that you spoke of. And those were the Avadel

14:49:58 6 documents. Do you remember those?

14:50:01 7 A. Did we speak of multiple Avadel documents? I thought
14:50:06 8 there was one.

14:50:07 9 Q. Let me try and be precise here.

14:50:14 10 I think we had PTX 1A and 1B is what I'm

14:50:21 11 referring to. Does that ring a bell?

14:50:27 12 A. Yes.

14:50:28 13 Q. Those were the two documents that you were going

14:50:30 14 through. They may be part of the same larger document; is

14:50:34 15 that right?

14:50:34 16 A. Yes.

14:50:35 17 Q. And we've just separated them into 1A and 1B is all I
14:50:42 18 meant.

14:50:42 19 A. Yes.

14:50:42 20 Q. Let me try and walk through this and I'll skip the

14:50:42 21 things I think we can hopefully skip. You looked at first

14:50:50 22 PTX 1B at page 1.1663 and what you were doing there right at

14:50:52 23 the start was identifying the fact that there were going to

14:51:00 24 be some testing done on the unlined, on an unlined vial,

14:51:00 25 right?

14:51:13 1 A. You know, honestly, I can't remember whether I looked
14:51:17 2 at that first or second. I'm not sure that that's
14:51:20 3 necessarily relevant.

14:51:22 4 Q. Okay. I'm just trying to trace along in the same way
14:51:25 5 and I actually misspoke. So what happened, though, is they
14:51:29 6 did testing of both lined vials and unlined vials
14:51:34 7 side-by-side basically, right?

14:51:37 8 A. They described the purpose of the testing
14:51:41 9 differently, so I am not a hundred percent sure they were
14:51:44 10 side-by-side.

14:51:45 11 Q. Okay. By side-by-side I meant at the same time using
14:51:49 12 the same process; correct?

14:51:50 13 A. One out of two, I'll say using the same process.
14:51:54 14 Again, I can't speak to whether it was the same time.

14:51:58 15 Q. Okay.

14:51:58 16 A. I have serious doubts that it was the same time.

14:52:01 17 Q. Fair enough. Let me be more precise. You agree
14:52:05 18 they're doing tests of their L-cysteine solution made by the
14:52:11 19 same manufacturing process and some of it is going to go
14:52:15 20 into unlined vials and some is going to go into lined vials;
14:52:20 21 right?

14:52:22 22 A. No. Maybe I can help by telling you what I do
14:52:27 23 believe.

14:52:27 24 Q. Go ahead.

14:52:28 25 A. I believe that it's most likely that two batches of

14:52:32 1 the product were produced by the same process, one batch
14:52:36 2 went into unlined vials and one batch went into lined vials.

14:52:42 3 Q. Great. Thank you. Both produced by the same
14:52:45 4 manufacturing process?

14:52:46 5 A. Both produced by the same manufacturing process.

14:52:49 6 Q. And when we're saying lined vials here and unlined,
14:52:54 7 that is the same thing as coated or uncoated, right?

14:52:57 8 A. It is the same.

14:52:58 9 Q. We saw the data that the coated or lined vials, the
14:53:05 10 aluminum stays very low, and then in the unlined vials the
14:53:12 11 aluminum goes up, do you remember that?

14:53:14 12 A. Yes, exactly the way they anticipated.

14:53:17 13 Q. And there was some discussion. And if could go to
14:53:23 14 PTX 1B, please. 1.1656. If we could pull up the heading
14:53:48 15 and paragraph at the bottom, please.

14:53:57 16 This is talking about what they are going to do
14:53:59 17 and what they expect to happen. Do you remember talking
14:54:02 18 about that?

14:54:04 19 A. You know, I'm sorry, can you ask that again, please?

14:54:07 20 Q. Sure. I think you had highlighted in that middle
14:54:12 21 paragraph the second line down that the vials were partially
14:54:14 22 filled. Do you see that? Filled into 10 mL unlined Type 1
14:54:20 23 vials. Right?

14:54:23 24 A. I don't believe we highlighted that. That is a fact
14:54:25 25 that they were partially filled into 10 mL unlined Type 1

14:54:30 1

vials.

14:54:30 2

Q. I'll accept what you think on the highlighting.

14:54:34 3

We're both working off of memory here. It says due to lack

14:54:38 4

of availability, the Type 1 Plus vials at the time?

14:54:41 5

A. Yes, that is correct, that's why they did that.

14:54:44 6

Q. They were using Type 1 Plus already at this time, and

14:54:47 7

they didn't have any available so they decided to fill some

14:54:50 8

with the Type 1?

14:54:53 9

A. Yes, that is reasonable.

14:54:55 10

Q. All right. And then if we could look at the bottom

14:54:59 11

paragraph, it says because of the use of the unlined vials,

14:55:02 12

it was anticipated that the aluminum content levels would

14:55:05 13

exceed the recommended levels. Right?

14:55:09 14

A. Yes, they anticipated that outcome.

14:55:12 15

Q. And that's because they expected -- I think you said

14:55:16 16

this on your direct, they expected what any skilled artisan

14:55:20 17

would expect, aluminum higher in the unlined vials versus

14:55:24 18

the lined vials. Fair?

14:55:28 19

A. Yes.

14:55:32 20

Q. All right. Now, the issue that arose is that the

14:55:36 21

lined vials, the coated vials had precipitates in them it

14:55:40 22

turned out, many of the samples, right?

14:55:44 23

A. Yes, that is correct.

14:55:48 24

Q. And they had to be rejected, right?

14:55:52 25

A. So in this particular case it means they didn't use

14:56:01 1 them in their stability study.

14:56:03 2 Q. Thank you. Okay. And so what they did in then
14:56:11 3 continuing to use the Schott Type 1 Plus vials, they sparged
14:56:16 4 with nitrogen, they added that to their manufacturing
14:56:20 5 process to help lower oxygen levels and prevent the
14:56:23 6 oxidation of the cysteine into cystine; right?

14:56:27 7 A. Yes, that is correct, they put a -- they put back a
14:56:31 8 sparging that they had taken out.

14:56:33 9 Q. Got you.

14:56:36 10 A. And to be clear, that's one of the steps that they
14:56:40 11 took.

14:56:40 12 Q. Right. They did -- they added some hydrochloric acid
14:56:45 13 also if I recall, does that sound right?

14:56:46 14 A. Yes, upon addition of the API they added hydrochloric
14:56:51 15 acid to lower the pH.

14:57:34 16 Q. Now, you pulled up another coat, if could go to, it's
14:57:40 17 the -- it's still in 1B, 1.1674. And the very bottom
14:57:50 18 paragraph. And the last sentence reads, I think you read
14:58:00 19 this, do you remember this, as had been observed in practice
14:58:10 20 and in other studies the apparent kinetics and equilibrium
14:58:12 21 chemistry of the various cysteine and cystine species is
14:58:20 22 complicated and not always predictable in a practical
14:58:24 23 sitting. Do you remember that?

14:58:25 24 A. Yes, you heard me read that.

14:58:27 25 Q. So if we take that quote down, if we just pop up in

14:58:30 1 the same page, in the bullets that are in the middle, the
14:58:37 2 second bullet of the second set of bullets, the second
14:58:42 3 bullet in the second set of bullets. So they did note that
14:58:47 4 samples that were nitrogen sparged did not exhibit cystine
14:58:51 5 precipitation. Right?

14:58:56 6 A. Yes, so after they implemented the nitrogen sparged,
14:59:00 7 they found out that they eliminated the cysteine formation.

14:59:07 8 Q. And they end this little bullet, without oxygen, no
14:59:11 9 cystine forms. Make sense?

14:59:13 10 A. Yes, without oxygen, there was no cysteine.

14:59:17 11 Q. No cystine?

14:59:19 12 A. I'm sorry.

14:59:21 13 Q. Without oxygen there was no cystine formed from
14:59:23 14 cysteine; right?

14:59:24 15 A. Yes.

14:59:29 16 Q. Team work.

14:59:31 17 You've looked at another couple more references
14:59:41 18 that relate to oxidation and so forth, one you mentioned the
14:59:46 19 Butler reference, do you remember that?

14:59:47 20 A. Yes, I do.

14:59:48 21 Q. And that was one that Dr. Baertschi talked about
14:59:51 22 also, right?

14:59:52 23 A. Yes.

14:59:52 24 Q. It was just there briefly and it does say that
14:59:57 25 sparging with nitrogen, that's a common process; right? Do

15:00:02 1 you remember that quote?

15:00:06 2 A. I confirmed that it speaks of nitrogen sparging.

15:00:10 3 Q. Would you agree nitrogen sparging is a common
15:00:13 4 process?

15:00:13 5 A. I would agree with that, yes.

15:00:16 6 Q. All right. And argon sparging is probably used less
15:00:22 7 frequently, fair?

15:00:25 8 A. There is a cost penalty to pay if you use argon.

15:00:28 9 Q. And so it's used less frequently, right?

15:00:31 10 A. I would believe that it would be an option that was
15:00:34 11 used when nitrogen did not work.

15:00:37 12 Q. That's my point exactly, if you tried nitrogen sparge
15:00:40 13 and it didn't work, everyone knows you can try argon sparge,
15:00:43 14 right?

15:00:46 15 Let me rephrase that for you. If you tried
15:00:49 16 nitrogen sparge and it didn't work, a person of ordinary
15:00:52 17 skill in the art would know you can try argon sparge; right?

15:00:55 18 A. Yes.

15:00:58 19 Q. Thanks.

15:01:01 20 We looked at the Waterman reference, you had a
15:01:04 21 quote from there, that's DTX 525. Let's talk about that
15:01:07 22 briefly. And you pulled up a quote from page 027. So DTX
15:01:10 23 525 at 027. You read the summary. Can you pull up that
15:01:13 24 full summary paragraph. And the next to last sentence
15:01:16 25 beginning with in the end, every drug presents a unique

15:01:39 1 situation. That's what you testified about on your direct,
15:01:41 2 right?

15:01:42 3 A. Yes.

15:01:42 4 Q. Right below it, what the Waterman article says is
15:01:48 5 it's hoped that the information will provide rapid, more
15:01:52 6 rapid and efficient handling of oxidation problems with most
15:01:56 7 drug products. Right?

15:01:58 8 A. That's what it says and that's what every author of
15:02:02 9 an article hopes.

15:02:03 10 Q. And we also know that strictly as a truth, every drug
15:02:08 11 presents a unique situation, so authors will say that pretty
15:02:12 12 frequently as well, correct?

15:02:14 13 A. I'm sorry, are you implying that that statement could
15:02:17 14 be used in other circumstances than oxidation? I think it
15:02:23 15 is a fair statement to say that the development of a
15:02:25 16 pharmaceutical product is a difficult process. And that
15:02:29 17 each specific case would represent some challenges.

15:02:31 18 Q. Some of those challenges are more frequently seen
15:02:40 19 than others, right?

15:02:42 20 A. No, I can't agree to that generalization.

15:02:47 21 Q. Every challenge that comes up in pharmaceutical
15:02:52 22 development is equally prevalent with every other challenge,
15:02:56 23 is that what you're saying?

15:02:57 24 A. No, that's not what I'm saying at all.

15:02:59 25 Q. Good. Then we just miscommunicated. What I'm saying

15:03:03 1 is some challenges, some problems arise fairly regularly and
15:03:08 2 other problems are rarer, less frequent?

15:03:11 3 A. I will agree with that.

15:03:12 4 Q. Oxidation is a problem that happens pretty regularly;
15:03:18 5 right?

15:03:25 6 A. Yes, I would agree with that.

15:03:28 7 Q. Thank you.

15:03:29 8 A. Again, I want to make it clear that there are drug
15:03:33 9 substances that are prone to oxidation, but there are
15:03:38 10 hundreds if not thousands of drug products out there that
15:03:43 11 are not prone to oxidation.

15:03:45 12 Q. Thank you.

15:03:48 13 L-cysteine is prone to oxidation?

15:03:51 14 A. Absolutely.

15:03:52 15 Q. And a person of ordinary skill in the art would know
15:03:54 16 that, right?

15:03:55 17 A. Yes.

15:04:41 18 Q. You looked at JTX 13N. Let's pull that up, JTX 13N,
15:04:51 19 just the cover page, please. Thank you.

15:05:10 20 Now, do you remember this document, JTX 13N?

15:05:14 21 A. Yes, I do remember this document.

15:05:16 22 Q. This is the Exela letter to the FDA where they report
15:05:20 23 some results and some plans and then it attaches that Schott
15:05:22 24 Type 1 Plus brochure; right, the data sheet?

15:05:24 25 A. Yes.

15:05:30 1 Q. Thanks.

15:05:30 2 I'm going to walk through a little bit here
15:05:33 3 without getting into too many details. But in this letter
15:05:36 4 -- first of all, you read this whole document as part of
15:05:40 5 your analysis in the case?

15:05:42 6 A. Yes, I did.

15:05:43 7 Q. And you remember that what was happening here was
15:05:46 8 that Exela had -- was trying to reduce aluminum, the FDA
15:05:52 9 said go ahead and reduce aluminum, right, and so they're
15:05:55 10 attempting -- they have attempted to do that using plastic
15:05:58 11 vials at this stage; right?

15:06:02 12 A. Yes, I recognize that the -- a letter speaks to a
15:06:05 13 failed effort of putting -- of developing a formulation in
15:06:10 14 plastic vials.

15:06:15 15 Q. Right. Okay. Thank you.

15:06:18 16 You know, I picked up something that I hadn't --
15:06:21 17 that maybe had slipped my mind. But the FDA was who
15:06:24 18 suggested using plastic vials. Do you remember that, do you
15:06:27 19 remember that from Dr. Koneru's testimony?

15:06:30 20 A. Yes, I do.

15:06:33 21 Q. Okay. So Exela does that, and then they have these
15:06:36 22 results where they're getting particulates and they realize
15:06:39 23 that the argon headspace is escaping and oxygen is going in,
15:06:42 24 they're getting particulates, do you remember all that?

15:06:45 25 A. I do remember all that.

15:06:56 1 Q. And then they tell the FDA their current action plan
15:07:00 2 which is the next page. And you pull up the two paragraphs
15:07:12 3 under current action plan. And the second sentence explains
15:07:19 4 what they're going to do. Therefore, Exela is procuring the
15:07:23 5 specially coated Schott Type 1 Plus glass vials that may
15:07:27 6 prove to be suitable. Do you see that?

15:07:29 7 A. Yes, I do.

15:07:29 8 Q. And then the next paragraph they say that the Schott
15:07:33 9 Type 1 Plus glass expected to be more resistant to leaching
15:07:37 10 of aluminum compared to uncoated vials. Do you see that?

15:07:41 11 A. I do see that.

15:07:41 12 Q. And they cite some data there from the Schott
15:07:44 13 brochure which is just a little lower on the page, it had
15:07:48 14 that little chart, do you remember that?

15:07:49 15 A. Yes, I do.

15:07:51 16 Q. Thanks. We can take that down. Not the whole page.
15:07:55 17 Leave the page up, remove the blow up. Thank you.

15:07:59 18 And the last paragraph it's talking about this
15:08:05 19 data it says there, that's the data from the Schott data
15:08:08 20 sheet, correct?

15:08:09 21 A. It is.

15:08:10 22 Q. Thanks.

15:08:10 23 And it says according to this data, the unfilled
15:08:13 24 vial is expected to contribute approximately three
15:08:17 25 micrograms per liter of aluminum at time zero. Do you see

15:08:21 1 that?

15:08:23 2 A. I see that sentence, yes.

15:08:27 3 Q. Great. Pull that down. Go to the next page, top
15:08:30 4 paragraph.

15:08:31 5 So the summary here is Exela plans to
15:08:43 6 manufacture these batches and they're also going to use a
15:08:47 7 new API, right?

15:08:50 8 A. Yes, they are.

15:08:51 9 Q. Let me back up a second. They had used that new API
15:08:55 10 when they tried the plastic vials and had the problems but
15:08:58 11 they are going to use that same source for the active
15:09:05 12 ingredient now with the Schott Type 1 Plus vials; right?

15:09:11 13 A. I don't remember whether they used the same API or
15:09:19 14 not.

15:09:19 15 Q. Let's just read it here. After --

15:09:22 16 A. I'm sorry, you're exactly right.

15:09:24 17 Q. You see it there?

15:09:25 18 A. I do.

15:09:26 19 Q. Okay. Got it. Thanks.

15:09:27 20 And they're going to use the same stoppers, do
15:09:32 21 you see that on the fourth line, right?

15:09:32 22 A. Yes, I see that.

15:09:34 23 Q. They're going to use the same manufacturing process,
15:09:37 24 other than the change in API, right, that's in the second
15:09:40 25 line?

15:09:41 1 A. Yes. Yes.

15:09:42 2 Q. Okay. And then they're going to submit that data;

15:09:47 3 right?

15:09:49 4 A. Yes, they are.

15:09:50 5 Q. Okay. Now, looking at what we just looked at on this

15:10:01 6 document, do you think that Exela is being dishonest with

15:10:04 7 the FDA at all in that letter?

15:10:09 8 A. I do not.

15:10:12 9 Q. Do you think anything they're saying in that letter

15:10:14 10 is unreasonable?

15:10:21 11 A. I believe that everything they said in that letter

15:10:25 12 with respect to aluminum leaching is reasonable.

15:11:31 13 Q. I want to talk to you about an issue --

15:11:42 14 A. Can you get closer to the microphone? Thank you.

15:11:45 15 Q. Thank you for the reminder. And I'll tell you this

15:11:49 16 is our, I think our last sort of major topic, a little bit

15:11:54 17 of clean up, so we're getting there. Thank you. I want to

15:11:58 18 talk about the post grant review proceedings on the '155

15:12:03 19 patent. Do you remember that?

15:12:06 20 A. Yes, I do.

15:12:07 21 Q. You have read those?

15:12:09 22 A. I'm sorry?

15:12:11 23 Q. That was part of what you analyzed for your opinions?

15:12:14 24 A. Yes, it is.

15:12:15 25 Q. Okay. We saw a little bit of that with

15:12:19 1 Dr. Baertschi. Do you remember that?

15:12:19 2 A. We saw a little bit of that with Dr. Baertschi.

15:12:22 3 Q. I want to go through it in a little more detail what
15:12:27 4 happened. So if we can pull up DTX 2 -- sorry, PTX 231.
15:12:46 5 This was one of the documents that came up. You remember
15:12:50 6 that what happened was there was a post grant review
15:12:54 7 requested on the -- I'm sorry, I went to the wrong one
15:13:00 8 first. I should be going to -- apologies, 226. 226 is the
15:13:17 9 '453 patent. Do you see that in the middle, right in the
15:13:19 10 middle?

15:13:19 11 A. Yes, I do see that. I'm sorry.

15:13:21 12 Q. No problem. I know it's hard to find. I'm just
15:13:24 13 trying to save us time without pulling it all up. The other
15:13:29 14 one that we'll look at in a second, that was the '155?
15:13:32 15 You're nodding.

15:13:33 16 A. Yes, I'm sorry.

15:13:34 17 Q. Let look at this 226. And first I want to talk
15:13:40 18 through the grounds. Let's go to page 6?

15:13:42 19 MS. FLANAGAN: Your Honor, objection. This is
15:13:44 20 outside the scope of the direct examination.

15:13:46 21 MR. DEVLIN: Dr. Baertschi, the same thing with
15:13:49 22 Dr. Baertschi, he didn't say anything about post grant
15:13:52 23 review. They went all into it. I'm doing the same thing
15:13:55 24 here.

15:13:56 25 THE COURT: Did you object?

15:13:56 1 MS. FLANAGAN: I was going to say they didn't
15:13:58 2 object, I did.

15:14:00 3 MR. DEVLIN: It feels like a waiver. Okay.
15:14:02 4 Here is the thing, he has a validity opinion.

15:14:11 5 BY MR. DEVLIN:

15:14:11 6 Q. Is your opinion in part based on your review of those
15:14:15 7 post grant review proceedings or did you ignore them?

15:14:23 8 A. Based in part.

15:14:25 9 MR. DEVLIN: May I proceed? It underlies his
15:14:29 10 whole opinion.

15:14:31 11 THE WITNESS: No, I'm sorry, I wouldn't say
15:14:33 12 that, sir.

15:14:36 13 THE COURT: You're going to go through like
15:14:39 14 specific -- you're going to go through specific parts of
15:14:42 15 these. He's just saying he read them, and you know,
15:14:45 16 consider them as part of his opinion, not that when you look
15:14:48 17 at page 6 and there are three grounds there that those are
15:14:51 18 what he considered. So I don't think it's fair to say
15:14:54 19 underlies his whole opinion.

15:15:01 20 MS. FLANAGAN: That's consistent with his report
15:15:04 21 which has two paragraphs that mention the post grant review.

15:15:07 22 THE COURT: What's the plan here?

15:15:09 23 MR. DEVLIN: These are in evidence, right?

15:15:12 24 THE COURT: Yes.

15:15:15 25 MR. DEVLIN: We'll do it on briefing.

15:15:18 1 THE COURT: You can make any argument you want.
15:15:21 2 I don't think you have to make it through a witness who
15:15:23 3 didn't opine or didn't testify about it.

15:15:25 4 MR. DEVLIN: We'll do it on briefing. Thank
15:15:27 5 you, Your Honor.

15:15:29 6 THE COURT: You're welcome, sir. I saved you
15:15:32 7 going through that.

15:15:33 8 THE WITNESS: I certainly appreciate it, Your
15:15:33 9 Honor.

15:15:33 10 BY MR. DEVLIN:

15:15:37 11 Q. For the record, the you're welcome is not back at me,
15:15:40 12 it was toward the witness, you appreciate it. Let's talk
15:15:45 13 about a little couple of last issues, the objective indicia
15:15:50 14 and a little on the claim. Remember the objective indicia,
15:15:53 15 the long felt need? And you point to Dr. Kuhn's testimony
15:16:00 16 and -- is it fair to say that's what you're mainly relying
15:16:04 17 on in support of your long felt need evaluation here?

15:16:08 18 A. No, as a matter of fact, I felt that there was
15:16:11 19 adequate evidence of a long felt need without hearing
15:16:14 20 Dr. Kuhn's testimony.

15:16:18 21 Q. Okay. I'll go through both. So Dr. Kuhn, you heard
15:16:19 22 his testimony when he did his long felt need analysis, what
15:16:22 23 he looked at were -- what he considered was the 5,000 parts
15:16:24 24 per billion on the label of the Sandoz product; right?

15:16:32 25 A. Yes.

15:16:41 1

Q. Thanks.

15:16:42 2

A. That's fine.

15:16:43 3

Q. All right. And the articles you looked at also were evaluating the Sandoz, the label -- if they told you about the Sandoz product at all, it was looking at the label of 5,000 parts per billion for aluminum; right?

15:16:46 4

15:16:52 5

15:16:55 6

15:17:00 7

A. Well, but the long-term unmet need has nothing to do with what is labeled, it's the fact that the product contained inappropriately high level of aluminum.

15:17:04 8

15:17:08 9

15:17:13 10

Q. Let me ask it this way. So when you considered long-felt need, did you consider the difference between the Sandoz product aluminum levels versus the claim or did you consider the difference between the Sandoz label and the claim?

15:17:17 11

15:17:23 12

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15:17:34 14

15:17:40 15

A. Yes.

15:17:40 16

Q. Which one, the label?

15:17:43 17

A. I considered the -- I considered -- yes, the levels that were indicated by the label.

15:17:48 18

15:17:50 19

Q. Okay. Thank you. Do you remember talking about reasonable expectation of success?

15:18:11 20

15:18:14 21

A. I do indeed.

15:18:15 22

Q. And I think you said that you never saw any evidence of anyone using a Schott Type 1 Plus vial with an L-cysteine product. Did I get that right?

15:18:18 23

15:18:25 24

15:18:28 25

A. Yes, I did say that.

15:18:30 1 Q. Okay. But before you said that, you talked about the
15:18:33 2 Avadel NDA which used a Schott Type 1 Plus vial with an
15:18:39 3 L-cysteine product; right?

15:18:41 4 A. Yes, that's correct.

15:18:43 5 Q. All right. Did you ever consider in your opinions
15:18:45 6 regarding obviousness the fact that two different sets of
15:18:49 7 people came up with the idea of using a Schott Type 1 Plus
15:18:53 8 vial with an L-cysteine solution independently around the
15:18:58 9 same time, did you ever consider that?

15:19:03 10 A. I considered it to be an interesting coincidence.

15:19:07 11 Q. Did you consider it relevant to your obviousness
15:19:10 12 opinions?

15:19:12 13 A. Yes.

15:19:14 14 Q. Okay. How so?

15:19:16 15 A. That I considered it to be an interesting
15:19:18 16 coincidence.

15:19:19 17 Q. That was it?

15:19:20 18 A. Yes.

15:19:21 19 Q. Did you think that it was evidence of the obviousness
15:19:24 20 of the idea, the fact that --

15:19:26 21 A. No, I considered it to be evidence of the unmet need.

15:19:30 22 Q. Okay. So -- great.

15:19:32 23 A. In fact, I'm surprised that more people weren't
15:19:35 24 developing drug products that filled that unmet need.

15:19:37 25 Q. Let me try to get that question out so I can

15:19:42 1 understand what you're saying.

15:19:43 2 A. I'm sorry.

15:19:44 3 Q. No, that's all right. We're close to the end so
15:19:50 4 we're both rushing. Let me be precise and we'll get there
15:19:54 5 sooner I think.

15:19:55 6 So when you considered the fact that these two
15:19:58 7 independent groups of people came up with the idea of using
15:20:02 8 the Schott Type 1 Plus vial with an L-cysteine product
15:20:06 9 around the same time, you thought that supported the unmet
15:20:12 10 need factor for objective indicia, right?

15:20:17 11 A. Yes.

15:20:18 12 Q. Did you think that that fact, that circumstance that
15:20:23 13 we're talking about, these two groups doing it around the
15:20:26 14 same time, that that might be evidence that the claims were
15:20:31 15 obvious, did you think about that?

15:20:33 16 A. I did not.

15:20:34 17 Q. And I just want to pull up claims 8, 9 and 10 of the
15:20:41 18 '713. We are very close. I just want to confirm something.
15:20:44 19 Actually I want to pull up the full set together with the
15:20:52 20 independent claims. Let me tell you what I'm getting at
15:21:00 21 because I think we can talk while that's happening.

15:21:03 22 So is it fair to say that the question of
15:21:10 23 nonobviousness to which your opinion relates are the
15:21:17 24 aluminum and the cystine elements of claim 1; is that right?
15:21:23 25 Did I understand you?

15:21:25 1 A. No, they also deal with the lead and Mercury, claims
15:21:30 2 8 and 9.

15:21:32 3 Q. Okay. Let me -- all right.

15:21:34 4 I may have misunderstood you. Let me see if I
15:21:43 5 can try it again, and if I did misunderstand you, that's
15:21:47 6 okay. But right, you're saying claims 8, 9 and 10 are
15:21:51 7 obvious, also, correct?

15:21:53 8 A. No. As a matter of fact, I'm saying exactly the
15:21:57 9 opposite.

15:21:59 10 THE COURT: He just said, he said they were
15:22:01 11 obvious. He was listening carefully and said no, I didn't
15:22:05 12 say they were obvious, I said they were not obvious.

15:22:11 13 Q. I'm sorry.

15:22:12 14 A. If my entire argument is that the --

15:22:15 15 Q. I'm sorry.

15:22:15 16 A. If it's not obvious, then.

15:22:19 17 Q. I apologize, I got that completely wrong and didn't
15:22:21 18 even realize what the Judge was saying. Your opinion is 8,
15:22:24 19 9 and 10 are not obvious?

15:22:27 20 A. Yes, that is correct.

15:22:29 21 THE COURT: And just so you don't worry, that's
15:22:31 22 been clear.

15:22:32 23 THE WITNESS: I'm sorry.

15:22:34 24 THE COURT: That was clear that that was your
15:22:35 25 opinion. Mr. Devlin had a little answer fall out.

Jenke - redirect

15:22:40 1 MR. DEVLIN: Absolutely.

15:22:41 2 THE WITNESS: Thank God I'm not the only one
15:22:43 3 that has that.

15:22:45 4 Q. So you do have an opinion that those claims are not
15:22:48 5 obvious, right?

15:22:49 6 A. I do have that opinion.

15:22:51 7 Q. Okay. And the opinion, though, that the analysis is
15:22:54 8 centered on the aluminum and cystine elements, did I
15:22:58 9 understand you correctly from your direct testimony?

15:23:04 10 A. I believe those are the primary considerations, yes.

15:23:18 11 MR. DEVLIN: Okay. Thank you.

15:23:18 12 Your Honor, I have some exhibits to move in. I
15:23:21 13 think they can wait until after redirect.

15:23:24 14 Nothing further, Your Honor. Thank you.

15:23:26 15 Thank you, Doctor.

15:23:26 16 THE COURT: Thank you. Redirect.

15:23:30 17 REDIRECT EXAMINATION

15:23:31 18 BY MS. FLANAGAN:

15:23:40 19 Q. It might go faster if I put things underneath the
15:23:51 20 Elmo so we'll see.

15:24:00 21 Dr. Jenke, do you remember being asked questions
15:24:07 22 about DTX 486, the Sandoz Canada Certificate of Analysis?

15:24:12 23 A. I do.

15:24:14 24 Q. And let me zoom in.

15:24:20 25 Does this Certificate of Analysis of DTX 486

15:24:28 1 relate to a pharmacy bulk packaging configuration of the
15:24:33 2 Sandoz product?

15:24:34 3 A. No, it does not.

15:24:35 4 Q. What size configuration does it relate to?

15:24:37 5 A. It is a 10 mL size.

15:24:49 6 Q. Is this the only Sandoz Canada Certificate of
15:24:54 7 Analysis you considered in forming your opinions in this
15:24:56 8 case?

15:24:56 9 A. It is not.

15:24:57 10 Q. And did you prepare a summary table of all of them
15:25:00 11 for your report like you did for the Allergy Labs
15:25:04 12 Certificates of Analysis?

15:25:05 13 A. Yes, I did.

15:25:10 14 Q. I have in front of me PTX 195. Do you recognize this
15:25:14 15 as the summary table of the Sandoz Canada --

15:25:18 16 A. I recognize it as a summary table.

15:25:19 17 Q. If we flip through it, we've got pages and pages;
15:25:24 18 correct?

15:25:25 19 A. Yes, it is a multipage summary.

15:25:28 20 Q. And I have a demonstrative showing that, that's PDX
15:25:32 21 513. This is pages 2 through 7 of PTX 195; correct? You
15:25:36 22 looked at all of these, sir, didn't you?

15:25:40 23 A. Yes, I looked at all of them, even though I can't
15:25:44 24 read them right now.

15:25:48 25 Q. I just want to call up one example and ask a couple

of questions. Here is ones that I pulled out. What is the aluminum level in lot number GT 7518?

A. At seven months it was 580 parts per billion.

Q. And that's a different value than we saw at the 150 parts per billion for the Certificate of Analysis you looked at on your cross-examination; right?

A. 150 is not 580.

Q. And did you see a lot of variability amongst the Certificates of Analysis for the Sandoz Canada product and report those in your summary exhibit?

A. Yes, there was variability in the assay results.

MS. FLANAGAN: Thank you, Dr. Jenke.

I am going to move in some exhibits now. PTX 194. PTX 195. We have JTX 4, the '713 patent that hasn't yet be admitted. PTX 227. PTX 228. PTX 271. PTX 1A. PTX 1B. And from yesterday, PTX 226.

MR. DEVLIN: No objection, Your Honor. And we would move in DTX 486 and PTX 226.

MS. FLANAGAN: No objection.

THE COURT: All right. Those are all admitted. Dr. Jenke, you are excused. Thank you very much.

THE WITNESS: Thank you.

THE COURT: I can't believe we just put one of the patents in at the very end of all the evidence.

Okay. Where are we?

15:34:32 1 given to the Court on April 15th?

15:34:34 2 THE COURT: Or even after April 15th if you want
15:34:36 3 to finish your briefs, get them to the people and, you know,
15:34:41 4 some time in the following week get them to us, that's fine.

15:34:44 5 MR. DEVLIN: Thank you, Your Honor.

15:34:45 6 THE COURT: All right. Anything else?

15:34:46 7 MS. DRAKULICH: No, Your Honor. Thank you.

15:34:47 8 THE COURT: All right. That was a very
15:34:49 9 interesting trial. Excellent presentations, really good.
15:34:53 10 And I do appreciate that. I know I was a little hard on you
15:34:56 11 guys sometimes. I'm just cranky sometimes, but it was not
15:35:00 12 because they were not excellent presentations.

15:35:02 13 MR. DEVLIN: Thank you, Your Honor.

15:35:03 14 THE COURT: All right. Thank you.

15 (Court adjourned at 3:35 p.m.)

16
17 I hereby certify the foregoing is a true and
18 accurate transcript from my stenographic notes in the proceeding.

19 /s/ Dale C. Hawkins
20 Official Court Reporter
21 U.S. District Court
22
23
24
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<p>'155 [22] - 531:3, 532:1, 537:10, 542:13, 545:5, 562:1, 576:7, 576:10, 576:17, 578:22, 580:2, 580:5, 582:3, 612:17, 621:1, 621:3, 621:12, 628:25, 629:3, 668:18, 669:14, 681:18</p> <p>'337 [24] - 588:18, 588:21, 592:12, 592:18, 606:15, 607:19, 608:8, 608:16, 608:20, 608:22, 609:4, 611:20, 612:2, 612:15, 612:24, 613:11, 613:24, 614:18, 635:2, 635:7, 635:8, 635:22, 647:20</p> <p>'453 [1] - 669:9</p> <p>'713 [23] - 523:12, 523:17, 523:18, 525:2, 525:8, 525:24, 526:23, 530:24, 531:14, 546:17, 580:2, 580:14, 580:16, 580:19, 581:13, 582:4, 613:16, 613:25, 614:5, 614:17, 629:10, 674:18, 678:14</p> <p>'719 [1] - 620:24</p> <p>'795 [14] - 523:11, 530:25, 531:15, 531:17, 531:18, 580:2, 580:6, 580:9, 581:22, 582:4, 612:21, 612:25, 613:4, 630:1</p>	<p>1 [97] - 523:12, 523:17, 525:2, 525:16, 525:17, 525:24, 526:5, 526:6, 530:24, 531:14, 538:13, 560:21, 562:23, 571:23, 580:6, 580:14, 580:17, 581:22, 582:4, 583:4, 591:25, 594:25, 595:1, 596:7, 597:22, 597:24, 598:2, 600:7, 601:9, 601:10, 601:15, 602:11, 606:21, 608:23, 609:24, 611:7, 612:20, 612:25, 613:5, 613:16, 613:25, 614:8, 614:13, 615:4, 615:7, 615:11, 615:17, 629:21, 633:8, 633:10, 633:16, 633:18, 633:21, 634:3, 635:18, 635:25, 636:1, 636:3, 636:5, 636:12, 640:18, 643:5, 643:23, 644:24, 646:7, 646:11, 647:1, 647:5, 647:13, 647:15, 650:21, 650:23, 651:15, 651:16, 652:19, 653:6, 653:14, 653:15, 655:6, 655:11, 655:12, 658:22, 658:25, 659:4, 659:6, 659:8, 660:3, 664:24, 666:5, 666:9, 667:12, 672:23, 673:2, 673:7, 674:8, 674:24</p> <p>1.1656 [1] - 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