IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant	)	C.A. No. 21-691-GBW
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	)	C.A. No. 21-1138-GBW
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	)	C.A. No. 21-1594-GBW

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Wilmington, Delaware
Wednesday, February 28, 2024
Trial Day 3

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BEFORE: HONORABLE GREGORY B. WILLIAMS
UNITED STATES DISTRICT COURT JUDGE

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APPEARANCES:

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-and-

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P R O C E E D I N G S

(REPORTER'S NOTE: The following jury trial was held in Courtroom 6B beginning at 8:45 a.m.)

THE COURT: Good morning. You may be seated.

All right. So I have reviewed the parties' joint submissions. Let's deal with these objections first.

With respect to Jazz's objections to Avadel's demonstratives DDX-WC 0002, 0.004, 0.089, this objection is sustained in part and overruled in part.

So, you know, an expert can't testify as to laws. The Court's role is to instruct the jury on the law. The expert can testify as to what standard he applied in reaching his opinions. So I think there was a question yesterday with the damages expert, with Jazz's damages expert that, you know, I thought was appropriate. It didn't cross the line. The difference here is that you got slides. So I'm not going to allow the slides, but the expert can testify as to what standard he applied.

MS. DURIE: Understood.

THE COURT: All right. Second objection has to do with JTX0217 and DTX0044. And this goes to Jazz's making

objections claiming under 401, 403 -- mainly 403, claiming that it's not relevant to enablement because it's unclaimed formulation. So what Jazz didn't address is Avadel's argument about relevancy on inventorship, and that's the one -- that's where I see it's relevant to. And that *Coda* case was instructive on that issue.

So with respect to that objection, I'm going to overrule it because I think the evidence is relevant at least in part -- the evidence is relevant at least to inventorship.

And then my understanding is that Avadel has withdrawn its objections with respect to Dr. Greenblatt, so that's off the table.

MS. DURIE: Yes, Your Honor.

THE COURT: All right. So that deals with the objections.

Time: Yesterday Jazz used 4 hours and 59 minutes, so Jazz has used a total of 8 hours and 4 minutes. Avadel used 1 hour and 31 minutes yesterday, so Avadel has used a total of 4 hours and 33 minutes.

Jazz has 4 hours and 26 minutes remaining. Avadel has 7 hours and 57 minutes remaining.

Please, both sides, keep in mind, leave time for your closings.

MS. DURIE: May I address a housekeeping matter?

THE COURT: I'm sorry?

MS. DURIE: Sorry. Just I had a housekeeping matter that I wanted to address.

THE COURT: Yes, yes. Any update on your witness?

MS. DURIE: Yes. It appears that she is unlikely to be able to testify. We had been hoping that she would feel well enough to be able to testify via Zoom. That is looking unlikely. It's not off the table, but it is just -- complete candor to the Court, it is looking unlikely, and we are going to make a decision today about what we're going to do in light of that. And we will update the Court later today, and I have told counsel that.

THE COURT: All right.

MS. DURIE: I have one purely administrative matter. There are three exhibit numbers that we need to correct on the transcript. I have conferred with counsel. DTX1554 should be DTX1454. JTX26411 should be JTX264.11. And PTX360 should be PTX0060.

THE COURT: All right.

MS. DURIE: There is one other issue that I wanted to raise. Your Honor had reserved yesterday on objections to certain portions of Mr. Bura's designations.

THE COURT: Right. I thought Mr. Calvosa had gotten up and said -- I remember you withdraw at least some

of them. I thought you were withdrawing all of them --

MR. CALVOSA: I withdraw with respect to a different issue where there was the question of --

THE COURT: Okay.

MR. CALVOSA: -- asking the witness about enablement, but not to --

THE COURT: All right. So I still need to rule on that one that I had -- I had reserved.

MR. CALVOSA: Yes.

THE COURT: I remember the first one I had set aside.

MS. DURIE: Right. So we may -- we may wind up playing that testimony other than in the order in which we had disclosed it.

THE COURT: Okay.

MS. DURIE: And we do intend to play that in our case, and I don't know how time is going to go today, but...

THE COURT: All right. All right. So I will rule on that before we bring the jury back in.

MS. DURIE: Perfect. I would -- we would appreciate that.

Final issue before we bring the jury in, I understand that what's going to happen is the first thing is Plaintiff rests. We have a Rule 50(a) motion. I thought it might make sense to just deal with this off the record

before the jury comes in so that the first thing that happens isn't them resting and my standing up and saying, I have a Rule 50 motion, and we can just put it on the record now.

THE COURT: Okay. That's fine.

Is Jazz fine with that?

MR. CERRITO: That seems reasonable, Your Honor.

THE COURT: Okay.

MS. DURIE: Okay. So, Your Honor, just for the record, pursuant to Federal Rule of Civil Procedure 50(a), defendant Avadel CNS Pharmaceuticals, LLC, respectfully requests that the Court grant judgment as a matter of law. Jazz has been fully heard on the issues of direct infringement and damages and has failed to meet its burden. Because there's no legally sufficient evidentiary basis for a reasonable jury to find for Jazz on these issues, the Court should grant judgment as a matter of law. Judgment as a matter of law is appropriate, when, quote, "a party has been fully heard on an issue during a jury trial and a court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue," closed quote. F.R.C.P 50(a)(1).

When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law or when indisputable record facts contradict or otherwise

render the opinion unreasonable, it cannot support a jury's verdict. *Brooke Group Limited v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 242 (1993).* Defendant Avadel moves for judgment as a matter of law on direct infringement of Claims 7 and 11 of the '488 patent. Jazz has failed to present evidence that would allow a reasonable juror to conclude that the accused Lumryz product literally infringes either Claims 7 or 11 of the '488 patent.

Instead, the evidence confirms that Lumryz lacks a core comprising at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate, as required by the asserted Claims 7 and 11 of the '488 patent.

In particular, the evidence unequivocally established that Lumryz comprises an inert or neutral core that does not contain GHB or any other drug.

In addition, Lumryz does not exhibit a sustained-release dissolution profile as required by the claims when tested in a Dissolution Apparatus 2 in deionized water at a temperature of 37 degrees and a paddle speed of 50 rpm.

Avadel also moves for judgment as a matter of law on the issue of damages. Jazz has not offered a legally sufficient evidentiary basis for the jury to accept the

royalty identified by Jazz's expert or established the royalty rate it seeks is reliable and supported by tangible evidence. In reaching his proposed royalty rate, Jazz's damages expert failed to properly apportion damages between the patents-in-suit and unrelated Jazz patents and between the patents-in-suit and Avadel's contribution.

For the reasons set forth, Avadel requests the Court enter judgment as a matter of law on the issues of infringement and damages.

THE COURT: All right. Let me hear from Jazz.

MR. CERRITO: Good morning, Your Honor.

Obviously Jazz opposes the motion. On the issue of the infringement with regard to the two claim elements that are still remaining, the core and the DI water dissolution profile, the Court and the jury heard substantial evidence, if not dispositive evidence, of infringement of both of those elements. Remind the Court that all other elements are admitted to the Court, so only those two outstanding.

With regard to the core issue, Dr. Little presented significant evidence. The patent -- the '062 patent of Avadel's discloses in tables 1a and 1b exactly the structure of the product and exactly the fact that the core exists from the IR microparticles and the modified-release particles. He also walked the Court and the jury through

the SEC filing where both the structures of the core is described in Legrand and the Micropump technology that Defendants are relying upon, where both those structures were disclosed to the United States Securities and Exchange Commission.

With regard to the testimony that you heard from Mr. Vaughn, Avadel's 30(b)(6) witness, he admitted that. He admitted infringement. I am going to quote from you the --

"Question: The core of the MR microparticles is the IR microparticles? That's what Avadel told the patent office in the '616 application that led to the patent-in-suit, the patent that we have been talking about?

"ANSWER: That's what it says, yes."

That's an admission.

Along with the actual admissions from -- that we read into the record with Dr. Little, those three provide substantial evidence of infringement, if not dispositive evidence of infringement, but certainly at least enough evidence that it can be sent to the trier of fact.

With regard to the DI water limitation, Dr. Little provided substantial testimony in evidence. He walked through the patents and showed where all that information concerning the DI water testing profile existed in their patent. Dr. Guillard testified that he had done three tests in DI water, averaged that information --

averaged the numbers out, and also presented it in their patent. That's an admission.

A reasonable jury could find for Plaintiffs on all counts.

With regard to damages, which is obviously unopposed, he provided -- Dr. Rainey provided sufficiently legal basis to establish -- for his theory. He did apportion and said any one of the claims could justify the reasonable royalty, so that is an apportionment and provided sufficiently legal basis for the jury to find on behalf of the plaintiff; therefore, we oppose.

THE COURT: All right. Let me take a short recess to collect my thoughts on these issues.

(Recess taken.)

THE COURT: All right. Be seated.

First, I'm going to deal with the JMOL motions, Rule 50 motions.

Avadel claims -- Avadel is moving for judgment as a matter of law under Federal Rules of Civil Procedure 50 on two bases: First, Avadel claims that there is not sufficient legal basis for a reasonable jury to find for Jazz on the issue of direct infringement.

Second, Avadel claims that there is not sufficient legal basis for a reasonable juror to find for Jazz on the issue of damages.

With respect to Avadel's motion for judgment as a matter of law on direct infringement, Avadel claims that Jazz has failed to present sufficient evidence for a reasonable jury to find in Jazz's favor on direct infringement of Claim 7 and Claim 11 of the '488 patent. Avadel claims that there is sufficient evidence that Lumryz meets -- or has satisfied the core limitation and/or the deionized water limitation.

Jazz responds that there has been sufficient evidence presented that Lumryz meets the core limitation and the deionized water limitation for a reasonable jury to find in favor of Jazz on direct infringement of Claims 7 and 11 of the '488 patent, including, Jazz points to, testimony of Dr. Steven Little, admissions by Avadel in this action, testimony by Dr. Guillard, and other purported evidence.

Thus viewing the evidence in the light most favorable to Jazz as the nonmoving party and giving Jazz the benefit of all reasonable inferences, the Court finds there is sufficient evidence of record to support a jury verdict in favor of Jazz on direct infringement. There are material issues of fact that have to be resolved by the jury with respect to the core limitation and the deionized water limitation and other issues on the claim.

With respect to Avadel's motion for judgment as a matter of law on damages, Avadel claims that Jazz has not

offered a legally sufficient evidentiary basis for a jury to accept the royalty identified by Jazz's damage's expert, Dr. Rainey, or that the royalty rate that Jazz seeks is reliable and supported by tangible evidence, and that Dr. Rainey, Jazz's expert, failed to apportion damages between the patents-in-suit and Jazz's unrelated patents. And failed to account for or apportion Avadel's contributions to the patents-in-suit.

Jazz responds that Dr. Rainey did provide a sufficient legal basis to support his damages theory, including his opinion on the reasonable royalty, and did properly apportion because he testified that any one of the claims could justify the reasonable royalty.

Having considered the parties' motion and response, and viewing the evidence in the light most favorable to Jazz as the nonmoving party and giving Jazz, as the nonmovant, the benefit of all reasonable inferences, there is sufficient evidence of record to support a jury verdict in favor of Jazz on the issue of damages.

Again, there are material issues of fact that remain for the jury to decide. For those reasons, the Court hereby denies Avadel's JMOL motions on direct infringement and damages.

Moving on to the issue of -- going back to the issue of the objection, Jazz's objection to the designations

of Scott Bura, on pages 65, lines 22-23; page 66, line 3; and page 115, lines 2-10, Mr. Bura -- I read the transcript and I see that Mr. Calvosa stressed that Mr. Bura was not testifying as a 30(b)(6) witness and is testifying in his personal capacity.

Thus, the questions asked of him, the first question, "Did you take any action to attempt to stop Jazz from copying the Avadel claims," and his answer, "I did not" -- although there was an objection to lack of foundation, since he was testifying in his personal capacity, he knows whether or not he took any action, he has personal knowledge. Thus, the objection is overruled.

Same with respect to line 15, lines 2-10. So overruled.

All right. So we've dealt with the issues. Let's get the jury.

(Whereupon, the jury entered the room.)

THE COURT: Ladies and gentlemen of the jury, good morning. Sorry for the delay. The Court had to deal with some issues before we brought you in.

MR. CERRITO: Good morning, Your Honor.

Plaintiffs rest their case.

THE COURT: All right. Plaintiff has rested its case. Next we go to defendant Avadel's case.

MR. BRAUSA: Good morning, Your Honor. Good

morning. Adam Brausa for Avadel.

As our first witness, we call Dr. Bruce Corser to the stand.

THE COURT: Dr. Corser, please take the stand.

BRUCE CORSER, having been called on the part and behalf of the Defendant as a witness, having first affirmed to tell the truth, testified as follows:

DIRECT EXAMINATION

BY MR. BRAUSA:

Q. Good morning, Doctor. Could you introduce yourself to the jury, please.

A. Hi. I'm Dr. Bruce Corser. I'm an internist, sleep doctor, and sleep researcher located in Cincinnati, Ohio.

Q. Thank you.

Can you tell us what a sleep doctor or sleep researcher does?

A. So as a sleep doctor, I see people with a wide variety of sleep disorders, such as sleep apnea, narcolepsy, insomnia. As a sleep researcher, I conduct a lot of research with the pharmaceutical and device industries to test new products.

Q. Outside of this case, have you ever worked for Avadel or Jazz before?

A. Yes, I have. I have conducted research for both Avadel and Jazz.

Q. **How long have you been a sleep doctor?**

A. **I have been involved in sleep medicine since 1989.**

Q. **And what's your formal training to be a sleep doctor?**

A. **So my training, I went to medical school at -- in Syracuse. I'm from Upstate New York. And then I went to University of Cincinnati for residency and fellowship training. After fellowship training, I became involved in sleep medicine and was board certified in sleep medicine in 1995.**

Q. **As a researcher, how do you stay up to date on developments in sleep science?**

A. **So I conduct a lot of research with pharmaceutical companies, so I see new medications long before they're approved. In addition, I attend meetings, I read a lot of journals. So, yeah, I have been involved in sleep medicine for many years.**

Q. **Are you familiar with oxybate therapies for the treatment of narcolepsy?**

A. **Yes, I am.**

Q. **How are you familiar with them?**

A. **I have been prescribing oxybate therapies since 2002 to patients, so I'm familiar with oxybates.**

Q. **Currently, which oxybate therapies do you prescribe to patients?**

A. **Xyrem, Xywav, and Lumryz, all three.**

MR. BRAUSA: Your Honor, at this time Avadel proffers Dr. Corser as an expert in sleep disorders and oxybate therapies.

MR. BRIER: No objection, Your Honor.

THE COURT: All right. Dr. Corser may testify as an expert in sleep disorders and oxybate therapies.

BY MR. BRAUSA:

Q. **Now, Dr. Corser, you have been in court for portions of the past two days, correct?**

A. **Correct.**

Q. **And we've heard narcolepsy talked about quite a bit, but I wanted to start, what causes it?**

A. **So ordinarily in our brains there's about 20,000 cells that produce a substance called orexin, and this is the main neurochemical in our brains that governs sleep and wakefulness. And people with a -- the major cause or type of narcolepsy, there's a deficiency of these cells in the brain.**

It's thought that the deficiency of these cells in the brain is due to autoimmune destruction of these cells. So in other words, the immune system attacks these cells in the brain, resulting in a deficiency in the main neurochemical that governs sleep and wakefulness.

Consequently, people with narcolepsy are very sleepy, they are sleepy during the day and they have very

disrupted sleep at night. So -- and narcolepsy is a chronic incurable disease, typically it requires a lifetime of medication.

Q. **When you say people with narcolepsy have "disrupted sleep," does that mean they are waking up multiple times a night?**

A. **It means that when we measure their brain wave activities, we see multiple disruptions in their sleep throughout the entire night, as compared to people who don't have narcolepsy. So this leads to severe daytime sleepiness.**

Q. **And how do you figure out if someone has narcolepsy?**

A. **Well, it's based on history, so we talk to the patient. And then we do testing, typically an overnight sleep study, followed by a series of naps the next day. And there's specific diagnostic criteria for the diagnosis of narcolepsy.**

Q. **How long typically does it take to figure out if someone has narcolepsy?**

A. **Well, unfortunately, between the onset of symptoms and the time of diagnosis, there may be a lag of 8 to 10 years. So, unfortunately, many people are not diagnosed promptly.**

Q. **And for those people who aren't diagnosed promptly, how does that affect their day-to-day life?**

A. **It's devastating. These people are thought to be lazy or -- you know, they -- they're -- and they don't realize that they've got a serious condition because they think that's normal for them. So often, you know, there's this very long lag between the onset of symptoms and diagnosis, so we commonly see this.**

Q. **Beyond daytime sleepiness, are there any other symptoms of narcolepsy?**

A. **So the most common form of narcolepsy is called narcolepsy type 1, so these people have very disrupted sleep at night and excessive sleepiness. And they have a condition called cataplexy.**

Q. **Can you tell us what cataplexy is?**

A. **Yes, so cataplexy is transient, that is brief episodes of muscle weakness, typically precipitated by emotional stimuli. So people with cataplexy may have muscle weakness manifesting as drooping eyelids. The head may drop. If somebody is holding something in their hand, they may drop it. If their -- their knees may get weak, the knees may buckle.**

So these are some of the manifestations of cataplexy. And this can be very disruptive to people's lives, very bothersome. So some very troublesome symptoms.

Q. **Have any of your patients suffered from cataplexy?**

A. **So I've got about several hundred patients in my**

total sleep practice that have narcolepsy, and I would say probably less than a third actually have cataplexy.

Q. Okay. So once you're diagnosed with narcolepsy, overall, what are the treatment options?

A. So the treatment for narcolepsy is typically twofold. One is that we prescribe medication at night that helps address the disrupted sleep, so -- and one of those therapies is oxybate.

And then there's the medicine we prescribe during the day to help people stay awake, so these are called wake-promoting medications. Or in some cases, we use stimulants, like Ritalin or Adderall, to help people stay awake.

And usually we often use a combination of both things, such as medicine at night as well as -- and medicine during the day to help people stay awake.

Q. If we think about oxybate therapies, why are those different than just traditional sleeping pills?

A. So oxybate therapy results in a dramatic increase in deep restorative sleep, it increases deep sleep by about 40 percent, so it's really a unique medication. And it addresses all of the symptoms of narcolepsy; it helps the excessive daytime sleepiness, it helps the cataplexy, and it helps the disruptive nocturnal sleep, so it addresses all three aspects of narcolepsy.

Q. **As a sleep doctor with 35 years of experience, do you have an opinion as how oxybate therapies overall compare to the other available therapies for narcolepsy?**

A. **In my opinion, oxybate therapy is the single most effective treatment for the symptoms of narcolepsy.**

Q. **Do you know how many people in the United States are diagnosed with narcolepsy, but not taking oxybate therapies?**

A. **So to give you a rough idea, there's probably about 200,000 people in this country that have narcolepsy. Only about 16,000 of those people receive oxybate therapy. So oxybate therapy is greatly underutilized. It's a very effective treatment, but it's, unfortunately, very underutilized for treatment of narcolepsy.**

Q. **Do you have any views as to why that's the case?**

A. **So part of it is the fact that up until recently there's been a -- only -- the only option has been twice-nightly treatment option; that is, people have to take one dose of oxybate at bedtime and a second dose two and a half to four hours later. So this has not been appealing, either for doctors or for patients.**

So imagine having to wake up every night for the rest of your life to take a second dose of medication.

Q. **You mentioned that you currently prescribe Lumryz?**

A. **Yes, I do.**

Q. **As a sleep doctor, do you believe that having Lumryz**

available as an option for patients could benefit patients that are not currently taking oxybate?

A. I do.

Q. Why is that?

A. So people like to have options, so it's nice to have -- when you go to a physician, it's nice to have various options. As a doctor, I would be remiss if I don't as least present to patients all of the options that are available to them.

So, you know, up until recently, Lumryz was not available. But since it has been available, we have been at least mentioning it as a treatment option for patients.

Q. From your perspective, are there any benefits that Lumryz might provide to some patients?

A. Well, there's a couple. One is that the medicine that is prescribed a more frequent -- a more frequent regimen; in other words, you have to take medicine two or three times a day. People are less adherent to that regimen as compared to a once-daily or once-nightly regimen. So that's one.

And then, you know, when we treat narcolepsy, the goal of therapy is to allow people to sleep well through the night, sleep uninterrupted. So we want to decrease the number of awakenings and arousals during the night.

Having to wake up to take a second dose of

medication is contrary to what we're trying to achieve with treatment. So a once-nightly regimen decreases or eliminates this forced awakening in the middle of the night. So for many patients, it is an attractive treatment option.

Q. **Do you know whether the FDA has weighed in on Lumryz as compared to other oxybate therapies?**

A. **Yes.**

Q. **Do you know what the FDA's conclusion was?**

A. **So the FDA deemed Lumryz superior to Xyrem and Xywav based on the fact that it's a -- represents a major contribution to patient care. And the fact that it's a once-nightly dosing regimen compared to twice-nightly dosing regimen.**

Q. **As a sleep doctor, do you agree with the FDA's decision?**

A. **Yes, I do.**

Q. **Now, you've heard that Xyrem has higher sodium than Xywav, correct?**

A. **Correct.**

Q. **And you're familiar with the sodium content of Xyrem, Xywav, and Lumryz?**

A. **Yes, I am.**

Q. **Xyrem and Lumryz have the same amount of sodium?**

A. **Correct.**

Q. **Xyrem has been on the market since 2002?**

A. **That's correct.**

Q. **And I think you just testified that you have been prescribing it since then?**

A. **That's right.**

Q. **Do you know whether there's any data from patients taking Xyrem over the past 20 years on the incidence of cardiovascular disease or other disease states linked to high sodium?**

A. **There is no evidence that sodium oxybate increases the risk of cardiovascular disease or hypertension. This is based on a number of studies, randomized studies, controlled studies, long-term safety studies. There was one study -- for example, there was one study published in the American Journal of Sleep Medicine, it's -- so there's a -- the author was Wang, and they looked at 26,000 people that were taking sodium oxybate and followed them over six years. The incidence of -- or the prevalence of hypertension in that population was 0.4 percent.**

So that's just one study, but there are many studies that have shown that there's been no increased risk for cardiovascular disease in people taking oxybate therapy.

Q. **When the FDA reached its decision about Lumryz, did it consider the sodium content of Lumryz as compared to Xywav?**

A. **Yes, they did.**

Q. **What was the FDA's conclusion?**

A. **They concluded that the benefit from a once-nightly regimen for treatment of the symptoms of narcolepsy outweighed the potential risk of excess sodium.**

Q. **Why did the FDA reach that conclusion?**

A. **Based on the long-term data available regarding sodium oxybate and no evidence of increased cardiovascular risk.**

Q. **And just to be clear, the FDA also sets the recommended daily allowance for sodium, correct?**

A. **Yes. The FDA recommends that people consume less than 2,300 milligrams, or 2.3 grams of sodium daily. That's really sort of an aspirational goal.**

Q. **Do you agree with the FDA's conclusion regarding the sodium content of Lumryz as it compares to Xywav?**

A. **Lumryz contains -- the maximum dose of Lumryz contains about 1.6 grams of sodium, whereas Xywav contains 92 percent less sodium than Lumryz. So there is less sodium in Xywav as compared to Lumryz.**

To give you some context, only 5 percent of the population in this country consumes on average less than 2,300 milligrams of sodium daily, only 5 percent. The average sodium consumption in this country is 3.6 grams of sodium.

And 75 percent of the sodium we consume is in

packaged foods. So unless you prepare all your food at home, you're going to consume around, you know, 3.6 grams of sodium daily. So it's very difficult to achieve a goal of less than 2,300 milligrams of sodium. 80 percent of the civilized world consumes between 2.3 grams and 4.6 grams of sodium daily.

Q. Thank you.

MR. BRAUSA: Pass the witness.

THE COURT: All right.

Cross-examination.

CROSS-EXAMINATION

BY MR. BRIER:

Q. Good morning, Dr. Corser.

A. Good morning.

Q. My name is Gabe Brier. I represent the plaintiff, Jazz Pharmaceuticals, in this case.

Dr. Corser, you're aware that the FDA-approved label for Lumryz contains a warning regarding high sodium content in Lumryz, correct?

A. Correct.

Q. And that warning says to monitor patients with heart failure, hypertension, or impaired functions, correct?

A. So -- yes, it was heart failure, impaired renal function, and hypertension.

Q. And the FDA saw fit that Avadel should include that

sodium warning on the label for Lumryz, correct?

A. **Correct.**

Q. **And, Dr. Corser, I believe earlier you said that options for sodium oxybate are a good thing, right?**

A. **Can you repeat that?**

Q. **Oh, sorry. I believe you said earlier that options for oxybate products are a good thing?**

A. **So, yeah, there's several options for oxybate therapy now, the Xyrem, Xywav, and Lumryz.**

Q. **And do you believe it's good to have those options?**

A. **Yes, I do.**

Q. **Okay. I agree with you on that.**

And you're aware that this is a patent infringement lawsuit?

A. **Yes, I am.**

Q. **You're not offering any opinions on whether the patents in this case are valid or not, are you?**

A. **No.**

Q. **You're not offering any opinions in this case regarding whether the named inventors on Jazz's patents are proper, are you?**

A. **No.**

Q. **And you're not offering any opinions regarding whether Avadel infringes the patents in this case, are you?**

A. **No.**

Q. **Don't you think that if Avadel is infringing Jazz's patents, then Jazz should be fairly compensated for that infringement?**

MR. BRAUSA: Objection, lacks foundation.

THE WITNESS: I have no opinion on that, I'm not a patent lawyer, I'm a doctor.

THE COURT: So --

MR. BRIER: No further questions, Your Honor.

THE COURT: All right.

MR. BRAUSA: No redirect.

THE COURT: All right. Dr. Corser, you may step down. Thank you, sir.

MS. DURIE: Good morning, Your Honor. And good morning, ladies and gentlemen of the jury, Daralyn Durie for Avadel. We call Dr. Claire Mégret to the stand.

Your Honor, may I approach the witness?

THE COURT: Yes.

CLAIRE MÉGRET, having been called on the part and behalf of the Defendant as a witness, having first affirmed to tell the truth, testified as follows:

DIRECT EXAMINATION

BY MS. DURIE:

Q. **Very good. Thank you, and good morning. Could you please introduce yourself to the jury?**

A. **My name is Claire Mégret.**

Q. **Can you pull the microphone just a little bit closer to yourself? The microphone a little closer?**

A. **(Complies.) Like that?**

Q. **Perfect, thank you.**

Where do you currently live?

A. **I live in Lyon, in France.**

Q. **Now, I see we have a translator here, are you able to testify in English?**

A. **I will try to testify in English.**

Q. **Can you describe your educational background for us.**

A. **Um, so I have a master's in physics and chemistry from the ESPCI, which is a institute of technology in Paris. I also have a PhD in theoretical physical chemistry.**

Q. **Did you used to work at Flamel?**

A. **Yes.**

Q. **When did you work at Flamel?**

A. **I worked from 9 -- 2005 until June 2015.**

Q. **And what was your role at Flamel?**

A. **I was a pharmacokinetics scientist.**

Q. **What is pharmacokinetics?**

A. **Pharmacokinetics is the study of how the drug acts in the body, a great definition is what's the body doing to a drug after it's administered?**

Q. **Is that sometimes called "PK"?**

A. **Yeah.**

Q. **So can you give us a real-world example of PK or pharmacokinetics?**

A. **When you're taking drugs, it's PK all the time. For example, with Tylenol, so it's a famous drug, you -- when you have a fever, pain, you have to take two pills, not one, not four, two. And you have to wait 6 hour before the second dose and that's, that's PK.**

Q. **Now, what was your contribution to the development of Lumryz?**

A. **I was involved in different steps. First, I was in charge of selecting sodium oxybate as an interesting treatment to be improved. Then I was also the PK scientist on the project doing all the PK stuff. I was also involved in the clinical studies, especially the early clinical studies, I was part of the design and the results.**

And finally, I was also involved in the design of the Phase III study, which is a study where you demonstrate the efficacy of the product.

Q. **How did Flamel decide to work on sodium oxybate?**

A. **So at Flamel, Flamel gives lists of a compound of potential interest to my group, the PK group, and I was in charge of sodium oxybate, so I look at the molecule, look at the treatment, I saw that the patient, to have a good night, would be obliged to wake up during the night to have a second dose. So I rapidly see that there was an interest**

to, a need to improve the treatment.

Q. Now, if you could please turn in your binder to JTX98.

A. 90 --

Q. 98. 9, 8.

A. Thank you.

Q. What is Exhibit 98?

A. So it's the slides for technical meetings of the FT218 project.

MS. DURIE: We offer Exhibit JTX98.

MR. CALVOSA: No objection, Your Honor.

THE COURT: JTX98 is admitted.

(Exhibit admitted.)

MS. DURIE: And if we could please publish JTX98.

BY MS. DURIE:

Q. We see in the lower right-hand corner, it's a little bit hard to read but there's a September 13th, 2012, date there.

What was the status of the project in September of 2012?

A. Yeah. So as I explained, there was a -- several step. First, it was the work on the sodium oxybate to see if it has an interest to be improved, if it can be improved.

Then after Flamel decided to translate this work

into a real project, then they give it this number, 218.

Then after there was the kickoff of the meeting -- of the project, sorry. And then after, there was this technical meeting, it's one of the first technical meetings, I think.

Q. And if we could please go to JTX98.18.1.

A. (Complies.)

Q. And if you take a look at the slide here, the caption at the top says, "PK Target."

Can you explain what "PK target" means?

A. So, to improve the treatment, I defined what should be the target in pharmacokinetics in order to have a once-nightly dose which is safe and efficient.

Q. And -- sorry.

A. Sorry, so it's a slide that explains that.

Q. And there's a bullet point underneath that that says: "The Micropump profile after 4.5-gram single administration should be close to IR profile after two times 2.5-gram doses..." and then you talk about the second dose, from 2.5 to 4 hours after the first.

What were you referring to here?

A. Yeah, I say that to be safe and efficient, so one-nightly dose should have some specificity, PK specificity that are similar to this -- this immediate-release treatment in order to be sure -- that --

that it works.

Q. And --

A. Sorry.

Q. Go ahead.

A. If I go into the details, there is mainly four features, PK features that I wanted for this PK target profile.

So the first one is -- that I wanted, that -- just after administration, deliver of sodium oxybate in the bloodstream, just after administration, goes up quite rapidly in order for the patient to fall asleep rapidly.

A second feature is that I wanted to have a PK profile for the once-nightly treatment with level not too high. I mean, if the level in the bloodstream is too high, it can be toxic.

So I said the immediate-release is not toxic so I want to limit not too high than the maximum concentration in the treatment I want to improve.

The third feature was regarding efficacy, so in order to be efficacious, I needed in my PK target, a minimum concentration, so level of sodium oxybate in the bloodstream quite high. So high as the minimum concentration that I have with two-dose treatment.

And the last feature is regarding the concentration at 8 hour. 8 hour after administration, it's

a moment of the morning, the patient has to wake up and at this time, he needs to be fully functional, not sleepy, so I knew that I wanted very low concentration at one -- at 8 hour after administration.

And these four features were my PK target, it's how I designed this target.

Q. Now, if we could go to slide --

MR. CALVOSA: I'm not sure Ms. Durie is calling for a narrative, but she got one, if we could just have more question and answer.

THE COURT: Understood.

Ms. Durie, be sensitive to that going forward.

MS. DURIE: I will endeavor that, Your Honor.

If we could go to slide 20, please.

BY MS. DURIE:

Q. And there's a slide here that says, "Pharmacokinetics of GHB."

First, what are we looking at?

A. Here, it's a scheme of everything that is important to understand the PK of sodium oxybate.

Q. And so I'm going to walk you through it and let's start at the top where it says, GIT."

What does that stand for?

A. So the square of the part of the body, which are really important, in the case of this molecule, of this

drug. And the arrow, the arrows are the pathway the drug can take. And the drug can only go in the -- in the -- in this pathway, it's a sense of the arrow.

Q. And when it says, at the top, "GIT," what does that stand for?

A. It means intestine.

Q. So when you have the dose and the arrow going into GIT, what are you showing there?

A. I show the absorption of the drugs, the moment the patient takes the drug.

Q. And then what happens after the drug goes into the intestine in this model?

A. So it goes to the liver first and then in the bloodstream.

Q. And --

A. And --

Q. What was significant to you, if anything, about the fact that the drug passes through the liver?

A. It's very, very important because in the liver, sodium oxybate is eliminated, the moment the drug clears, cleared from the body, it's in the liver. So it's very important because before reaching the bloodstream and before being efficient, it's eliminated. It's such liver elimination here.

Q. And what implications did that have for you in

constructing your model?

A. **It's really important in the way I understood the molecule and I designed the target release profile. Because to be efficient, sodium oxybate has to go to the plasma and it has to overcome the liver. So I knew that I need very big wave of sodium oxybate to be administered in order to overcome this -- the liver and the elimination and reach the bloodstream and then you can see efficacy because of the liver in the bloodstream.**

Q. **Let's now turn to JTX213 in your binder.**

A. **(Complies.)**

Q. **What is JTX213?**

A. **It's another meeting a week later.**

MS. DURIE: We offer JTX213.

MR. CALVOSA: No objection, Your Honor.

THE COURT: JTX213 is admitted.

(Exhibit admitted.)

MS. DURIE: And if we could please publish 213.13.

BY MS. DURIE:

Q. **At the bottom of this slide, there's a reference to three different targets. Can you explain to us what those different targets are?**

A. **So here, there is different points. So target 1 and target 2 are my proposal for a target release profile for**

this once-nightly product. And in brackets, i.e., opposite what Jazz presented in their presentation, which is a different approach.

Q. Now, when you say this is a "pulsatile profile," what did you mean by "pulsatile"?

A. So for this target 1, I wanted to have two -- two of the overnight dose in two wave; one wave is like immediate-release for the beginning of the night, and the second way should be delayed and should be, as I say, very rapid to overcome the liver and to cover the end of the night, so it's my target 1.

Q. Now, you can take that down.

If we go up to the top, there's a reference for requirements for the clinical study. What was the clinical study that was being proposed here?

A. So for the clinical study, I proposed to test the -- some -- these targets, of course. I recall some of the feature I wanted to -- for the target PK profile, in order to say yes, it works, or it doesn't work.

And I write on this that I wanted this study to be conducted in therapeutic condition, and that was so very important.

Q. Let me ask you, why was it important to you to conduct that study under therapeutic conditions?

A. Sodium oxybate, PK, is also influenced by food. It

means that if you take sodium oxybate near -- just after a meal or near a meal, the concentration in the bloodstream will decease. The patient has to take this drug at bedtime, so it's overall -- it's basically, like, two hour after their last meal. And so in this condition, called post-fed, you observed lower level in the bloodstream that in other condition, which are called fasted. In fasted, you have high level of drug that are observed, but it's not realistic for the patient.

And in this study, I wanted to be able to conclude, yes, it works or it don't works -- it doesn't work. So I wanted this realistic condition, the realistic condition in order to be able to conclude.

Q. Could you please turn in your binder to JTX214.

What is JTX214?

A. It's a presentation of project FT218.

MS. DURIE: We offer JTX214.

MR. CALVOSA: No objection, Your Honor.

THE COURT: JTX214 is admitted.

(Exhibit admitted.)

MS. DURIE: And please publish slide 11, 214.11.1.

BY MS. DURIE:

Q. And what do we see on this slide, Dr. Mégret?

A. So from my target of release, I give that to Hervé

and he has to translate that to do formulation, and that are the three formulation we are -- we were testing in the first clinical study.

The CR type 1 and CR type 2 are relative to the target 1 I presented before. And the CR type 3 is my target 2.

Q. And if we now turn to slide 30, there is a comparison with the Jazz CR tablet. Why were you comparing your formulations with the Jazz controlled-release tablet?

MR. CALVOSA: Objection, Your Honor. This is a relevancy objection. I'd be happy to explain at sidebar.

THE COURT: Okay.

(Whereupon, a discussion was held at sidebar as follows:)

MR. CALVOSA: This is another one of those questions where I have no problem with the question and the story that she's telling, but she said they're comparing it to Jazz's Cr profile; that's the sustained-release patents. The sustained-release patents do not have any pharmacokinetics claim elements. I just don't want the jury to get confused on this comparison. She's saying it's different, but this has nothing to do with deionized water.

MS. DURIE: I'm not going to suggest that it does.

MR. CALVOSA: I know the jury is going to take

inference. If we could get the instruction we had yesterday, I'd be fine with the testimony going forward.

THE COURT: Well, I don't think I even got what you said; I doubt the jury is going to get that. So I don't think there's a need for an instruction. If at some point you think there is, we can readdress it.

MR. CALVOSA: Okay. As long as you didn't understand it, Your Honor...

(Whereupon, the discussion held at sidebar concluded.)

BY MS. DURIE:

Q. **So, again, Dr. Mégret, why were you doing --**

MS. DURIE: If we could put that back up.

BY MS. DURIE:

Q. **-- why were we doing -- why were you doing this comparison with the Jazz controlled-release tablet?**

A. **So first, on this slide, I presented the results of our first clinical study, and so we see that there is this -- the PK profile of the three prototypes, and I wanted to have an idea to -- to see that -- if they were working or not or so against the pattern of -- the pattern of Jazz's results, even if in this -- in their patent, it was in the fasted state, so it was not realistic, but it was to have an idea.**

And we see right on this figure that all

prototypes make -- met all the four features I have defined to say, yes, it works when the Jazz results don't reach these features. So I was concluding that all results were absolutely better than that of Jazz results.

Q. **Now, if we could please turn to slide 32.**

There's a reference here to an ongoing clinical trial. What were you describing on this slide?

A. **So after the first study had these very good results, we had conducted a second study with only two out of the three prototypes. CR 2 and 3, and here is the of the -- of the -- design of the study.**

Q. **And -- thank you.**

And the CR 2 prototype that you're referring to here, is that the one the company eventually picked to develop further?

A. **Yes.**

Q. **And which prototype was that from your original prototypes?**

A. **It was the target 1.**

Q. **Now, if you could please turn to DTX1177 in your binder. It is a press release.**

A. **DTX, sorry.**

Q. **1177.**

A. **Thank you.**

MS. DURIE: We offer DTX1177.

THE WITNESS: Yes.

MR. CALVOSA: No objection, Your Honor.

MS. DURIE: Thank you.

If we could publish 1177.

THE COURT: DTX1177 is admitted.

(Exhibit admitted.)

MS. DURIE: Sorry. Thank you.

BY MS. DURIE:

Q. **What is 1177?**

A. **It's a press release that Flamel published to explain the very good results of -- for the first clinical study and also to say that we were doing this second clinical study.**

Q. **And when were those results published?**

A. **It's written April 7, 2014.**

Q. **Now, if we can please turn in your binder to DTX30.**

A. **Yes.**

Q. **What is DTX30?**

A. **It's one of my patent application.**

MS. DURIE: We offer DTX30.

MR. CALVOSA: No objection, Your Honor.

THE COURT: DTX30 is admitted.

(Exhibit admitted.)

BY MS. DURIE:

Q. **And if we can now turn to JTX260.**

A. **Yes.**

Q. **What is JTX260?**

A. **It's another of my patent application.**

MS. DURIE: We offer JTX260.

MR. CALVOSA: I believe JTX260 is already in evidence.

MS. DURIE: Oh.

MR. CALVOSA: But to the extent it's not, there's no objection.

MS. DURIE: Very good.

Then if we could publish JTX260 in evidence.

BY MS. DURIE:

Q. **And so, Dr. Mégret, this is a patent application on which you were named as an inventor; is that right?**

A. **Yes.**

Q. **And if we could please go to pretreatment 260.109.2, there is a table of results in your patent, table 18b. What does this table show?**

A. **So this table show the concentration of the PK profile of the test product -- so it's CR 2 -- in one of the clinical study at different doses.**

Q. **And if we look down specifically at eight hours, what do these numbers represent?**

A. **Sorry. Can you repeat the question?**

Q. **Yeah, if we look down specifically at eight hours at the highlighted row, what do those numbers represent?**

A. **This number represents the concentration in the bloodstream, so it is a plasmatic concentration in microgram per mL, milliliter, of plasma.**

Q. **And what was the concentration after the 8-hour mark for the 7.5-gram test product?**

A. **It's 19.7 microgram per mL.**

Q. **Now -- and for the 9-gram product, what was the concentration?**

A. **The 25.5.**

Q. **And that's microgram per mL?**

A. **Yeah, microgram per mL. Sorry.**

Q. **And -- now, you're aware that FT218 was approved for administration to narcolepsy patients by the United States Food and Drug Administration?**

A. **Yes, yes.**

Q. **What was your reaction when you learned that it had been approved?**

A. **I was very, very happy. Very happy for the patient that they finally have the possibility to have a one-nightly treatment. That's great. And personally, I was so very proud to be part of that.**

MS. DURIE: Thank you, Dr. Mégret.

Pass the witness.

THE COURT: All right. Cross-examination.

CROSS-EXAMINATION

BY MR. CALVOSA:

Q. **Hello, Dr. Mégret. Good to see you again.**

A. **Hello.**

Q. **The testing that you just went through with the jury and your counsel, that was not in vitro dissolution testing in deionized water, right?**

A. **Which testing? The last example?**

Q. **All of the testing you just went through with your counsel, it was not in vitro dissolution testing in deionized water, right?**

A. **No. It was clinical results.**

Q. **So not in vitro dissolution testing in deionized water, right?**

A. **No.**

Q. **All of the pharmacokinetic testing that you went through with your counsel was done after March 24, 2011, right?**

A. **March 24th -- March what?**

Q. **March 24th, 2011.**

(Interpreter clarification.)

THE WITNESS: Yes, yes, sorry.

MR. CALVOSA: No worries at all.

THE WITNESS: -- repeat the number. Sorry.

MR. CALVOSA: No worries. Thank you.

THE WITNESS: Yes.

MR. CALVOSA: No further questions, Your Honor.

THE COURT: All right. Redirect?

MS. DURIE: No, Your Honor.

THE COURT: All right. Dr. Mégret, you may step down. Thank you.

THE WITNESS: Thank you.

MS. DURIE: Your Honor, at this time we have some exhibits simply to move into the record by agreement, if I could just read the exhibit numbers.

THE COURT: All right.

MS. DURIE: It is DTX262, DTX410, DTX667, DTX668, DTX672, DTX690, DTX692, DTX1366, DTX1426, DTX1518, DTX1675, and JTX240.

THE COURT: All right.

MR. CALVOSA: And no objection, Your Honor. Just so you know, the agreement was for convenience of the witness. Mr. Allphin was allowed to return home early today instead of coming back up just to identify the documents.

THE COURT: All right. DTX262, DTX410, DTX667, DTX668, DTX762, DTX690, DTX692, DTX1366, DTX1426, DTX1518, DTX1675, and JTX240 are all admitted.

(Exhibits admitted.)

THE COURT: All right. Avadel, you may call your next witness.

MR. YUE: Good morning. Good morning, Your

Honor. Herman Yue for Avadel.

We call Alexander Klibanov to the stand.

THE COURT: All right. Dr. Klibanov, please take the stand.

MR. YUE: May we proceed, Your Honor?

THE COURT: Yes.

ALEXANDER KLIBANOV, having been called on the part and behalf of the Defendant as a witness, having first affirmed to tell the truth, testified as follows:

DIRECT EXAMINATION

BY MR. YUE:

Q. Good morning, Dr. Klibanov.

A. Good morning.

Q. Could you please introduce yourself to the jury?

A. Good morning. My name is Alex Klibanov.

Q. And what is your title?

A. I am currently a professor emeritus of chemistry and bioengineering at MIT, where I taught a number of undergraduate and graduate courses and also conducted research in many areas of chemistry for more than 40 years.

MR. YUE: I apologize, Your Honor. May we approach with the demonstratives?

THE COURT: Yes.

BY MR. YUE:

Q. Dr. Klibanov, could you please briefly describe your

educational background?

A. **I received my master's degree in chemistry in 1971 from Moscow University in Russia, and my PhD in chemical enzymology, which is a branch of medicinal chemistry, in 1974 from the same university.**

Q. **And when did you come to the United States?**

A. **I was very fortunate to come to the United States legally in 1977, and I became a naturalized United States citizen in 1983.**

Q. **What did you do once you came to the United States?**

A. **For the first almost two years, I worked as a postdoctoral research chemist at the University of California, San Diego. And in 1979, I became a professor at MIT.**

Q. **What is your experience with pharmaceutical formulations?**

A. **I have about half a century of experience of developing and studying pharmaceutical formulations. I published numerous papers in this area. I have many issued United States patents in this area. I also have consulted for many pharmaceutical companies.**

In addition to that, over the years, I started six pharmaceutical companies of my own. And I have been on the boards of directors and on scientific advisory boards of those companies and of many others.

Q. **Have you been involved in the development of any drugs that were approved by the FDA?**

A. **Yes. Two of the drugs that I have been involved in the development of have been approved by the FDA for use in the United States.**

Q. **Have you won any professional awards?**

A. **I have been very fortunate to have been repeatedly recognized by my peers, and I have a fairly long list of professional awards. I will just mention two: I was elected to the United States National Academy of Sciences, which is viewed as one of the highest professional honors that can be given to an American scientist.**

And I also was elected to the United States National Academy of Engineering, which is among the highest professional honors that can be bestowed on an American engineer.

MR. YUE: Your Honor, we offer Dr. Alexander Klibanov as an expert in pharmaceutical formulations.

MR. NIMROD: No objection.

THE COURT: All right. Dr. Klibanov may testify as an expert in pharmaceutical formulations.

THE WITNESS: Thank you, Your Honor.

BY MR. YUE:

Q. **Dr. Klibanov, why are you here today?**

A. **I'm here to explain my opinion that Avadel's Lumryz**

product does not infringe asserted Claims 7 and 11 of Jazz's '488 patent.

Q. **What is the relationship between Claims 7 and 11 of Jazz's '488 patent to Claim 1 of that patent?**

A. **Well, both Claim 7 and 11 depend from Claim 1. And, therefore, these two asserted claims incorporate all claim limitations of Claim 1 of the '488 patent.**

MR. YUE: Mr. Jarrett, could you please put up JTX003, page 30, which is already in evidence. Thank you, Mr. Jarrett.

BY MR. YUE:

Q. **Dr. Klibanov, what are we looking at here?**

A. **We're looking at a portion of Claim 1 which recites a formulation which contains sustained-release portions, and the sustained-release portion includes a core, and this core includes at least one pharmaceutically active agent.**

Q. **And what does a core limitation require, in plain English?**

A. **In plain English, the claimed core must contain a drug.**

Q. **And did you prepare some demonstratives to aid in your testimony today?**

A. **I did.**

MR. YUE: Mr. Jarrett, could we please put up DDX-AK-001.

BY MR. YUE:

Q. **Dr. Klibanov, what are we looking at here?**

A. **We're looking here at a simplified and color-coded figure 1 taken directly from Avadel's '062 patent. And we see IR microparticle on the left and MR microparticle on the right. And this is a cross section of both, of course.**

Q. **And what's the difference between these two microparticles in terms of their structure?**

A. **The core between the two is exactly the same. The drug layer around the core is also exactly the same. The only difference is that a MR microparticle also has a modified-release coating on top of the drug layer, which controls release of the drug from the microparticle.**

Q. **Now, according to Dr. Little, what is the core of these microparticles?**

A. **Dr. Little opined that the core changes when you go from left to right. And in the modified-release microparticle, the core, somehow, also includes the drug layer.**

Q. **And do you agree with Dr. Little?**

A. **I do not.**

Q. **Why not?**

A. **Well, because a formulator would understand that just because you put an extra layer at the very top doesn't change what the core is.**

Q. **What would a formulator understand to be the core of the Lumryz microparticles?**

A. **The formulator would understand that the core is pharmaceutically neutral or inert; in other words, it contains no drug in it.**

Q. **What evidence do you have for your opinion regarding the core of these microparticles?**

A. **I have two buckets of evidence; the first one comes from Avadel's submission to the FDA that covers the Lumryz product, and the second one comes from Avadel's '062 patent.**

Q. **Let's start with Avadel's submission to the FDA. Can you please turn to what's been labeled JTX227 in your binder.**

MR. YUE: And, Your Honor, we'd move to admit JTX227 into evidence.

MR. NIMROD: No objection.

THE COURT: JTX227 is admitted.

(Exhibit admitted.)

BY MR. YUE:

Q. **Dr. Klibanov, what is this document?**

A. **This is a portion of a new drug application submitted by Avadel to the FDA which, as I just mentioned, covers Lumryz.**

Q. **And why is this document important to your analysis?**

A. **It is important because in submitting a new drug**

application to the FDA, Avadel must provide a complete and accurate description of the product.

MR. YUE: Mr. Jarrett, could we please go to page 5. And let's blow up figure 1.

BY MR. YUE:

Q. Dr. Klibanov, what are we looking at here?

A. We're looking again at a cross section of a modified-release microparticle.

Q. And how does this support your opinion?

A. As the jury can see, at the very middle of these circles, we have an entity that is called inert core, meaning that the core is pharmaceutically inert. It doesn't contain the drug, it is surrounded by a drug-loaded layer.

Q. Let's go to Avadel's '062 patent.

MR. YUE: And, Mr. Jarrett, could we please bring up page 74 of JTX260.

BY MR. YUE:

Q. Now, Dr. Klibanov, do you recall Dr. Little testifying about table 1b, as in bicycle, from Avadel's patent?

A. Yes, I do.

Q. And do you agree with Dr. Little's analysis of that table?

A. No, I do not.

Q. Why not?

A. **Because it appears that Dr. Little reads table 1b in isolation and ignores the rest of example 1, of which table 1b is a part. In particular, he ignores table 1d, as in David.**

MR. YUE: Mr. Jarrett, could we please pull up example 1, it's column 47, lines 2-7. Thank you.

BY MR. YUE:

Q. **Dr. Klibanov, what does example 1 here tell a formulator?**

A. **The very first sentence of example 1 specifically refers to tables 1a, 1b, 1c, and 1d as covering IR and MR microparticles, as well as their mixtures. So this first sentence specifically directs a formulator to consider all the tables in context with each other and, in particular, consider table 1b in context with table 1d, as in David.**

Q. **Is there another point that this paragraph makes to a formulator?**

A. **Yes. The second sentence specifically states that "the physical structure of these microparticles is described in figure 1."**

Q. **Let's go ahead and start with table 1d.**

MR. YUE: Mr. Jarrett, could we please pull that table up.

BY MR. YUE:

Q. **Dr. Klibanov, what's described here in table 1d, as**

in David?

A. As the jury can see at the top, it describes the finished composition. So the finished composition necessarily contains both immediate-release microparticles and modified-release microparticles, it's a mixture.

Q. And what does the table 1d "as in David" here tell a formulator about the core of the Lumryz microparticles?

A. It specifically says in the highlighted line that the core for IR and MR microparticles is one and the same. And namely, it is a microcrystalline cellulose sphere, which is indisputably pharmaceutically inert; it doesn't have a drug in it.

Q. And what about that entry right above the highlighted entry that says sodium oxybate, what does that tell a formulator?

A. It tells a formulator that it is a sodium oxybate containing the drug substance, further confirming that the core does not have a drug in it.

MR. YUE: Now, Mr. Jarrett, could we please bring up DDX-AK-002.

BY MR. YUE:

Q. Dr. Klibanov, what are we looking at here?

A. We're looking at a color-coded and simplified table 1 from Avadel's '062 patent. The figure itself, figure 1 itself is shown at the top. And below it we have a box that

presents the legend to this figure.

Q. And what does figure 1 tell a formulator about the core of the Lumryz microparticles?

A. The figure itself clearly indicates to a formulator that the core is exactly the same, both on the left and on the right, it's that gray circle in the middle.

Q. And what about the legend below it, what does that tell a formulator?

A. That confirms that immediate-release and modified-release microparticles have the same core, and further directs a formulator at the very end to example 1 of which tables 1b and 1d are a part.

MR. YUE: And, Mr. Jarrett, could we please pull up table 1b, as in bicycle, of the '062 patent, that's JTX260.

BY MR. YUE:

Q. Dr. Klibanov, why do you disagree with Dr. Little's interpretation of table 1b, as in bicycle, of the Avadel patent?

A. Because when the pharmaceutical formulator looks at the description of the function of IR microparticles in this table, the formulator will understand that the description of the function here is incomplete.

Q. And what do you mean by that?

A. What I mean by that is that we just saw that the IR

microparticles contain both the core and the drug layer that surrounds this core. And, therefore, the formulator would understand that the function of IR microparticles should read core of MR microparticles and drug substance.

Q. Dr. Klibanov, do you have any support for your opinion from Avadel's patent other than example 1 that we've been looking at?

A. I do.

Q. Okay.

MR. YUE: Mr. Jarrett, can you please bring up DDX-AK-003.

BY MR. YUE:

Q. What are we looking at on this slide?

A. On the left-hand side we see a portion of the '062 patent that's outside of example 1. And we have the same cross section, color-coded cross section on the right-hand side. And the two parts are color coordinated.

Q. And what would a formulator take from this disclosure?

A. Two important things; first of all, that the drug layer and the core are two separate items. And second of all, that the term "core" in Avadel's patent means the same thing as the inert core, meaning that the core is necessarily inert.

Q. Now, under Dr. Little's opinion of what the core of

the Lumryz modified-release particles are, would this listing of a core coating in a drug layer that we see here, would that make any sense?

A. No, it would make no sense at all.

MR. YUE: Mr. Jarrett, could we please pull up DDX-AK-004.

BY MR. YUE:

Q. Dr. Klibanov, based on all of the evidence that you considered, what is your conclusion about whether or not the Lumryz modified-release microparticles have a drug-containing core?

A. Well, again, the jury can see that the claim language for the core requires the core to contain a drug. As I have just demonstrated, the Lumryz product does not have a drug in its core. Therefore, Lumryz does not infringe Claims 7 and 11 of Jazz's '488 patent.

MR. YUE: Thank you, Dr. Klibanov. Pass the witness.

THE COURT: All right. Cross-examination?

MR. NIMROD: Good morning, ladies and gentlemen. My name is Ray Nimrod. I'm one of the attorneys for Jazz.

CROSS-EXAMINATION

BY MR. NIMROD:

Q. Good morning, Dr. Klibanov.

A. Good morning, sir.

MR. NIMROD: Mr. Lewis, could we please pull up JTX260, the Avadel '062 patent?

THE WITNESS: Yes, sir.

MR. NIMROD: And can we go to page .70, which is the last sections Dr. Klibanov just testified about. That's column 40, if we can blow up the bottom section.

BY MR. NIMROD:

Q. **You just gave testimony regarding what's called one sub-embodiment of the modified-release portion; is that right?**

A. **Yes.**

Q. **And I think, as you stated, this is not in example 1, right?**

A. **It refers to example 1, but it's outside of example 1.**

Q. **It's outside of example 1, I think you just said that, right?**

A. **That's right.**

Q. **Okay. Great.**

MR. NIMROD: Now, Mr. Lewis, could we please go to columns 47 and 48, that's 0.74, please.

BY MR. NIMROD:

Q. **And this is where we see example 1 start. This is in columns 47 and 48 of the '062 patent, correct?**

A. **Correct.**

Q. **All right.**

MR. NIMROD: Now, if we could please blow up table 1a again.

BY MR. NIMROD:

Q. **You showed the jury this on your direct, do you recall?**

A. **That's right.**

Q. **And in table 1a, we have the -- the header is "The composition of IR microparticles," right?**

A. **Yes.**

Q. **And for the IR microparticles, the table states that, "Microcrystalline or MCC is listed as the core." Is that right?**

A. **Yeah, and specifically microcrystalline cellulose here is listed as the core.**

Q. **I believe you said before, maybe previously, that the oxybate drug substance is then layered on to the MCC core to add the drug to the -- to make the IR microparticle, right?**

A. **That's right.**

Q. **And for drug layering, I think you called it before, that's a process where you take a neutral core and then you add drug layering on top of the core; is that right?**

A. **On top of that neutral core, yes.**

Q. **Okay, that's drug layering?**

A. **That's right.**

Q. **Let's move to table 1b, please. The title of table B is "Composition of MR Microparticles," right?**

A. **Yes.**

Q. **Okay. And it includes an entry for IR microparticles, right there?**

A. **Yes.**

Q. **And then it says that the function of that is, it reads, "core of MR microparticles," correct?**

A. **Correct.**

Q. **And I think you just testified to the jury that there was some error in the table, that it wasn't complete?**

A. **It was incomplete, that's correct.**

Q. **So you're saying it was an error?**

A. **I wouldn't call it an "error," but it's incomplete, it's an oversight.**

Q. **An "oversight," all right.**

Now, you've testified before, haven't you, that in your view, the '062 patent's use of the word "core" in some instances supports Dr. Little's opinion and in some instances, it supports your opinion, right?

A. **Yes, if taken in isolation, it supports Dr. Little's opinion. If taken in the context of the entire patent, it supports my opinion.**

Q. **So your testimony, under oath, was that there are instances in the '062 patent where the use of the word**

"core" supports Dr. Little's opinion, right?
A. Yes.
Q. And the portion that you were referring to was table 1b where he was pointing for his opinion, right?
A. Yes, when it's reviewed in isolation.
Q. Okay. Now -- so he was focusing on table 1b, right?
A. Yes. And he, as I said, analyzed it in isolation from the rest of tables.
Q. Now, could we please turn to PTX -- you were in court when Dr. Little testified, correct?
A. Yes, I was.
Q. And you're here to rebut Dr. Little's testimony?
A. To respond to Dr. Little's testimony.
Q. "Respond," a better word.
And you heard him testify yesterday about a request for admission?
A. Yes.
Q. Okay. And, in fact, that was in Dr. Little's reports that you reviewed before you prepared your reports for the case, right?
A. That's correct.
Q. Okay.
MR. NIMROD: Now, could we please put PTX726.31.
Okay. If we could just highlight -- yes, thank you.

BY MR. NIMROD:

Q. **The request for admission stated that, Avadel was to admit that, quote, "the modified-release portion of example 1 of U.S. Patent 10,272,062 (the composition of which is provided in table 1b of said patent) corresponds to the controlled-release portion of defendant's NDA product."**

Do you see that?

A. **I do.**

Q. **And you see also that the parenthetical here ("the composition of which is provided in table 1b of said patent") is spelled out directly in the request.**

Do you see that?

A. **That's correct, in parenthesis, before doing example 1.**

Q. **Okay. Now let's go back, again, to table 1b, there's the request for admission directed, Avadel's attorney, strike two, go back to table 1b, please.**

Okay. So the request for admission in the parenthetical specifically called out the composition of table 1b, which is titled, "Composition of MR microparticles," right?

A. **Yes.**

Q. **And that's the table that says, "Component IR microparticles"?**

A. **Yes.**

Q. **And then lists core of MR microparticles, right?**

A. **As a function, correct.**

Q. **And it doesn't say "sodium oxybate"?**

A. **It does not.**

Q. **It says "core of MR microparticles," right?**

A. **That's right, that's why if you read it in isolation, that's what you would get.**

Q. **You would think, Wow, if you read this, it's pretty obvious it's incomplete, right, that's what you're saying?**

A. **I don't know if it's "pretty obvious," but a pharmaceutical formulator would understand that incomplete when read in the context of the rest of example 1 and indeed the rest of the '062 patent.**

Q. **Okay. Let's go back to the request for admission.**

A. **Yeah.**

Q. **Please.**

The answer that Avadel gave was, "Subject to and without waiving the foregoing general and specific objections, Avadel admits this request."

Do you see those words?

A. **I do.**

Q. **And you understand Avadel did not say in that request, actually table 1b, which is called out, is incomplete, did it?**

A. **Avadel said what it said.**

Q. **Okay. And you understand that Avadel had a month or more to prepare an answer to something like that, this is something that's taken seriously?**

A. **I'm sure it was taken seriously and I see nothing wrong with what Avadel said because table 1b, it specifically indicates, needs to be read in the context of table 1 -- sorry, for example 1.**

Q. **And Avadel did not say in its response, "denied, look to other portions of the patent, such as column 40," right?**

A. **There was no need to look to other portions because example 1 was right in the question.**

Q. **And Avadel did not say "denied" because table 1 is incomplete and you should instead just look to the NDA, did they?**

A. **No, Avadel said what it said, but example 1 was right in the question, whereas table 1b actually was in parenthesis after that.**

Q. **And table 1b is the only table that is called out specifically in that request for admission, pointed out directly to Avadel, right?**

A. **Well, example 1 was actually called out and table 1b was in parenthesis.**

Q. **Right. My question to you was: Would you agree table 1b was the only table that was specifically called out in that question?**

A. **That was specifically listed there, correct.**

Q. **So the question directed Avadel right to table 1b, right?**

A. **I disagree with that.**

Q. **All right. Let's turn to another subject.**

In your expert report, you've stated that your view was that, "A person of skilled formulator, or a POSA, would not view the core as being all portions of the pellet underneath the topcoat, but would rather view the core of the pellet to be its innermost portion."

Do you recall that?

A. **Yes, in the context of Lumryz product.**

Q. **Right.**

Now, you have seen other formulators refer to the core of a modified-release pellet as all the portions of the MR pellet, haven't you?

A. **Not in the context of the Lumryz product.**

Q. **Well, you said you were testifying about what a skilled formulator would think, right?**

A. **Would understand with respect to the Lumryz product specifically.**

Q. **Okay. Could we -- could you look in your binder and turn to Exhibit 875, please.**

A. **Okay.**

Q. **Do you -- are you there now?**

A. **Yes.**

Q. **Okay. You recognize Exhibit 875 as the Liang reference?**

A. **I do.**

Q. **And you're familiar with that reference?**

A. **Yes.**

Q. **Okay. It's a reference that relates to oxybates and formulations of oxybates; that you know?**

A. **In general, yes.**

MR. NIMROD: Your Honor, we move to admit DTX875, please.

MR. YUE: No objection.

THE COURT: Okay. DTX875 is admitted.

(Exhibit admitted.)

MR. NIMROD: Could we call up the abstract, please.

BY MR. NIMROD:

Q. **The abstract of the Liang reference is directed to a dosage form containing an immediate-release component of the oxybate and one or more delayed/controlled-release components.**

Do you see that?

A. **I do see that.**

Q. **Okay. Now let's turn to DTX875.11, please. And if we could just call up paragraph 44, 45, there we are.**

So in the patent, there's a section with a title in paragraph 44 called the "Immediate-Release Component."

Do you see that?

A. I see that section.

Q. Okay. And one of the -- the immediate-release component, one of the dosage forms can be a particle, a bead or a pellet, is some of the options, right?

A. Where are you reading?

Q. Right here in the third line of paragraph 45, "It can be a particle, a bead or a pellet."

A. A granulate, a powder, a tablet, a minitablet, as a capsule and many other things, yes.

Q. One of which is a pellet?

A. That's correct.

Q. Thank you.

MR. NIMROD okay. Could we please turn to paragraph 56. You can call up paragraph 56.

BY MR. NIMROD:

Q. Paragraph 56, the formulators in Liang state, "Preferably, if the immediate-release component is a solid pellet, bead, or minitablet or the like, that component is also used as the immediate-release core of the pH-sensitive delayed/controlled-release particles by coating them using materials and methods similar to the barrier coats or the overcoat as described herein."

Do you see that?

A. **I do.**

Q. **Okay. So Liang, a formulator in a patent that you had reviewed, states that you can use the immediate-release component as your core for the controlled-release tablet, right?**

A. **But not for the Lumryz product.**

Q. **Well, this patent is not directed to Lumryz, is what you're saying.**

A. **Exactly right. That's exactly my point.**

Q. **But it's written by a formulator skilled in the art, right?**

A. **True. In other products, a core may include a drug. It's just that in Lumryz, it does not.**

Q. **Okay. Now let's go down to paragraph 57 and 58, please, the next paragraph.**

This is a section of Liang, the formulator Liang and his team titled "Delayed/Controlled-Released Particles." So now we've moved from the immediate release to delayed release, controlled release.

And it states: "The immediate-release core of the pH-sensitive delayed/controlled-release particles, (i.e., beads, pellets, minitabs, granulate) of the current invention comprises," and it goes on to talk about active ingredient, right?

A. **Yes.**

Q. **Okay. So it's saying here that you can take the immediate-release particle and use it as a core in -- for the formulations of these oxybate particles, right?**

A. **Yes, but not in Lumryz.**

Q. **Okay. Now let's go to paragraph 69 of Liang, please.**

It says here in paragraph 69, "The immediate release cores in the pH-sensitive delayed/controlled-release particles of the current invention are made by techniques and equipment known in the art, for example..."

And so it's saying here you can make these cores for our invention, the cores that are going to be used for the controlled release, by various techniques known in the art, right?

A. **Again, but not in Lumryz.**

Q. **And one of the technologies that Liang, a skilled formulator, in a patent that you put in your report, says that you can use is "drug layering." Do you see that?**

A. **Yes, I have no problem with that.**

Q. **And I asked you earlier, about five minutes ago, drug layering is something where you have an inert core and you layer the drug on top of it, right?**

A. **I mean, that's certainly one possibility.**

Q. **Well, that's what you told me and the jury it was. I said, Isn't that what drug layering is? And you said, Yes.**

A. **Yes.**
Q. **Okay.**
A. **And I can still tell you that, but that's not Lumryz.**
Q. **All right. So this formula, though, is saying I am going to take something, an inert core, layer the drug on it, and I'm going to use that as my core, that whole thing that results, for my sustained-release particle, right?**
A. **Yes, but not for the Lumryz product, once again.**
Q. **Okay. Just to be clear, Lumryz is made by drug layering, correct?**
A. **It's made by spraying a solution of a drug on the inert core.**
Q. **Okay. If we go back to paragraph 56, please.**

Excuse me, 56, yes.

So Lumryz is made in a way where you take an immediate-release component and then you use that and you then, as stated in paragraph 56, coat them, that component, "using materials and methods similar to the barrier coats or the overcoat as described herein," right?

A. **That's what it says.**
Q. **Okay.**

MR. SCHULER: No further questions.

THE COURT: All right. Redirect?

MR. YUE: No further questions, Your Honor.

THE COURT: All right. Dr. Klibanov, you may

step down. Thank you.

THE WITNESS: Thank you, Your Honor.

THE COURT: All right. Let's give the jury the morning break at this time.

(Whereupon, the jury left the courtroom.)

THE COURT: All right. We'll take 15 minutes and come back at 11:45 a.m.

(Break taken.)

THE COURT: All right. Thank you. Be seated until the jury comes.

(Whereupon, the jury entered the room.)

THE COURT: Avadel, you may call your next witness.

MR. SILVER: Good morning, Your Honor. Dan Silver on behalf of Avadel.

Hi, ladies and gentlemen.

Our next witness is going to be by deposition. We're going to be playing a portion of the deposition of Mr. Scott Bura, Jazz's director of process development. Mr. Bura is a formulation scientist who works at Jazz and is a named inventor on the '782 patent.

May I approach with clip reports, Your Honor?

THE COURT: Yes.

MR. SILVER: Thank you.

(Video deposition was played for the jury as

follows:)

BY MR. NIMROD:

Q. Good morning, Mr. Bura.

A. Good morning.

Q. What was your initial role when you joined Jazz in 2013?

A. My initial role was as process development.

Q. What was the first project that you were involved in around 2015?

A. That was using resins.

Q. And did that involve both an immediate-release component and some other type of component?

A. I don't recall specifically.

Q. And do you have a recollection as to why you were pursuing ion exchange resin technology for oxybate?

A. We were looking at a once-nightly option.

Q. And is it fair to say that if the -- the theory was that if the oxybate is taken up, to some extent, by the resin, it will take time for the oxybate to get released in the body?

A. That's not my field of expertise.

Q. Did you have an understanding as to how resin technology might facilitate once-nightly dosing?

A. Yes.

Q. What was that understanding?

A. **That it was a means to capture the active and deliver it into the patient.**

Q. **And for those of us that are not experts in the field, what are ion exchange resins?**

A. **That depends on the context.**

Q. **In the pharmaceutical context, are you able to describe what ion exchange resins are?**

A. **No.**

Q. **Okay. Are they polymers?**

A. **I am not able to answer that.**

Q. **Are the ones that you personally experimented with -- were they polymers?**

A. **I don't recall the specific resins that we experimented with.**

Q. **Have you ever physically seen an ion exchange resin?**

A. **Yes.**

Q. **What form was it in? Was it solid, liquid?**

A. **Small beads.**

Q. **And is it fair to say that the goal was to get enough oxybate taken up by the resin that it would be protected, for some period of time, through the transit of the body?**

A. **I don't know.**

Q. **Did you come to a personal view that you had accomplished something that was novel?**

A. **I don't recall.**

Q. **So as I understand it, sitting here today, you don't have a recollection of ever having concluded that you accomplished something novel with your ion exchange resin project?**

A. **I don't recall making conclusions. I don't recall making conclusions.**

Q. **That you had achieved something novel?**

A. **I don't recall.**

Q. **Are you able to tell the Court what you personally considered novel about your work?**

A. **About this work?**

Q. **Yeah.**

A. **No, I don't recall.**

Q. **I guess you -- you're still at Jazz today?**

A. **I am, yes.**

Q. **Okay. Did you take any actions to attempt to stop Jazz from copying the Avadel claims?**

A. **I did not.**

Q. **Mr. Bura, in your review of the examples from the specification, did any of them involve a sachet formulation?**

A. **I did not read the word "sachet" in the examples.**

Q. **Do you believe that a person -- another scientist could achieve a once-nightly dosing for sodium oxybate or any other oxybate for a sachet suspension product in water using the information that is set forth in your patent?**

A. **I don't know.**

Q. **So what was the packaging form that JZP-324 was supposed to utilize as of 2020?**

A. **A sachet.**

Q. **Do you know when JZP-324 was designated to be a sachet? It was already a sachet when you came on in 2020?**

A. **It was already a sachet when I came on, yes.**

(End of video deposition.)

MR. SILVER: Your Honor, up next we're going to play a portion of the deposition of Mr. Philip McGarrigle, senior intellectual property counsel at Jazz.

Mr. McGarrigle is an attorney who supervised the filing of Jazz's patent applications with the Patent Office. He will be discussing the prosecution of the '782 patent as well as certain -- as well as, excuse me -- yes, '782 patent as well as certain disclosures regarding sachets that Jazz made during prosecution of a different but related patent application.

And we're going to introduce into evidence through Mr. McGarrigle JTX009, JTX012, and JTX059, which I understand are not objected to.

THE COURT: What was that last one, JTX059?

MR. SILVER: 059, Your Honor.

THE COURT: All right. JTX009, JTX012, JTX059, any objection?

MR. NIMROD: No objection, Your Honor.

THE COURT: All right. They are admitted.

(Exhibits admitted.)

MR. SILVER: May I approach with binders, Your Honor?

THE COURT: Yes.

MR. SILVER: Thank you.

(Video deposition was played for the jury as follows:)

Q. **How long have you worked at Jazz?**

A. **I started working in December of 2012, so it's coming up on ten years.**

Q. **And what exactly is your role at Jazz?**

A. **My role is to work on intellectual property matters at Jazz, and that has changed over the ten years. When I first got there, I was the only intellectual property person, so I was handling a large basket of things, versus now, which I'm handling less because we have more people. And that would include trademarks and copyrights and patents and regulatory and due diligence and various other things.**

Q. **What basket of things are you currently handling?**

A. **I'm more focused on just working on oxybate. I'm working less hours, I'm a part-time person now. And I'm helping recruit some other people to fill my position.**

Q. **What outside lawyers do you interact with, with**

respect to the IP portfolio for oxybate?

A. **I would interact with Cooley, Jones Day, Schwegman and Lundberg. I think that's it.**

Q. **Who at Cooley works on Jazz's oxybate portfolio?**

A. **Jason Valentine. I'm just going to wait for you to write it down.**

Q. **Are there any other in-house counsel at Jazz with responsibility for patent prosecution related to the oxybate portfolio?**

A. **No.**

Q. **And I don't think we actually established this, but you are a lawyer, correct?**

A. **Yes.**

Q. **When you draft a patent for Jazz, do you file it yourself, or does it go to outside prosecution counsel before it's filed?**

A. **It's -- it goes to outside prosecution -- as a general matter, it goes to outside prosecution counsel.**

Q. **And do you supervise outside patent prosecution counsel during the course of the prosecution of those patents?**

A. **Yes.**

Q. **In your work at Jazz, do you have any responsibility for monitoring Avadel's patent portfolio?**

A. **Yes.**

Q. **So looking at Exhibit 8 briefly.**

A. **Exhibit 8.**

Q. **That is the '782 patent, correct?**

A. **This is the '782 patent.**

Q. **So the Exhibit 6, the '064 application, ultimately issued as Exhibit 8, the '782 patent; is that right?**

A. **Exhibit 6, the -- '064 patent, right?**

Q. **'064 application, yes.**

A. **Yeah, application, issued as the '782.**

Q. **And I'd like to look, again, at the claims of the '064 application, which start on Bates 195.**

A. **195, okay. Got it.**

Q. **All right. Do you know who drafted these claims?**

A. **No.**

Q. **Do you know whether it would have been either you or Mr. Valentine?**

A. **Yes.**

Q. **I'm asking if you recall any time you showed any set of claims over the course of prosecution to the -- of the '064 patent to any of the inventors --**

A. **Okay.**

Q. **-- prior to the issuance of the '782?**

A. **I don't remember any specific instance where I did that.**

Q. **You've been handed Exhibit 9. Do you recognize this**

as U.S. Patent 10,736,866 to Flamel?
A. When you say "recognize it," I mean, just by reading it, that's what it says.
Q. Did you or Jason Valentine -- do you know whether you or Jason Valentine referred to the claims of the '866 patent during the drafting of the claims of the '064 application?
A. Yes.
Q. Did either you or Jason Valentine refer to the claims of the '866 patent during the drafting of the claims of the '064 application?
Did either you --
A. Yes.
Q. -- or Jason Valentine refer to the claims of the '866 patent?
A. Either Jason or Phil referred to the claims of the '866, okay.
Q. During the drafting of the '064 application?
A. Yes.
Q. Do you know whether you personally referred to the claims of the '866 patent during drafting of the '064 application?
A. No.
Q. Okay. Process of elimination then.
Did Jason Valentine refer to the claims of the '866 patent during the drafting of the claims of the '064

application?
A. Yes.
Q. Did you tell him to refer to the claims in the '866 patent during the drafting?
A. I don't recall specific -- I don't recall.
Q. Did you more generally instruct Jason Valentine to review Avadel's patent portfolio in drafting the claims of the '064 patent application?
A. Yes.
Q. So with the aid of Exhibit 12, can you identify Exhibit 11 as the '487 application that led to the '488 patent?
A. Yes.
Q. Excellent. So looking at page -- well, actually, we will do this one real quick.
Were you involved in the prosecution of the '487 application?
A. Give me one second. Yes.
Q. All right. And who else was involved in the prosecution of the '487 application?
A. '487, right?
Q. Yes.
A. Mike Tuscan, Michael Tuscan; Sandhya Deo, D-E-O; me; Clark Allphin.
Q. Do you know who drafted these claims?

A. **No. No.**

Q. **Fair to say it would be either you or Ms. Deo?**

A. **No.**

Q. **Is it possible it was also Mr. Tuscan?**

A. **Yes.**

Q. **So it would have been one of the three of you, Ms. Deo, or Mr. Tuscan that drafted the claims in the '487 application?**

A. **Yes. Yes. Yes.**

Q. **Do you know whether any one of you, Ms. Deo, or Mr. Tuscan referred to any Avadel patent or patent publication in the process of drafting or revising these claims?**

A. **Yes.**

Q. **Did any of you, Mr. Tuscan, and Ms. Deo refer to any Avadel patent or patent publication in the course of drafting the claims of the '487 application?**

A. **Yes.**

Q. **Which of those three people referred to the Avadel patents or patent applications during the drafting of the '487 claims?**

A. **Mike and Sandhya. And -- and Clark.**

Q. **With the stipulation of nonwaiver, did you instruct Mike, Sandhya, and Clark to refer to Avadel patents and patent applications during preparation of the claims of the**

'487 patent application?

A. Yes.

BY MR. CERRITO:

Q. Mr. McGarrigle, can you take a look at what has been marked as Plaintiff's Exhibit 1. And do you know what that document is?

A. It says that it is an applicant-initiated -- well, on the other page it's a summary, it's a summary of an interview that was conducted in this case.

Q. Okay. And do you recall discussing anything with the patent examiner during this interview about Jazz's sachet patent claims?

A. Yes.

Q. What -- what did you discuss?

A. Jason Valentine took over the -- the discussion of the slides. And we had a slide discussion of the rest of it at the end, and I mentioned that there was an Avadel patent that was similar. And then we cited to the examiner the number and pointed out where it was and --

Q. Similar in what way?

A. Similar in that it had the sachet in it.

Q. Can I hand you what we'll mark for identification as Plaintiff's Mr. McGarrigle 2.

Mr. McGarrigle, I have handed you Plaintiff's Exhibit 2, it's a copy of United States Patent Number

10,952,986, do you see that?

A. Yes.

Q. And do you recognize this patent?

A. The number isn't overly familiar with me, but the claims are familiar.

Q. The claims are familiar. Is this the patent that you referred to to the examiner?

A. Yes.

Q. Okay. And did the examiner allow Jazz's -- sachet claims --

A. Eventually.

Q. Did the examiner make any note, record of your conversation regarding Avadel's sachet patent in the notice of allowance?

A. In the notice of allowance, there was some language that referred to the patent.

(End of video deposition.)

MR. YUE: Good morning, again. Your Honor, we'd like to call our next witness, Mr. Joseph Matal, to the stand.

THE COURT: All right. Mr. Matal, please take the stand.

JOSEPH MATAL, having been called on the part and behalf of the Defendant as a witness, having first affirmed to tell the truth, testified as follows:

DIRECT EXAMINATION

BY MR. YUE:

Q. **Good morning, Mr. Matal.**

A. **Good morning.**

Q. **Please introduce yourself to the jury.**

A. **I'm Joe Matal, I'm a patent lawyer in Washington, DC. And I served as acting director of the U.S. Patent and Trademark Office from 2017 to '18.**

Q. **Could you please briefly tell us about your educational background?**

A. **I have a BA from Stanford University and a law degree from Boalt Hall School of Law to UC Berkeley.**

Q. **And how did you come to work for the Patent Office?**

A. **I first joined the Patent Office through the solicitor's office, that's the part of the Patent Office that represents the agency in court.**

Q. **And what did you do after your time in the solicitor's office?**

A. **After solicitor's office, I went into the front office, and eventually served as acting director of the agency in charge of the whole agency.**

Q. **And can you give us a sense of what your responsibilities were as the acting director?**

A. **You're in charge of all 12,000 employees, the budgeting, managing, you know, the entire organization.**

MR. YUE: Your Honor, at this time we'd like to profer Mr. Matal as an expert in Patent Office practice and procedure.

MR. NIMROD: No objection, Your Honor.

THE COURT: All right. Mr. Matal may testify on the Patent Office practice and procedure.

BY MR. YUE:

Q. **Mr. Matal, what are you here to talk about today?**

A. **Patent Office policy and procedure, and in particular the rules requiring the disclosure of claim copying when claims have been copied from another application.**

Q. **Now, before we get into the specific opinions, can you give the jury a brief description of the process for getting a patent?**

A. **Sure, you start by filing an application, it begins with what's called a specification; that's a description of your invention that's good enough so that other people can make and use the invention. Then eventually you file claims that kind of mark out the boundaries of what you claim as your invention. And then the examiner examines it and decides if it meets the conditions of patentability.**

Usually, there's initially a rejection. People claim a little too much or there's some other problem. But even after you're rejected, then you can counter and even amend your claims. And usually, even when a patent issues,

there's this back-and-forth process before claims ultimately issue.

Q. And is there a name for this back-and-forth process you were just referring to?

A. Examination or patent prosecution.

Q. And is there a name for the written record that results from this back-and-forth with the Patent Office?

A. Yeah, it's called the file wrapper or the prosecution history.

Q. Mr. Matal, are you familiar with the claims of Jazz's '064 application?

A. Yes, I am.

Q. And just to remind us, what patent did the '064 application eventually issue as?

A. The '782 patent, the patent that's at issue in this case, or one of the two.

Q. And did you compare the claims of Jazz's '064 application with the claims of Avadel's '866 patent?

A. Yes, I did.

Q. And what did you think about the claim language?

A. The claim language is very similar between the Avadel -- the earlier Avadel patent and the Jazz patent.

Q. And what do you understand Jazz's explanation to be for why the claim language between that application and Avadel's '866 patent was so similar?

A. **Well, as we just saw in the testimony from Jazz's lawyers, they admit that they -- they referred to the earlier Avadel patent when they drafted their own patent claims.**

Q. **Now, assuming the jury finds that Avadel copied -- excuse me, assuming the jury finds that Jazz copied Avadel's claims, what should Jazz have done during prosecution?**

A. **The Patent Office has a rule that if you copied your patent claims in your application from another person's application, you have to tell the Patent Office about it. You have to inform us about the copying.**

Q. **And if Jazz had, in fact, copied Avadel's claims, is there any reason Jazz wouldn't have notified the Patent Office of that copying fact?**

A. **No, you -- no matter what, if you copied someone else's patent claims, you have to tell the Patent Office that you did that.**

Q. **All right. I'd like to unpack your opinions a little bit.**

To begin with, are you familiar with something called a Manual of Patent Examine Procedure?

A. **Yes, it's the Patent Office's rules governing examination and it's published on the agency's website so that people can know all the rules that the Patent Office applies and expects them to follow during patent**

prosecution.

Q. **Is that manual sometimes referred to as the "Patent Office rules"?**

A. **Yes.**

Q. **Okay. What experience do you have with interpreting these rules?**

A. **Among other things, when I was at the solicitor's office, we're one of the offices in charge of updating the rules to make sure that -- it reflects, the rules reflect recent court decisions or changes in the statute, changes in the law.**

Q. **Could you please turn to the tab DTX499 in your binder.**

MR. YUE: Your Honor, at this time we'd like to move DTX499 into evidence. I apologize, we didn't hand up the binders, one moment, please.

BY MR. YUE:

Q. **All right. Let's try the that again. Could you please turn to DTX499 in your binder.**

A. **So the tabs I have here are just the various parts of the report, I don't have a tab for "DTX."**

MR. YUE: Apologizes, we'll get the right binder to you in a moment, sir.

May I approach again, Your Honor? Thank you.

THE COURT: Yes.

BY MR. YUE:

Q. **Third time is a charm. Can you go ahead and look at DTX499? It should be the document in front of you.**

A. **(Complies.)**

MR. YUE: And we'd like to move it into evidence, Your Honor.

MR. NIMROD: No objection.

THE COURT: DTX499 is admitted.

(Exhibit admitted.)

MR. YUE: And, Mr. Jarrett, if you can go ahead and put that up on the screen, thank you.

BY MR. YUE:

Q. **Mr. Matal, what are we looking at?**

A. **This is a section of the Patent Office's governing examination rules that are on the agency's website.**

Q. **And can you walk us through the relevant rule?**

A. **Sure, so the relevant rule is 2001.06(d). And this is the rule that requires that if you copy your patent claims from someone else, you have to disclose it to the Patent Office.**

The first sentence up there talks about an older proceeding called interferences where you also have to disclose copying. It cites it, by way of analogy, that if you -- when you disclose copying in an inference, you identify the number of the patent and the number of the

claims that you copied.

The most important sentence is the second one and as you can see it says: Clearly, the information required, you know, as to the source of copied claims is material information under the Patent Office's rules.

And "material information" is a buzzword we use in the Office that designates anything that -- if you know about it as a patent applicant, you have to tell us about it. So if we labeled something "material information," that means, if you know it, you have to tell us.

So when this rule tells you that, clearly, the fact that you copied your patent claims from another party is material information, that's Patent Office language for, you have to tell us if you copied someone else's claims.

BY MR. YUE:

Q. And why do the patent rules have this requirement?

A. Two kind of interrelated reasons: The fact that you copied your patent claims from another person's application goes to two of the core requirements for patentability.

First of all, it goes to inventorship. It naturally raises doubts that you're the true inventor if you copied your claim language, you know, from another person.

And relatedly, it raises concerns about written description support. If you copied your claim language from another person's application but you don't actually have,

you know, written description support for that, you've basically stolen that other person's invention.

Q. What if the applicant truly believes they invented what they claimed?

A. That's great. In fact, we require you to sign an oath as part of your patent application where you swear that you believe yourself to be the inventor. But in addition to filing that oath, if you did copy your claim language from another person, you have to notify the Patent Office.

Q. Now, you mentioned something called an "interference proceeding" when you were describing this rule.

Does this rule only apply to interference proceedings?

A. Absolutely not. It applies to all applications regardless of when they are filed -- the Patent Office always wants to be informed about a claim copying when it has occurred.

Q. Now, you've reviewed the prosecution history of the '782 patent?

A. Yes, I have.

Q. Did you see anything in the prosecution history of the patent relating to claim copying?

A. No, I did not. There's no indication anywhere in the prosecution history of the '782 patent that claims were copied from Avadel or from anyone else's prosecution.

Q. **Did you see any mention at all of Avadel's '866 patent?**

A. **It is cited in an information disclosure statement.**

Q. **And what's an "information disclosure statement"?**

A. **An information disclosure statement is a form that you submit to the Patent Office telling the Office about potentially material references.**

MR. YUE: Mr. Jarrett, could we go ahead and put up DDX-JM.003. Thank you.

BY MR. YUE:

Q. **Mr. Matal, what are we looking at here?**

A. **These are the several information disclosure statements that Jazz submitted when it was prosecuting its patent.**

Q. **And about how many different references did Jazz provide to the Patent Office?**

A. **There are over 350 references cited in these IDSs.**

Q. **And is the Avadel '866 patent among those references?**

A. **Yes. Although I can't read it from here, it's the highlighted reference down at the bottom.**

Q. **And you added that highlighting, right?**

A. **Yes.**

Q. **Now, what, if anything, did Jazz do to call attention to that '866 patent during prosecution of its '782 patent?**

A. **Nothing. It did cite it, you know, among 350**

references, but, you know, the requirement to cite potentially a material prior art is one thing, the requirement to tell the Office if you committed claim copying is a separate requirement.

The Office doesn't want to just be told that this reference exists, that it's out there. It wants to be informed of the fact that you copied your claims from someone else's application.

Q. **Thank you.**

Were you here for the testimony of Mr. McGarrigle, Jazz's patent attorney?

A. **Just now, yes.**

Q. **Did you hear testimony from Mr. McGarrigle that the examiner was told about an Avadel patent with sachet claims during the prosecution of a Jazz patent?**

A. **Yes.**

Q. **And just to be clear, was Mr. McGarrigle testifying about the prosecution of either one of the Jazz patents in this case?**

A. **No, no, it was about a different patent.**

Q. **And what did you see in the prosecution history of this other Jazz patent indicating that they had told the patent examiner anything about claim copying?**

A. **So I looked through the prosecution history of this other unrelated patent and that application history also has**

no -- no notice given to the Patent Office of any claim copying.

Q. I'd like to switch gears for a moment.

Are you familiar with something called the America Invents Act?

A. Yes, I am.

Q. And how are you familiar with that Act?

A. Among other things, I served as a counsel for the U.S. Senate and I assisted senators with negotiation and drafting of the America Invents Act.

Q. And what impact did the America Invents Act have on this requirement that you just described to notify the examiner of claim copying?

A. None whatsoever. The America Invents Act made a lot of changes, it was the first major overhaul of the patent system since the 1952 Act, but it did not change the reasons why you want claim copying to be disclosed to the Patent Office when it has occurred.

MR. YUE: Mr. Jarrett can we go ahead and put up DTX499 again. And can we go ahead and zoom in on Rule 6(d). That's the callout that you did earlier.

Thank you.

BY MR. YUE:

Q. Mr. Matal, we're going back to that Rule 6(d) that you just talked about.

Is there anything in here that indicates that this rule no longer applies after the passage of the AIA or the America Invents Act?

A. **No, there isn't. And, you know, the America Invents Act made a lot of changes to the law. It changed the way that you record your priority, for example. And there are parts of the law that no longer apply since the enactment of the American Invents Act in 2011.**

When that's the case, the Patent Office makes that clear in its rules. So the rules that no longer apply to these, you know, post-America Invents Act patents, you know, there's always a clear disclaimer put in there that says: This only applies to pre-AIA patents or, you know, this rule now only applies to post-AIA patents.

The fact that there's no disclaimer in here is the -- the Office doesn't want to keep you guessing and this is their way of letting you know this rule on claim copying still applies to all patents whether they were filed before or after the America Invents Act.

MR. YUE: Thank you, Mr. Jarrett.

BY MR. YUE:

Q. **Mr. Matal, was there anything else that stood out to when you reviewed the prosecution history of Jazz's '72 patent?**

A. **Yes, the nonpublication requests.**

Q. **And what is a nonpublication request?**

A. **So, you know, the, Patent Office, or, really, the law enacted by Congress wants patent applications to publish at a certain point in the process, that's just so the public can have notice of what people are planning to claim in a patent.**

So at a certain point in time, your application will publish but there's an exception to that called a nonpublication request. You can request that your application not be published.

Q. **What are the downsides to filing a nonpublication request?**

A. **So, again, the law generally wants people to publish, so it basically imposes a penalty for seeking nonpublication and the penalty for requesting nonpublication, is that you forego all patent rights outside of the United States.**

So if you get nonpublication and your claims aren't published, you can't have patent rights anywhere in any foreign country outside of the U.S.

Q. **In your experience, how common are these nonpublication requests?**

A. **Not at all common. It's less than one in ten applicants who seek nonpublication and forego foreign patent rights.**

Q. **And what stood out to you about Jazz's nonpublication**

request in particular?

A. Two things. One is, you know, these are pharmaceutical patents. They're -- they tend to be valuable. You want to -- pharmaceutical products work in foreign countries as well. You're giving up a lot of money if you forego all foreign patent protection.

The other thing that struck me about these particular requests is this was the second generation of these -- you know, these Jazz patents. The underlying application describing Jazz's invention had already been published in those earlier applications. So the thing I called the specification where you describe what your invention is and how to make or use it, that was already published. That had already been published for these earlier patents. The only thing that wasn't published as a result of Jazz's seeking nonpublication in this case was the patent claims themselves.

BY MR. YUE:

Q. And what was the practical effect of Jazz's nonpublication request?

A. The practical effect of seeking nonpublication in these circumstances was that Avadel and the rest of the world -- you delayed as long as possible the day when Avadel would learn about these particular patent claims. As Avadel's CEO testified the other day, they didn't learn

about these claims until -- until the day they'd been sued on this newly issued patent.

MR. YUE: Thank you, Mr. Matal.

I'll pass the witness.

THE COURT: All right. Cross-examination.

MR. NIMROD: Thank you, Your Honor.

If I could pass up a binder, Your Honor?

THE COURT: Yes, you may approach.

MR. NIMROD: Thank you.

CROSS-EXAMINATION

BY MR. NIMROD:

Q. Good afternoon, Mr. Matal.

A. Good afternoon.

Q. Just to make sure we're all on the same page, your testimony today related to Jazz's asserted '782 patent, not the other asserted patent, correct?

A. Yes.

Q. Okay. And to be clear -- I think it's clear from your testimony -- the '782 patent you talked about is an AIA patent?

A. Yes.

Q. And in contrast, the other one you didn't talk about, this '488 patent, is a pre-AIA patent, right?

A. I --

Q. You don't know?

A. **I don't have any reason to doubt you, no.**

Q. **All right. So for AIA patents, you would agree that proof of inventorship is a section 112-compliant patent application, meaning that a patent specification has adequate written description and enablement support, correct?**

A. **Yes, yes, I agree.**

Q. **Now, let's talk a little bit about the Patent Office, and as a starting point, during your time at the Patent Office, you never served as a patent examiner, did you?**

A. **No, I was never an examiner.**

Q. **And then after you left the Patent Office, before you were in the Patent Office, you never prosecuted patent applications as part of your practice, did you?**

A. **No, I did not.**

Q. **Okay. Now, you would agree, would you not, that the role of the patent examiner is to make sure that each patent application satisfies all the conditions of patentability of the statutes which are sections 101, 102, 103, and 112, right?**

A. **Yes.**

Q. **And section 112 was the one that's very pertinent to a lot of the cases going on, and that is the one that has enablement and written description, right?**

A. **Yes.**

Q. **Okay. And an examiner is assigned to an application. That examiner then reviews the patent drawings, the written description, and the claims of the application, right?**

A. **Yes, the examiner tests for all -- all conditions of patentability.**

Q. **Okay. Now, you mentioned the MPEP on direct, right?**

A. **Yes, the Patent Office rules, yes.**

Q. **And then you -- I think you showed the jury one portion of it, correct?**

A. **Yes.**

Q. **Okay. Can you turn in your binder to PTX1955, please.**

A. **Yes.**

Q. **You recognize PTX1955 as another MPEP section?**

A. **Yes.**

Q. **All right. And it is a section on guidelines for the examination of patent applications under section 112?**

A. **Yes.**

MR. NIMROD: Your Honor, we move to admit PTX1955.

MR. YUE: No objection.

THE COURT: Okay. All right. PTX1955 is admitted.

(Exhibit admitted.)

BY MR. NIMROD:

Q. **Now, do you understand -- you're reviewed this section in the past, I assume?**

A. **Yes.**

Q. **Okay. And this is the section that provides detailed instructions to an examiner as to how to conduct a written description analysis to make sure an application is compliant with section 112 in that regard, right?**

A. **Yes. Yeah, that appears to be that -- focused on that, yes.**

Q. **Okay. And the exhibit is about -- or the section is about 25 pages long or so, right?**

A. **I'll take your word for it.**

MR. NIMROD: Okay. And if we just turn to page .001 and we can highlight -- this right here, please, Mr. Lewis.

BY MR. NIMROD:

Q. **There's a section that informs an examiner of the general principles regarding compliance with written description. Do you see that?**

A. **Yes.**

MR. NIMROD: And, Mr. Lewis, if we can turn to page .003, it's two pages later.

BY MR. NIMROD:

Q. **It's a section on examining original claims, right?**

A. **Yes.**

Q. **And then there's a special section on .004, the next page, on new or amended claims, right?**

A. **Yes.**

Q. **And, in fact, you would agree, would you not, that the MPEP instructs an examiner to conduct a written description analysis when an applicant amends or adds new claims, right?**

A. **Yes, you test for all the conditions of patentability.**

Q. **Right. So when Avadel -- excuse me, Jazz added new claims, the examiner, following the MPEP, would have to look for written description again, right?**

A. **In every case, you test for all of the conditions of patentability.**

MR. NIMROD: Okay. Okay. Can we go to .008, please.

BY MR. NIMROD:

Q. **And then the section 3 here, on the bottom, there's another page you talked about. It was eight pages later. "Determine whether there is sufficient written description to inform a skilled artisan that inventor was in possession of the claimed invention as a whole at the time the application was filed."**

Do you see that?

A. **Yes.**

MR. NIMROD: Then if we can turn to .015, please. Actually, the bottom of 14 and 15.

BY MR. NIMROD:

Q. **There's a section at the bottom of 14 that says, "New claims, amended claims, or claims asserting entitlement to the benefit of earlier priority date or filing date under..." these certain sections of the statute, right?**

A. **Yes.**

Q. **Okay. So when someone is saying, Well, I actually invented something earlier in my application chain, the examiner is instructed on how to make the determination about whether or not that invention was kind of like there all along or not, right?**

A. **Yes, you'd always test for written description support to the -- whatever they claim priority to.**

MR. NIMROD: Okay. And if we go to .025, please.

BY MR. NIMROD:

Q. **There's also a section called "Incorporation by Reference," 2163.07(b). Do you see that?**

A. **Yes.**

Q. **And it states, "Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the**

specification."

Do you see that?

A. **Yes.**

Q. **It goes on. "The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed."**

Do you see that?

A. **Yes.**

Q. **Okay. So the examiner is, then, instructed on how to handle things like incorporation by reference as well when doing the description analysis.**

A. **Yes, the Office's rules allow incorporation by reference, incorporation of material you previously published elsewhere. You don't have to repeat the whole thing. You can just cite it.**

Q. **Okay. And then the next sentence actually says, "Replacing the identified material incorporated by reference with the actual text is not new matter," right?**

A. **Yes.**

Q. **Okay. Great.**

Now if you could look in your binder to PTX1956, please. Is PTX1956 a copy of the detailed guidance to the examiners for how to handle the enablement requirement analysis?

A. **Yes, section 2164, yes.**

Q. **And it's over 25 pages of -- 20 pages of detailed help for the examiner on how to do that, right?**

A. **Yes.**

MR. NIMROD: Okay. Your Honor, we move to admit PTX1956, please.

MR. YUE: No objection.

THE COURT: All right. PTX1956 is admitted.

(Exhibit admitted.)

BY MR. NIMROD:

Q. **Okay. Now, you've mentioned this MPEP section about instructing or advising the Patent Office when there's been claim copying, right?**

A. **Yes.**

Q. **Okay. Now, the MPEP already states that if a person adds new claims, the examiner is supposed to do the 112 analysis, including written description, no matter what, right?**

A. **Yes, you always test for written description and the other conditions of patentability.**

Q. **So whether or not somebody says, I copied these exact claims or not, the examiner has to go off and do that analysis and see was that invention really there or not, right?**

A. **Yeah, ideally they would find these -- these things**

on their own, yes.

Q. Well, they have to go -- according to those 25 pages I showed you in it, and go through to make sure these new claims are actually supported by the person who put these new claims in, right?

A. Yes, yes.

Q. Okay. And you made a comment -- I think I may have got it right -- absent written description support, you're basically -- you've basically stolen somebody's invention, right? In your words.

A. Well, if you copied claims. If you didn't copy anyone's claims and you don't have written description support, then it's just an invalid patent. But if you copied the claims from someone else and it turns out you don't have that support, then it's basically the theft of an invention.

Q. Well, in this situation, the examiner actually did the analysis, right?

A. Well, yeah -- yeah, they -- I'm sure the examiner tested -- went through standard procedure and tested for all the conditions of patentability. The only thing that was missing here was the examiner wasn't informed about copying, if that occurred.

Q. So -- but the standard -- just to be clear so the jury understands this, the standard for examining written

description and patentability, written description analysis and enablement, for example, is no different when you are told you're copying claims or the examiner is not told that. They have to go and do the right analysis either way by the same standard, right?

A. The substantive standard is always the same. You just want to take a closer look if you know that the claims are copied from another person's application.

Q. And there's nothing that you cited to the jury in these -- I think I showed you two documents that go on for about 50 pages that say there's any different standard that's applied when you copy claims versus not copied claims, right, you didn't cite a thing for the jury during your direct?

A. Well, I did cite -- well, opposing counsel cited the language requiring disclosure of claim copying.

Q. Right. My point is that once the examiner has the claim, the standard for how you conduct the analysis is the same. And nothing that you've cited in the MPEP shows a different standard for review once the examiner has it in its hands, right?

A. The substantive standard you would apply would be the same. Again, just claim copying naturally raises questions about these issues and makes you want to -- want to take a closer look.

Q. **So the examiner did take a look here, let's go to JTX12.123, please. This is part of the file history you already testified about?**

A. **Is this in the folder you just -- yes.**

Q. **I think you've already testified about this in your expert report and your deposition, this is part of the file history where the examiner is making the priority determination for the claims that you called copied.**

Do you recall that from your --

A. **So you're on page 123?**

Q. **123, that's right.**

A. **Let me flip to that.**

MR. NIMROD: Can you turn to the prior page, Mr. Lewis, please.

BY MR. NIMROD:

Q. **Just for some context here, there's a section in the examiner's office actions entitled Priority?**

A. **Yes.**

Q. **And priority determination requires the examiner to determine whether or not the claims have written description and enablement support, right?**

A. **Yes.**

Q. **And these are for the claims that you called copied, right?**

A. **I'm not -- I'm not expressing any judgment about what**

the evidence shows, whether it shows copying, that's for the jury to decide, for the claims that are in dispute here.

Q. Okay. All right. And so the priority section, the examiner goes through and evaluates all the different applications, right, that's part of her -- her job, right?

A. You go through the priority chain, yes.

Q. Okay.

MR. NIMROD: Go to the next claim, please.

BY MR. NIMROD:

Q. The final determination of the examiner is, therefore, the earliest priority -- this is for the Jazz application -- for the claimed subject matter is February 18, 2016, the effective filing date of serial number 15/047,586, right?

A. Yes.

Q. So the examiner made the determination that as of the application that was filed by Jazz in February 18, 2016, the invention was fully disclosed and supported in accordance with Patent Office rules, right?

A. I'm sure the office -- the examiner was informed of the priority claim, knew what they were claiming earliest priority to. I'm sure the examiner followed the rules, but the examiner was never informed about claim copying.

Q. My question is: Did the examiner follow the rules, look at the claims that are at issue here, and decide that

the invention disclosed in these Claims 1-24 were already disclosed in a February 18, 2016, filing by Jazz; isn't that what that filing is?

A. **The examiner applied all of the rules, determined it met the conditions of patentability, but wasn't informed about claim copying.**

Q. **My question, sir, is: Did the examiner make a finding that the invention of Claims 1-24 was disclosed, in her view, as of February 2016? Isn't that what that means, a priority determination?**

A. **The examiner issued the patent, meaning she concluded it that all of the conditions were met. Again, we have a separate rule requiring disclosure of claim copying.**

Q. **Sir, you're not answering my question. My question is: By making the priority determination, the examiner concluded that Claims 1-24 of Jazz's patent application were fully supported by Jazz's application from February 2016; that is the import of her ruling; isn't that correct, sir?**

A. **The examiner did a routine examination, determined the claims were met, and allowed a patent to issue, yes.**

Q. **Based on that priority date?**

A. **Relying on that priority date, yes.**

Q. **Now, sir, there's nothing improper about drafting claims in the continuation to try to read on a competitor's product; is that right?**

A. **No, yeah, you can -- as long as you have written description support, you can try to kind of capture your competitor's products, yes.**

Q. **And, in fact, you're entitled to do that, right?**

A. **It's within the bounds of the law, yes, as long as you have actual support and are the inventor.**

Q. **Okay. And it's not improper to amend or insert claims intended to cover a competitor's product if your application otherwise complies with all the requirements of patentability, right?**

A. **If you meet all the conditions of patentability, you're entitled to a patent, yes.**

Q. **Okay. And on the last subject, the nonpublication request, the Patent Office rules allow for you to make nonpublication requests, right?**

A. **It's within the letter of the law.**

Q. **All right. And then you made a comment about forfeiting foreign rights, but you also noted that these were continuations. Isn't it the case, sir, that no foreign rights would be forfeited if your parent applications have already been published and filed overseas?**

A. **Well, presumably, if you're seeking another patent, it's different, and you have a reason for seeking that other patent. And in that other patent where you sought nonpublication, you're not going to be able to seek --**

obtain any foreign rights.

Q. One final question, sir. It is true that you have not given any opinion regarding whether Jazz copied Claim 24 of the '782 patent, have you?

A. I note that they are similar, but -- it's the jury's job to decide what happened in this case.

Q. Actually, your opinion was on the similarity of Claims 1-4, sir, wasn't it?

A. Yes, those are the initial claims that are alleged to have been copied.

Q. And you didn't have any portion of your opinion where you opined that Claim 24 was similar, did you?

A. Well, I mean --

Q. Sir, did -- my question is: Did you give an opinion like that in your expert report on Claim 24; yes or no?

A. I analyzed the initial claims, other claims like the ones that issued that depend from that and obviously related to it. But, no, I focused on the initial claims that Jazz copied after Avadel had published its patent claims.

Q. Okay.

MR. NIMROD: No further questions, Your Honor.

THE COURT: All right. Redirect?

REDIRECT EXAMINATION

BY MR. YUE:

Q. Just two questions, Mr. Matal. Do examiners

sometimes make mistakes?

A. Unfortunately, yes. Yes, they -- they work very hard but there's a lot of record to review, and occasionally patents issue that shouldn't have.

Q. And is an examiner more likely to make a mistake when claim copying hasn't been disclosed?

MR. NIMROD: Objection.

MR. CERRITO: Objection, Your Honor.

MR. YUE: Withdraw the question.

Thank you, Your Honor.

THE COURT: All right. Mr. Matal, you may step down, thank you, sir.

MR. SILVER: Your Honor, Avadel next calls Vivian Gray to the stand.

THE COURT: All right. Ms. Gray, please take the stand.

VIVIAN A. GRAY, having been called on the part and behalf of the Defendant as a witness, having first affirmed to tell the truth, testified as follows:

DIRECT EXAMINATION

BY MR. SILVER:

Q. Good afternoon, Ms. Gray.

Can you please introduce yourself to the jury?

A. Yes, my name is Vivian Gray, I live in Hockessin, Delaware. I am a consultant for the pharmaceutical

industry. I'm self-employed, my company name is VA Gray Consulting.

Q. And what exactly does VA Gray Consulting do for the pharmaceutical industry?

A. So, I advise clients on anything that has to do with dissolution testing. Mainly, I would advise them on their FDA filings, their method development, troubleshooting.

Q. Ms. Gray, the jury has heard a little bit about dissolution in this case, can you tell them what is dissolution in a pharmaceutical context?

A. So it's when a powder enters into a liquid and forms a solution. Another way of looking another it, it tests the speed and amount of drug dissolved over time.

Q. Ms. Gray, how long have you worked in the pharmaceutical dissolution field?

A. About 40 years.

Q. Where did you begin your career?

A. At the USP.

Q. I'm not familiar with -- I now know because I know you know what the USP is, but the jury may not know.

What's the USP?

A. So the United States Pharmacopeia. The United States Pharmacopeia is a nonprofit, nongovernmental, standard-setting organization for the pharmaceutical industry. The USP is a book, essentially, full of

standards, legal standards and test procedures. This is one volume of five. And now it's online, so it's no longer using all this paper.

Q. **And how does the USP relate to dissolution in particular?**

A. **In the USP there are many standards that relate to the dissolution procedure and also in the test procedures for the dosage forms. There is a dissolution test in all those dosage forms.**

Q. **So, Ms. Gray, you mentioned you started your career at the USP. What did you do after you left the USP?**

A. **Well, first off, at USP I had various positions, mainly in the laboratory. But my last position was called the scientific liaison, and my job was to interact with the expert committee -- let's see, the volunteer expert committee on dissolution.**

So this expert committee is outside the USP, it's not staff. These are the experts that make the decisions or make the approval of any standards that go into the USP.

So I had a relationship with them as a liaison. And then after I left USP and was no longer staff, I was elected to be on this committee, this expert committee.

Q. **How long did you serve on that expert committee?**

A. **Over 20 years, and I'm serving to this day.**

Q. **Have you authored any publications relating to dissolution, Ms. Gray?**

A. **Yes, over 60 peer-reviewed articles, including about seven book chapters on dissolution. And I have coauthored this book, the Handbook for Dissolution.**

Q. **And do you have any other roles related to the publishing of dissolution-related research?**

A. **Yes, I am a managing editor of a quarterly journal, Dissolution Technologies, that is -- that contains peer-reviewed articles on dissolution.**

MR. SILVER: Your Honor, at this time Avadel proffers Ms. Gray as an expert in dissolution and dissolution testing.

MS. MURPHY: No objection, Your Honor.

THE COURT: All right. Ms. Gray may testify as an expert in dissolution and dissolution testing.

MR. SILVER: Thank you, Your Honor.

And, Your Honor, I'm just going to admit three exhibits that are not objected to so we can run more smoothly through the examination, if that's okay. And those are DTX570, DTX564, and DTX585.

MS. MURPHY: No objection, Your Honor.

THE COURT: All right. DTX570, DTX564, DTX585 are admitted.

(Exhibits admitted.)

MR. SILVER: Thank you.

BY MR. SILVER:

Q. **Ms. Gray, have you prepared demonstrative slides to assist in your presentation today?**

A. **Yes, I did.**

MR. SILVER: Mr. Jarrett, if we could pull those up, please. There we go.

BY MR. SILVER:

Q. **So, Ms. Gray, why don't we start off by telling the jury, what were you asked to do in this case?**

A. **So I was asked to assess whether the patent disclosed the MAMM formulation, and did it disclose the MAMM formulation with the dissolution profile using the dissolution conditions.**

Q. **I think the last witness's testimony was focused on the '782 patent. Which patent are you focused on?**

A. **'488.**

Q. **And what did you conclude, Ms. Gray?**

A. **That -- that no -- no MAMM -- excuse me, no MAMM formulation was disclosed and no MAMM formulation was disclosed that had the dissolution profile.**

Q. **And we'll come back to your conclusion in a minute, but let's first talk -- we've heard about a person of skill in the art, I'm going to refer to them as a skilled scientist.**

How, if at all, do you relate to a skilled scientist?

A. **So I have a bachelor's degree with 6 to 10 years of experience in the pharmaceutical or related industries. I'm also a member of a team. And also my expertise in dissolution lends itself to helping with -- or drug delivery and other pharmaceutical characteristics.**

Q. **So based on your experience, would you have qualified as a person of skill or a skilled scientist relevant to the '488 patent in 2011?**

A. **Yes, I would.**

MR. SILVER: Okay. We can take that down, Mr. Jarrett.

BY MR. SILVER:

Q. **Now, you mentioned dissolution, Ms. Gray, and we've seen various graphs showing dissolution.**

Can you explain to the jury what a dissolution profile is?

A. **Okay. All right. So you see on the screen, look at one side as the percent dissolved, that's how much of the drug that actually goes into dissolution and on the bottom is hours.**

So at the first point, at 1 hour, you have about 38 percent dissolved. At the second point, at 2 hours, you have about 62 percent dissolved. And then all the way out

to 6 hours, you have 100 percent released.

Q. And how do you get this dissolution profile, how is dissolution measured?

A. Let's see, how is it measured? You have apparatus -- well, first off, the procedure for measuring dissolution is in the USP, it's a general chapter called "Dissolution."

And in that general chapter, it talks about many, many ways -- how you would do this procedure and it also describes seven apparatus.

Q. Are any of those apparatus relevant to the '488 patent?

A. Yes, Apparatus 2, 3 and 7.

Q. Okay. Let's take a look at those Apparatus. Excuse me. Slides are a bit out of order, I'm afraid.

MR. SILVER: Mr. Jarrett, can we have DDX-VG-9, this is good, DDX-VG-10.

BY MR. SILVER:

Q. Ms. Gray, can you tell the jury what's shown on the slide, please.

A. So these are the three apparatus that I just said were involved in the patent. And let me just talk about the one on the left at first. Because this is -- I just want you to get an idea of what this dissolution test is all about.

You have a glass container, we call it a vessel,

then you have this liquid in there, the liquid is called the dissolution medium, and then you drop a dosage form into the vessel, you start the paddle and that starts the dissolution. And then you take samples over time, so this is -- essentially, I just wanted to describe dissolution to you.

Now, I'll talk about these different apparatus.

So with Apparatus 2, it's called the paddle, and you can see that it is stirring, there's a gentle stirring motion, and it's measured in revolutions per minute or rpm. In this particular case, it's 50 rpm. So as you can see, that's a very gentle rotation and that's similar to how you might be mixing sugar into your tea, a very gentle rotation.

Then the Apparatus 3, which is called the reciprocating cylinder, you can see that this apparatus is different. It goes up and down. It has an up-and-down stroke. It is similar to me as shaking your salad dressing, you know, it's more of an up-and-down motion, and it can be quite vigorous. And in the patent, the dip rate, it's called dips per minute, and it is 30 dips per minute.

Apparatus 7 has the same mechanism as Apparatus 3, in that it is an up-and-down motion, similar, like, again, to shaking your salad dressing, and it also has a fairly vigorous motion up and down, and also is -- dips per minute, measured in dips per minute.

Q. **Thank you, Ms. Gray.**

So, now that we understand the dissolution apparatus, let's look briefly at the summary chart of the examples of the patent and focusing solely on the apparatus column, can you tell the jury which Apparatus are used in the examples of the '488 patent?

A. **So we have USP 2 and USP 7.**

Q. **Thank you, Ms. Gray.**

MR. SILVER: Why don't we take that down for now, Mr. Jarrett.

BY MR. SILVER:

Q. **So, Ms. Gray, I have a question for you. If you tested the same dosage form in Apparatus 2 and Apparatus 7, would you get the same dissolution profile?**

A. **No.**

Q. **And why do you say that?**

A. **Well, for one thing, as I just showed you, the mixing is different. And so you can't -- you can't predict that if you got a certain profile in, let's say, in Apparatus 2, that you would get it in Apparatus 7 because you have this extreme difference in the way that it gets mixed.**

Q. **Fair enough.**

What conclusions can you draw with dissolution results obtained using Apparatus 7 about how a drug would dissolve in Apparatus 2?

A. **You can't.**

Q. **And why not?**

A. **Because, like I just explained, they are entirely different apparatus. They mix in a different way, and with the paddle, it's 50 rpm, and with the Apparatus 7, it's 30 dips per minute, so it's just apples and oranges.**

Q. **Would a person of skill in the art or the skilled scientist that we're talking about in 2011 have known that, Ms. Gray?**

A. **Yes, yes.**

Q. **And how would they have known that?**

A. **In a couple of ways. One is that if you look in the USP, they describe these apparatus. And it would describe for a paddle, that -- the Apparatus 2 at 50 rpm and then the Apparatus 7 would be in dips per minute, so you would already know just by reading that, that the mechanism, the mixing mechanism is different.**

And then my book, we do talk about how you can't really, you can't really say that your product would dissolve the same in one apparatus or another because of the challenges of the different mixing mechanism.

And, you know, this includes flow pattern, turbulence, all kinds of other things other than just simple mixing.

Q. **Ms. Gray, were you in court earlier this week when**

Mr. Allphin testified?

A. **Yes.**

Q. **And do you recall him testifying that results between USP 2, the paddle, and USP 7, the up-and-down motion, don't really differ that much?**

A. **Yes, I do.**

Q. **And do you agree with that testimony?**

A. **No.**

Q. **And why not?**

A. **Like I just said, you know, these two apparatus are quite different. The speed is 50 rpms with the paddle and 30 dips per minute with the Apparatus 7. You have this up-and-down motion with Apparatus 7 and you have this gentle mixing with Apparatus 2.**

Q. **Other than you telling us that, Ms. Gray, is there any support for that in the literature otherwise?**

A. **There is an article written by Dr. Rohrs that I have seen.**

Q. **Okay. Please turn in your binder to DTX570 which has been admitted into evidence.**

Okay. What is DTX570?

A. **This is the article written by Dr. Rohrs and the work that he did with his group of scientists, and it is about comparing Apparatus 3 to apparatus -- to other apparatus and see if there is any way to correlate or understand any kind**

of predictability going from one apparatus to another.

Q. And what did Dr. Rohrs and his team conclude?

A. He concluded that you can't make that assumption. You can't make an assumption that there's predictability going from one apparatus to another.

Q. Okay. And why not?

A. Like I've said already, you know, we know that these two apparatus are quite different as far as their mixing and there's really no way to compare the way that -- well, hydrodynamics is a big word but it just talks about the flow and the way it goes around and around.

Q. Now, you mentioned before --

A. I --

Q. Sorry, I didn't mean to cut you off. Were you finished?

A. Well, up and down with Apparatus 7 and around and around with that paddle.

Q. Thank you.

You mentioned Rohrs looked at Apparatus 3. The patent talks about Apparatus 7. So how, if at all, does the difference between Apparatus 3 and Apparatus 7 impact your view of Rohrs?

A. Well, when I showed the three apparatus earlier, you could see that Apparatus 3 and Apparatus 7 both had that same reciprocating up-and-down motion, so I have no

difficulty with saying that behavior of Apparatus 3 and Apparatus 7 are very, very similar.

Q. **Earlier this week, Mr. Allphin testified about a signed statement he filed with the Patent Office; do you recall that?**

A. **Yes.**

Q. **Okay. And Mr. Allphin indicated that he believed that the patent examiner would have known that Mr. Allphin was clearly referring to testing conducted in Apparatus 7; do you recall that?**

A. **Yes.**

Q. **And do you agree with that statement?**

A. **No.**

Q. **Why not?**

A. **Well, because Apparatus 7 is -- well, first of all, I'll say that I was a little bit upset that he filed a document, signed a document with a dissolution method that left out the apparatus, which is absolutely a critical part of the method, but any way, one of the reasons I was feeling uncomfortable about that is that Apparatus 7 is a very obscure apparatus.**

It's only used in -- we have in USP, we have over maybe 2,000 monographs that have these apparatus in them and maybe one, two might be with Apparatus 7. So it's obscure. It's not an apparatus that anyone, unless they

were really specialized with dissolution, would know.

So not only is the apparatus obscure; knowing that that apparatus has these 30 dips per minute and the flow rate associated with it is a stretch too far. In other words, if you barely know anything about the apparatus, to know that it would have that kind of characteristic is something that I find hard to believe.

Q. Thank you, Ms. Gray.

So we've talked about the apparatus. Earlier you mentioned a medium. What is medium?

A. So medium is the liquid, as I showed on my little, you know, diagram there that there was this vessel, this glass container, and it had liquid in it. And that liquid is the -- we call that the dissolution medium.

Q. And is there only one dissolution medium?

A. No, no. There are many, many dissolution mediums.

Q. I'm sure the jury has probably learned more about dissolution than they want to know. We won't walk through them all, but can you use water as a dissolution medium?

A. It's not favored. I mean, you can use it, but it's discouraged, yes.

Q. And turn in your binder to DTX564, which is admitted into evidence and we'll put it up on the screen.

Are you there, Ms. Gray?

A. Yes, I am.

Q. **What is DTX564?**

A. **So this is an FDA guidance for industry about dissolution testing.**

Q. **All right. And what year was this guidance issued?**

A. **In 1997.**

Q. **If we turn to the page numbered DTX564.0015.**

A. **Yes.**

Q. **We'll put it up on the screen.**

A. **Mm-hmm.**

Q. **Can you tell the jury what the FDA had to say about the use of water as a dissolution medium?**

A. **Okay. If you look down at the last paragraph, that fairly large paragraph, and go down about eight or nine lines, it says, "Use of water as a dissolution medium also is discouraged because test conditions, such as pH and surface tension, can vary depending on the source of the water and may change during the dissolution test itself due to the influence of the active and inactive ingredients."**

In other words, because of the wide pH range and other things, this is not an ideal, not really. It's a fairly discouraged dissolution medium.

Q. **Now, we've heard about pH throughout the trial, but how is pH relevant to dissolution?**

A. **Well, in two ways: The pH -- a formulation could very well have pH-dependent or pH-independent**

characteristics and the drug itself, its solubility, may -- you know, how it dissolves, would -- could very well be influenced by pH also.

Q. Can you give us an example of an ingredient that has a -- that's impacted by pH?

A. The MAMM formulation.

Q. Okay. Speaking of MAMM, Ms. Gray, let's go to DDX-VG-15. And can you remind us of your ultimate opinions in this case?

A. Well, I -- my ultimate opinions are that there's no MAMM formulation disclosed in the patent and there's no MAMM formulation that has the required dissolution profiles.

Q. So now that we know a little bit more about dissolution, I want to talk about why that is. So can you tell the jury why it is that you came to these conclusions?

A. Well, I examined the patent and especially looking at the examples in the patent, and you can see that there are 12 examples here of, you know, testing, you know, in the patent. And right there in Column No. 1 or Column No. 2, you can see that none of these examples included the MAMM formulation.

Q. Well, let's take a look at example 2. Example 2 doesn't use MAMM, but it's in the claimed USP 2 apparatus at 50 rpm in deionized water, right?

A. That's true.

Q. **Okay. So why doesn't that give you an indication as to how a MAMM formulation would behave in that environment?**

A. **Well, first off, MAMM is not tested. What they did test was a compound that is what we call pH independent. And so it would obviously behave differently from a pH-dependent to a pH-independent formulation.**

Q. **And what is your basis for saying that a MAMM-containing formulation would behave differently than the tested formulation?**

A. **Well, like I said -- well, like we agreed that MAMM is pH dependent. So, therefore, it -- it functions differently.**

Q. **Ms. Gray, turn in your binder, please, to DTX585.**

And can you tell the jury what this is? And we'll put it on the screen as well.

A. **So this is another FDA guidance.**

Q. **And what year was this FDA guidance issued?**

A. **1997.**

Q. **Let's turn to page 0018, using the numbers at the bottom, and focus in on at the top.**

And, Ms. Gray, can you tell the jury how does the FDA characterize the addition or the deletion of a release-controlling excipient?

A. **They characterized it as having a significant impact on the formulation quality and performance.**

Q. **And if one were to replace the formulation tested in example 2 with the MAMM co-polymer, would that be the addition or deletion of a release-controlling excipient?**

A. **Yes, it would.**

Q. **And when the FDA calls something a "significant impact," how does that impact the dissolution profile of the product?**

A. **It could have a significant impact and change.**

Q. **And so what does the FDA require in that event when it comes to dissolution?**

A. **So they require that with this scale-up formulation that you do dissolution testing.**

Q. **So you would need to do new dissolution testing?**

A. **Yes.**

Q. **Couldn't rely on the old profile?**

A. **No, that's why you do a new one, to compare it with the profile and see what the change is.**

Q. **Thank you.**

MR. SILVER: You can take that down.

BY MR. SILVER:

Q. **So based on what the FDA has said and what a skilled scientist would understand about the performance of a MAMM formulation when tested in accordance with -- well, strike that.**

Based on what the FDA has said about changes

to -- of excipients, what would a skilled scientist understand about the performance of a MAMM-containing formulation when tested in accordance with example 2 of the '488 patent in terms of how it would behave in the dissolution environment?

A. There's no way of knowing.

Q. Ms. Gray, we talked about the examples. Is there anything outside the examples of the patent that conveys whether the inventors had a MAMM-contained formulation or the MAMM formulation with the required dissolution profile?

A. No.

Q. Nothing at all?

A. No.

Q. Is MAMM mentioned in the patent?

A. There is -- MAMM co-polymer is mentioned once, and you can see the patent pages all laid out there. There are 30, over 30. And you can see -- zero in on that one page and in the middle of the page, it mentions in a paragraph the MAMM co-polymer, that's it.

Q. So from your perspective, what would one, a skilled scientist, looking at this patent, understand about the performance of a MAMM -containing formulation?

A. Nothing.

Q. So in view of everything we've just discussed, Ms. Gray, what is your opinion regarding the '488 patent?

A. **So there's no MAMM formulation disclosed in the patent. There's no MAMM formulation with the required dissolution profiles disclosed in the patent.**

MR. SILVER: Thank you, Your Honor, and Ms. Gray. We pass the witness.

THE COURT: All right. At this time we're going to give the jury the lunch break.

(Whereupon, the jury left the courtroom.)

THE COURT: All right. We'll come back at two o'clock.

(Recess taken.)

MR. SILVER: Your Honor, I wanted to tell you something, but I'll do it at the next break we have, if that's okay.

THE COURT: All right.

MR. SILVER: All right. Thank you.

MS. MURPHY: May we approach with binders? Thanks.

CROSS-EXAMINATION

BY MS. MURPHY:

Q. **Nice to see you again, Ms. Gray. My name is Liz Murphy. I'm one of Jazz's attorneys.**

Ms. Gray, you are the president of a consulting firm that offers dissolution testing services, correct?

A. **I'm sorry. Would you say that again?**

Q. **You are the president of a consulting firm that offers dissolution testing services, correct?**

A. **Correct.**

Q. **You and your firm could run dissolution testing on any apparatus, right?**

A. **Yes.**

Q. **Including Apparatus 2?**

A. **Yes.**

Q. **And Apparatus 7, which you describe as somewhat obscure?**

A. **Yes.**

Q. **And Apparatus 3?**

A. **Yes.**

Q. **And you could do dissolution testing in different kinds of media, right?**

A. **Yes.**

Q. **Including deionized water?**

A. **Yes.**

Q. **And just water?**

A. **Just water? I don't know that that's a medium that I would use.**

Q. **Okay. But it could be done using your firm, right?**

A. **Well, if I -- if -- what it is is my firm hires a laboratory to do the testing, okay, and then we respond to whatever we're requested to do and whatever requested**

testing we're supposed to make. So it's just -- I can't think of a situation where I would hire somebody to test just water, but I guess it's possible.

Q. In any event, you and your firm direct dissolution testing under a variety of conditions, including the ones you talked about today, correct?

A. Correct.

Q. And you've testified as an expert before in other cases, right?

A. I have.

Q. And would you agree with me that in the vast majority of those cases, you've presented dissolution testing to support your opinions?

A. Yes, I did.

Q. Okay. And you could have supported your opinions in this case with dissolution testing, correct?

A. I wasn't asked to do any dissolution testing.

Q. You could have requested samples from Avadel, right?

A. I wasn't asked to request samples from Avadel.

Q. You could have requested samples from Avadel and tested them in Apparatus 2, right?

A. I wasn't requested to do such a thing.

Q. But you didn't, you did not, in fact, do that for this case, right?

A. I didn't do any testing.

Q. **And you didn't do any testing under any apparatus, including the ones we talked about in this case, right?**

A. **Correct.**

Q. **Now, you just told the jury that the type of apparatus is an absolutely critical part of the method, right?**

A. **Yes.**

Q. **And you told the jury that the type of dissolution media is also critical to the operation, right?**

A. **Yes, it's an important component of the method, yes.**

Q. **And it's your opinion that those components matter for purposes of the formulations described in the patent, correct?**

A. **I don't know that I said that in particular that the dissolution media -- well, yes, I did, okay.**

Q. **Okay. But you presented no testing to support that opinion that those differences would actually matter in the context of this patent, correct?**

A. **That is true.**

Q. **You presented no testing at all in this case, right?**

A. **I did not.**

Q. **Now, the '488 patent, which is the patent you were discussing before, relates to formulations of GHB, right?**

A. **Correct.**

Q. **You have not studied the properties of GHB for this**

case, correct?
A. I have not.
Q. And you haven't presented any testing on the properties of GHB, correct?
A. I have not.
Q. And you haven't studied or presented on any properties such as solubility of GHB for this case, right?
A. No.
Q. It's also your opinion that the pH of deionized water varies, correct?
A. Yes.
Q. And you rely on literature for that opinion?
A. Yes.
Q. You didn't actually measure the pH of deionized water for purposes of your opinion, right?
A. Yes, and I will add that it is -- you can't measure the pH of water.
Q. You can still measure the pH of deionized water, it's not a complicated thing to do, right?
A. You cannot reliably measure the pH of water.
Q. But you relied on literature that purports to say what the pH of deionized water is in this case, right?
A. Yes, there was -- I don't know if they used a pH electrode, I think they did conductivity-something, something else other than a pH meter.

Q. **The authors of those papers were able to measure the pH of deionized water, right?**

A. **Yes. Yes.**

Q. **Okay. But that's something that you did not do for this case, right?**

A. **No, it's -- we know in the lab that it's unreliable to measure the pH of water because there's -- it absorbs carbon dioxide. And, frankly, when you try to measure the pH of water, it just drifts, you can't get an accurate measurement.**

Q. **And isn't it true that the influence of an active ingredient can change the pH of deionized water?**

A. **I think that's what the FDA says, that the pH -- we can go back and look at the definition, but that is something that can happen.**

Q. **And GHB is the active ingredient at issue in this case, right?**

A. **Correct.**

Q. **And you've conducted no analysis or study of the influence of GHB on the pH of deionized water, correct?**

A. **I did no testing.**

Q. **You told the jury that the '488 patent lacks written description because there's no example that contains MAMM copolymers, correct?**

A. **I didn't use those words.**

Q. **It's your --**

A. **My words were that the patent did not disclose the MAMM formulation.**

Q. **It's your opinion that MAMM formulations are different from formulations that do not contain MAMM, correct?**

A. **Repeat that question, let me make sure I got it right.**

Q. **In your opinion, the properties of MAMM formulations are different than the properties of formulations that do not contain MAMM, correct?**

A. **I pointed out that there was a difference and some MAMM was a pH-dependent function excipient and there were others that were pH independent.**

Q. **And it's your opinion that the properties of MAMM, specifically the pH dependency of MAMM, makes a difference that's relevant to the patent at issue, right?**

A. **Well, my opinion is, is that there's no MAMM formulation disclosed in the patent.**

Q. **You're not a formulator, correct?**

A. **That is correct.**

Q. **You're not an expert in pharmaceutical formulations, right?**

A. **That's correct.**

Q. **And you have no expertise in the properties of MAMM**

copolymers, right?

A. I do not.

Q. In fact, prior to your involvement in this case, you did not even know what MAMM copolymers were, correct?

A. That is true.

Q. And despite this lack of knowledge or expertise, you also presented no testing to support your opinions in this case, right?

A. I also presented no what? I'm sorry, repeat the sentence.

Q. Despite your lack of knowledge or expertise regarding the properties and formulations of MAMM copolymers, you also did no testing to support your opinions in this case, right?

A. I did no testing.

Q. And you told the jury that you disagreed with what Mr. Allphin said on the stand earlier this week?

A. I don't know if I said I disagreed with him, I just pointed out some of the things that bothered me that he said.

Q. Are you suggesting that he was lying on the stand?

A. I would not suggest that.

Q. And Mr. Allphin actually worked with GHB formulations, correct?

A. I am assuming so since he was the inventor of this patent.

MS. MURPHY: Thank you, no further questions.

MR. SILVER: No redirect, Your Honor. Thank you, Ms. Gray, and I'll come help you with your binders.

May I approach, Your Honor?

THE COURT: Yes.

MR. SILVER: Thank you, Your Honor.

THE COURT: Ms. Gray, you may step down.

All right. Avadel, you may call your next witness.

MR. SCHULER: Your Honor, Avadel calls for its next witness Dr. William Charman.

THE COURT: Dr. Charman, please take the stand.

WILLIAM CHARMAN, having been called on the part and behalf of the Defendant as a witness, having first affirmed to tell the truth, testified as follows:

DIRECT EXAMINATION

BY MR. SCHULER:

Q. **Dr. Charman, can you introduce yourself to the jury, please.**

A. **Yes, good afternoon. My name is William or Bill Charman. I am a professor in pharmaceutical science. I'm a pharmaceutical formulator. And I work at Monash University in Melbourne, Australia.**

Q. **What has been your role as a professor at Monash, Doctor?**

A. **I have taught undergraduate and graduate courses in pharmacy and pharmaceutical science. I have led many research programs focused broadly around drug delivery and the formulation of medicines. I have had a particular interest in difficult-to-formulate medicines. Most recently there, I was the dean of the school, and I led the school to becoming the number one ranked school of pharmacy in pharmaceutical science in the world.**

Q. **What is your educational background?**

A. **I have a pharmacy degree from Australia at an undergraduate level. I then came to the United States and completed my graduate research and PhD studies at the University of Kansas.**

Q. **What did you do after obtaining your PhD in Kansas?**

A. **I worked as a formulator in a pharmaceutical company in New York for a number of years.**

Q. **How often are you back in the United States?**

A. **About every other month over the last many years.**

Q. **Now, what organizations -- what types of organizations have you worked with during the course of your career?**

A. **I've advised governments around the world. I have advised the World Health Organization. I've had advisory roles at the Gates Foundation. And I've advised probably well over 20 pharmaceutical companies here in the United**

States and in Europe and in the UK.

Q. Now, what specifically did you work with the Gates Foundation?

A. I was an inventor, co-inventor of a new approach for a single tablet to cure malaria.

Q. Have you worked on any formulations that have become FDA-approved medicines?

A. Yes, numerous products.

Q. Can you provide some examples?

A. Those products include medicines in the field of pain relief, infectious disease, cardiovascular disease and others.

Q. What is your particular expertise within the field of formulation science?

A. Drug delivery broadly, but more specifically working with drugs that are difficult to formulate. Formulation is a pretty interesting thing. And if you've got a drug with difficult properties, how do you then develop a formulation so the drug, the raw material can then become a medicine.

Q. And what -- I guess what is formulation, for those of us that aren't in the field?

A. The drug is the raw material. We often call the final product the drug, but actually the drug itself is the raw material. What you take as a patient is a medicine, the medicine is a formulated drug.

So every medicine that you take, every medicine in a medicine cabinet has been formulated. And the reason that the raw material has to be formulated to produce the medicine is to ensure that it works reproducibly in a patient each time they take it, that it provides the benefit that the patient expects from it.

You can't just take the raw drug on its own. How do you take it? It's variable. It's possibly not stable. So the confidence that a patient has is in the formulated medicine, not the drug on it's own.

Q. **Doctor, have you authored any publications related to your research in the field?**

A. **Yes, around about 390 publications and communications.**

Q. **And have you received any awards relating to your research?**

A. **Yes, awards from the United States, from Europe, and from Australia.**

Q. **And have any of those awards related to controlled release?**

A. **Yes, there's one award in 2006. There's an international society called, if you believe it, the Controlled Release Society, that's focused on the controlled release of medicines. And that society awarded me, in 2006, the career achievement award for oral drug delivery for**

modified controlled-release medicines.

MR. SCHULER: Your Honor, Avadel proffers Dr. Charman as an expert in formulation science and sustained- and modified-release technology.

MR. CALVOSA: No objection, Your Honor.

THE COURT: Okay.

MR. SCHULER: Can you summarize the opinions --

THE COURT: In those areas.

BY MR. SCHULER:

Q. **Doctor, can you summarize the opinions you're here to offer today?**

A. **Yes, I have opinions with respect to each of the '488 and '782 Jazz patents. My opinion with respect to the '488 patent is that it is invalid for lack of written description. It is also invalid for lack of enablement. For the '782 patent, the same opinions, lack of written description and lack of enablement.**

And I also have some opinions that I will share with regard to inventorship.

Q. **Have you prepared a set of demonstratives to assist with your testimony here today?**

A. **Yes, I have.**

Q. **Now, let's begin with your opinions on written description and inventorship from -- first of all, written description, what were you asked to analyze in terms of**

written description?
A. I was asked to analyze to the expectations or the standards for written description, as to whether or not the '488 and '782 patent met those requirements.
Q. And in terms of what materials that you examined, what were you examining those patent specifications for?
A. With regard to written description?
Q. Yes.
A. There are two aspects. With regard to the written description, that's the specification part of the patent. It needs to provide evidence to a person of skill in the art, which effectively is a formulator. But there is demonstration of the full scope of the claims of the invention that's described in the patent.
Secondly, there has to be a demonstration that the -- to a person skilled in the art that the named inventors actually had possession of what they've claimed at the time that the patent was filed.
Q. Now, you referred to the person of skill, a formulator.
MR. SCHULER: Could you put up DDX3.
BY MR. SCHULER:
Q. What standard did you apply for the person of skill in the art?
A. Well, it's on the screen here. That's quite

complicated. It describes people with different levels of education, different levels of experience. Jazz's experts and myself agree with what's here. And I think the simplest way of describing it is that it's an experienced pharmaceutical formulator with experience knowing how to formulate the raw material drug into a medicine.

There's no disagreement with regard to this POSA. And what I'll do today, rather than saying person of skill in the art, I'll just use the term "formulator."

Q. And what standard were you asked to apply in forming opinions relating to inventorship?

A. Inventorship, the standard for inventorship is, again, described, and that standard is that the inventor named on the patent actually had possession of the invention that is described in the patent.

Q. And what standard of proof did you apply in examining these issues you're going to testify about here today?

A. The standard of proof is -- has to be clear and convincing evidence of support for my opinion.

Q. And what did you conclude with respect to whether Jazz was in possession of and conveyed through the specification the full scope of the claimed inventions?

A. I concluded Jazz did not for the '488 and for the '782 patent.

Q. And did you conclude that some -- did you form an

opinion as to whether someone else was in possession of the subject matter of those patents?

A. Yes, I did.

Q. Who?

A. Scientists at Avadel.

MR. SCHULER: If you could please put up DDX5.

BY MR. SCHULER:

Q. What was the basis for your analysis regarding who was in possession of those claimed inventors?

A. So the decision is this key aspect as to whom possessed what the invention was.

There were five aspects that informed my opinions here with respect to possession. Firstly, there's a lack of disclosure within the Jazz patents of the inventor's actually having possession of what that invention was.

Secondly, I had the ability or opportunity to review Jazz documentation outside of the patent itself and that documentation, at the appropriate timing in terms of filings here, highlighted skepticism that Jazz, itself, internally had with regard to the inventions of the claims.

Thirdly, I have been through the Avadel patents and I find in the Avadel patents specific formulations and clarity with regard to what was invented and a description of how that invention was made and what it was.

Fourthly, similar to where I had the opportunity to look at Jazz internal information, I've had the chance to look at Avadel internal information and as listed in point four, that internal work is consistent with my opinions.

And then fifthly, this change in claims that you've heard about, this curious change where the claims that were in Jazz, then changed to something quite different, that abrupt change mirrored what was described in Avadel.

Q. **All right. You mentioned this scope of the claims, let's talk about claim scope.**

What are the key requirements of Claims 7 and 11, which depend on Claim 1?

A. **Yes, Claim 7, it describes the sodium salt of gamma-hydroxybutyrate, that's the raw material, that's the drug, not the medicine, but the drug.**

Claim 11 describes some specific release characteristics, that's the dissolution characteristics of a formulation when it's tested under those prescribed conditions and they all relate back to Claim 1.

Q. **And what function is recited by the claims of the '488 patent?**

A. **It is the sustaining of oxybate release.**

Q. **And what construction did you apply to sustained release?**

A. **The Court provided a construction of the term, a definition and what that term or what that construction says is that the sustained-release portion, right, there's an immediate release and sustained release, the sustained-release portion is that portion of the formulation that isn't the immediate release part and the sustained-release portion releases over a period of time.**

Q. **What are the structural requirements of the claim with respect to the functional coating on the sustained-release portion?**

A. **So this is taken from Claim 1 of the '488 patent. I've attempted to represent diagrammatically what it is describing. The examples in the '488 patent are all directed to a tablet.**

So the purple there is my representation of a tablet and the aqua around the outside is my representation of a functional coating that's put on the outside of the tablet.

Within that functional coating, the only requirement is that it can -- is that it includes MAMM and that it includes MAMM at 20-50 percent.

The other remaining 50-80 percent is not described.

Q. **Now, what conclusion did you reach as to the breadth of the claims given a lack of any other structural**

requirements of the functional coating?

A. I concluded that the claims are very broad.

Q. And what is depicted here on DDX009?

A. So this diagram, I'm going to walk you through it, so be patient with me. On the left-hand side this is a range of potential dosage forms, right, so this is the formulated medicine.

Within the patent, there's a description of tablets and a description of capsules. What is in the red dotted box there are other potential formulations that, in fact, Jazz have asserted are included within the claim scope. That includes things such as patches, lozenges, microparticles, liquid solutions, suspensions, and films, so that's the range of potential final medicines that are encompassed within the scope of the claim.

Q. What did you conclude with respect to the functional coating?

A. Each one of those boxes represents a way of achieving that functional coating or potentially achieving and they are some of the complementaries or some of the ingredients that can provide a functional coating.

Q. What did you conclude with respect to pore formers?

A. The specification describes pore formers, there's thirty-plus pore formers and I have listed a number of those pore formers on the slide there.

Q. **And what did you conclude with respect to ingredient classes?**

A. **Formulations have a number of ingredients present within, the specification appeared -- or that aspect of the specification appearing at the bottom of the right-hand part of the slide is from the patent specification and it describes classes of different ingredients that are then included with those other components to then form that range of formulations.**

So those ingredient classes, it's important to remember that there's numerous individual ingredients that make up each class and then that gets multiplied, if you like, across the different classes, then combined with pore former's functional coatings to give that range of dosage forms.

Q. **What is your opinion, Doctor, with respect to whether the '488 patent specification demonstrates to a formulator that the inventors have possession of the full scope of what they claimed?**

A. **I've concluded that it does not demonstrate that.**

Q. **Why is that?**

A. **There's three primary aspects with regard to what's not present within the specification.**

Firstly, is that the '488 specification, and I'll show you some data for this in a moment, is focused on

tablets. You've heard that much of the issue here is around these microparticles, they don't appear within the '488 specification.

Secondly, as you've heard already, there's no formulation described in that specification that includes MAMM.

And, thirdly, there is no data, as required by those claims, under the claim conditions of a formulation that contains MAMM.

The third point is sort of obvious. If you don't have a formulation with it, you can't have data under conditions of such a formulation.

Q. Now, what does the specification tell a formulator, Dr. Charman, that you found particularly pertinent to your analysis?

A. Yes, GHB is a difficult to formulate drug. I'll explain more in a moment and why. This excerpt here from the specification says that formulating GHB into a unit dosage form. So that's the complete dosage form for a patient, presents many challenges just on it's own, but those challenges are magnified when the goal of the formulation project is to provide the controlled-release of GHB; in other words, it's hard enough to do just on it's own but then when you're trying to get an extended-release dosage form, it's even harder.

Q. **What are some of the particular difficulties identified in the specification?**

A. **Okay. A little bit of formulation. High dose, well, if you got a large amount of drug to formulate, you're going to need a lot of ingredients to help formulate it to modify the release, simple point.**

Q. **And what does that mean as a practical matter, Doctor?**

A. **I have tried to take a simple example. So on the left-hand side there, I have represented Tylenol. Common painkiller. 300 -- the drug in Tylenol is called acetaminophen and the amount of drug in Tylenol is 325 milligrams, less than half a gram.**

For an extended release, modified release, once-nightly formulation of sodium oxybate, the amount of drug is up to 9000-milligram. Right. So if you do the math here, that's the equivalent of 27 times -- up to 27 times the amount of drug that's present in a single Tylenol tablet. So you can see the challenge here, no one is going to take 27 tablets, I'm not suggesting that's what would be done, but you can see the magnitude of the formulation problem having to deal with that amount of drug to try and formulate it.

Q. **And what is the next challenge that the specification highlights?**

A. **It highlights GHB is very soluble. That means that it dissolves rapidly and significantly in water. The problem that leaves for a formulator, if you're formulating it and you have a solvent, a liquid, as you're trying to prepare these formulations, it might be dissolving in things before you've actually made it. You can get to a mess very quickly, that's one of the additional challenges.**

Q. **And what is the final challenge that the specification highlights?**

A. **It highlights that in terms of its chemical structure, oxybate is quite small as a molecule. And that means that it is highly permeable, let me give you an analogy.**

If you think of a mosquito net, bear with me, a mosquito net, the net represents a film, right. The film in the mosquito net keeps the mosquito out, but something small, like a gnat, goes straight through. So that's the challenge if you're using a film to control the release of oxybate. It's small. It can get into the film, it can disrupt the film or go through it before you finalized the formulation.

Q. **Doctor, in light of all of those potential difficulties, what would a formulator expect to see to believe that an inventor possessed a sustained-release formulation of GHB?**

A. **Leaves substantial challenges. The more substantial the challenge, the more the demonstration needs to be that, in fact, the inventor had achieved what they are purporting to have invented. Examples, data, in a situation such as this.**

Q. **All right. Now let's start with your first basis for your opinion that it doesn't describe microparticles, how many times is the word "tablet" mentioned in the '488 specification?**

A. **I counted this up, it appears 81 separate times.**

Q. **And what -- how many times does the specification use the term microparticles?**

A. **I counted that as well, zero.**

Q. **Now, Doctor, we've got, for those following along we're in JTX003 at column 4, lines 15-25. What does the specification say about powders?**

A. **So, this is describing -- sorry, the question was about?**

Q. **Yeah, what does it say about powders?**

A. **Powder, yes, sorry. It describes in the top highlighted yellow part there, the immediate-release component, not the sustained release, but immediate-release component could be provided, as an example, as dry powder.**

Q. **And have you considered whether this portion also discloses microparticles?**

A. **No, no.**

Q. **Why not?**

A. **This is a dry powder and that's clearly not a microparticle.**

Q. **Now, doesn't the next sentence say the IR or immediate-release component may also be formulated as a part of this single-dosage form that integrates both the immediate release and controlled-release?**

A. **Yes. It does. And that's the next sentence and then second area highlighted there in yellow says that in such an embodiment, the formulation may be provided in the form of a coated tablet, so, in other words, the two proportions put together and made into a tablet which is then coated.**

Q. **And what is your conclusion as to whether this portion of the specification provides a disclosure of microparticles for sustained release?**

A. **It doesn't.**

Q. **Why can't a formulator just apply the teachings about a tablet and make microparticles out of it?**

A. **Well, these are some of the challenges of formulation science. There's a number of reasons. The most significant is just the difference in size between a small microparticle and a tablet. The number of microparticles that are required and the challenges of then coating them.**

Q. **Have you prepared a demonstrative to assist in**

explaining that?

A. Yes. So this is drawn to scale. I had to make the Tylenol tablet that big to show you how small the microparticles actually are. If it was just the size of a Tylenol tablet, you'd hardly see it. The difference in diameter or the width of the microparticle -- and this is to scale of the microparticles that are described in Lumryz -- the microparticle is about 1/27th the width of what a Tylenol tablet is, so these are very small.

Q. How many microparticles -- Lumryz microparticles would you need to supply the same amount of drug as a 325-milligram Tylenol tablet?

A. Yeah, so I calculated, of those very small microparticles, how many of them do you need to provide the same amount of drug as would be in the tablet. It's somewhere between about 15-17,000 of them in order to provide the same amount of drug.

Q. Why does that difference matter?

A. Well, it matters for lots of reasons. If you're going to modify release through the microparticles, the modified-release microparticles, each one needs to be coated and it needs to be uniformly and repeated -- uniformly coated and the same for each one of them. So imagine having to coat uniformly each one of those 17,000 microparticles to give you what's the equivalent of the amount of the drug

that's present in Tylenol. That diagram represents about 6,000 microparticles, right? You get the idea. That's a challenge in terms of working with that.

Now, of course, if you could formulate oxybate as a tablet, you would. It's a lot more straightforward to do and easy for the patient to take.

You go to these more, shall we say, complex approaches because you've got no option but to go there in order to be able to provide the medicine so that it can be dosed once a night for the patient.

Q. Now, what is depicted on DDX22?

A. So we've spoken about the difference in volume. That was the number. Now I'm representing the difference in surface area. That unfolding was the surface area of the coating that would be on a single tablet. On the right-hand side there, what I've done to scale is to represent the surface area relevant to about 15-17,000 microparticles. You can see there's an enormous increase in the amount of area from all of those microparticles that needs to be uniformly coated to provide the sustained release.

Now, of course, this is just a representation. Later on the modified-release particles and the immediate-release are then combined later, but this is just a representation to highlight the challenge of the difference in surface area.

Q. **Have you ever attempted to make coated microparticles out of a tablet formulation?**

A. **Yes, I have.**

Q. **And what happened?**

A. **I was working as part of an experienced formulation team and we were unable to do that, exactly for these reasons. If the area is so much bigger you need more excipients, more ingredients, and actually how can you do it in a reproducible way. So I was -- myself and my team, we were unable to do that.**

Q. **Now, sir, turning to the examples, what do the examples of the '488 patent involve?**

A. **There are 12 examples described in the specification of the patent, and each example is a coated or refers to a coated tablet.**

Q. **Now, is there any evidence in the specification that microparticle formulations were made or that any testing was conducted on them?**

A. **No.**

Q. **Now, in terms of possession -- in terms of possession and inventorship, what other evidence did you consider as to whether Jazz was actually in possession of particle or multiparticulate formulations at the time?**

A. **I concluded that there was no demonstration of possession of a formulation of MAMM.**

Q. **What evidence did you look at?**

A. **I looked into the specification.**

Q. **And in terms of Jazz's internal documents, what did you look at?**

A. **I've had access to those internal documents, and I've similarly seen that there wasn't an example of such a formulation.**

MR. SCHULER: Now, can we pull up DTX661.

BY MR. SCHULER:

Q. **What is DTX661?**

A. **This is an internal e-mail from Mr. Allphin that we saw on Monday, and as part of this e-mail, he's commenting that there's an awareness that Flamel has a Xyrem-like candidate.**

Q. **And if you can look in the -- just to the left of the cutout, what is the date?**

A. **At the top there --**

Q. **Maybe look on your screen.**

A. **It is March 2014.**

Q. **All right. And how does that compare to the filing date of the application that eventually turned into the '488 patent?**

A. **This is about three years after that was filed.**

Q. **Now, if we could turn to the next page -- or the prior page, this is Mr. Allphin writing to colleagues, and**

he says in the third -- sorry, the fourth paragraph, "One thing to keep in mind, both Impax and Supernus are very good at developing bead formulations and keen on 505(b)(2). Both have heritage in drug delivery, and both would certainly be aware of the formidable challenges with sodium oxybate. I think that one would have taken a bite at this if they thought it even had a remote chance of being feasible."

How did that inform your opinions on possession?

A. What this is saying is that it's identifying a challenge associated with attempting to formulate these extended-release formulations and that companies with experience with bead formulations, he's skeptical that they would have been able to do it. If they had a chance, they would have this. This is the whole issue of challenge and whether it's possible, so this is skepticism.

Q. Doctor, if you turn in your binder to JTX219. What is it?

A. This is a Jazz document from September 2009.

MR. SCHULER: Your Honor, I'd move for admission of JTX219.

MR. CALVOSA: No objection.

THE COURT: JTX219 is admitted.

(Exhibit admitted.)

MR. SCHULER: So if we could publish that.

BY MR. SCHULER:

Q. **And what year is this, Doctor?**

A. **2009.**

Q. **What month?**

A. **September.**

Q. **Now, if we could go to 219.18. What is depicted on this page of the slide?**

A. **This is describing --**

Q. **I'm sorry. It's on the screen for you.**

A. **Yes, thank you. This -- the heading of the slide is "Platforms that Were Considered." Platform is a technology type, sort of approaches, and it says further down there "the platforms that have been rejected include film-coated beads or pellets."**

Q. **And in what year did Mr. Allphin say he was doing his work that led to the '488 patent?**

A. **Prior to that, around about 2009, that sort of timeframe.**

Q. **Now, if you could pull up DDX34. What is -- I'm sorry. Yeah, what -- this has an excerpt from DTX250. What is DTX250?**

A. **This is an internal Jazz document from August 2014 entitled Flamel Market Intelligence.**

Q. **And what is the current assumption listed on the top part of DDX35?**

A. **Yes, the assumption highlighted there says,**

"Historically, drug formulation issues have challenged the development of multiparticulate bead formulations."

Q. And what comment did Mr. Allphin offer?

A. So the comment he's offered to that says, "Sodium oxybate multiparticulate bead formulations pose challenges which Flamel may not fully appreciate."

Q. And how would that inform your analysis as to whether Jazz had possession of multiparticulate formulations even as -- even in 2014?

A. Well, this is demonstrating that it wasn't in possession.

(Reporter clarification.)

BY MR. SCHULER:

Q. Now, if we could please go back to DDX23.

Now, let's discuss your opinions about MAMM, Doctor. What did you conclude about whether the specification demonstrates possession of a sustained-release formulation that includes MAMM?

A. I concluded that it does not.

Q. Is MAMM mentioned in the specification?

A. Yes.

Q. In what context and for what purpose is MAMM mentioned?

A. MAMM is mentioned in this part of the specification under a heading of pore formers. Pore formers may or may

not been included within respect to this functional film. There are different pore formers listed. There are, in fact, three classes of pore formers with all those words up there. The third class of pore formers are these so-called enteric polymers.

There are three examples given of those enteric polymers, and they are on the right-hand side: Cellulose acetate phthalate, MAMM that we know, and polyvinyl acetate phthalate. They are the three examples of enteric polymers listed.

Q. Now, is there any indication in the specification that MAMM is a special or desirable ingredient?

A. No. If you read the sentence in blue there, so immediately following those enteric polymers being described, the sentence says, "However, incorporating enteric components in the film may result in delivery characteristics that exhibit some level of sensitivity to gastric and intestinal transit times."

This is talking about variability. You don't want variability in a medicine. So it's listed, but it then comes with a warning.

Q. And did that warning get repeated in the specification, Doctor?

A. There are other parts of the specification that repeat that sort of warning. On the right-hand side,

earlier in the specification in column 8, it talks about previous references where dosage forms have worked in a pH-dependent manner -- that's this enteric approach -- and then that similarly includes a warning, which says "when those polymers or enteric materials are used on a tablet, they can lead to intra- and inter-patient variability."

Now, what that means is -- intrapatient variability means if I took a medicine today, it may not work in me if I took it again tomorrow. That's intra-. Inter-patient variability means it might work for me, but it wouldn't work for you. That's not a good thing.

Q. So would a formulator take from these portions of the specification -- I'm sorry. What conclusion would a skilled formulator take from these portions of the specification with respect to whether to select MAMM from the potential list of pore formers?

A. Well, where MAMM is listed or enteric polymers are listed, the warning effectively is the same. So it's a teaching away or -- it's certainly not identifying MAMM to use.

Q. Now, have you considered Jazz's expert Dr. Moreton's opinions on these issues?

A. Yes, I have.

Q. And what does he point to in the specification as alleged support for selecting MAMM?

A. **He points to some phrases in column 18. In one of those phrases where it mentions the word "enteric coating," it doesn't mention "MAMM." It mentions "enteric coating," which is a class of materials. But, again, as soon as the word "enteric coating" is described -- and this is on a tablet -- it comes with a similar warning: Limits start-up time, gastric residence, and associated variability.**

Q. **And what did Dr. Moreton point to next?**

A. **In that same column, there's another way that those enteric polymers are described. Again, enteric pore formers, this is as a pore. Previous one was in terms of a coating there. Again, enteric comes with a warning, and the warning in this case is sensitivity to food effects and gastric volatility. So whether it's transit time, food effects, intra- or inter-patient variability, it's variability.**

Q. **And so what would a formulator conclude from these statements when placed in context of the entire specification?**

A. **Well, it's certainly not suggesting choose MAMM.**

Q. **Now, what example, if any, in the '488 patent specification utilizes MAMM?**

A. **Of the 12 examples, MAMM is not included in a single one.**

Q. **Is there anything that would lead a formulator to**

select MAMM as the key structural feature of a sustained-release formulation from this list?

A. **So back to this slide. Range of dosage forms, different coatings, different pore formers, different ingredient classes, MAMM, you can see at the bottom of the green column there, there's nothing to identify that. It's the needle in the haystack sort of thing. It's not obvious to choose it.**

Q. **And what conclusion did you form as to whether the specification would convey to a formulator that the inventors had possession of a MAMM formulation?**

A. **I concluded they did not.**

Q. **Now, we'll move forward, your last one was -- oops, I'm sorry -- no data under claimed conditions. Did you hear Ms. Megret's opinions regarding whether the specification has data to support the claims?**

A. **Yes, I heard her.**

Q. **Do you agree with those opinions?**

A. **I do.**

Q. **Why?**

A. **She described clearly the fact that there's specific conditions. USP 2, particular conditions for that to be operated under. There was no example of a MAMM formulation tested under those conditions that are required for the claim. You either have it or you don't. It wasn't there.**

Q. **What conclusion did you form as to whether there was any data testing microparticulate formulations?**

A. **There was none.**

Q. **And how does that inform your opinion about whether the specification demonstrates possession of what is now claimed as the invention?**

A. **It doesn't.**

Q. **Now, given the issues you identified, what conclusion did you form about whether the specification satisfies the written description requirement?**

A. **I concluded it doesn't. And we've been through each of those examples. So I put a cross with regard to microparticulate formulation, MAMM coatings, or data under those conditions, for the '488 specification.**

Q. **Now, turning now to possession, what data do you understand that Dr. Moreton points to with respect to the alleged possession of MAMM formulations, even though the information was not in the patent specification?**

A. **Dr. Moreton, in his report, referred to individual data files that he referenced that were in the files at Jazz.**

Q. **And what analysis did you undertake with regard to those data files?**

A. **So each of the data files that he described, I went and looked at the data for the experiments of the**

formulations that he described. On the left-hand side, the experimental citations; in other words, the notebook references, when it was done, and so on. The right-hand side, under the formulation, each of these tests was of a tablet. Right. And this is the '488. So each test was a tablet.

And then I looked in detail at each of those examples that Dr. Moreton cited, and each of them used USP 2 Apparatus -- sorry, none of them used USP 2 apparatus, and hence, I have put a cross in each of those boxes. None of them were tested using the required apparatus. Hence, a cross in each of the boxes under USP 2.

In terms of deionized water, five did not use deionized water, two did. But to meet the claims, you've got to have all of the requirements. And there's too many red crosses there.

Q. Were you here for opening statements, Doctor?

A. I was.

Q. And did you hear Jazz's counsel say that -- put up this slide and say that -- show that Mr. Allphin conducted experiments on MAMM sustained-release formulations?

A. Yes.

Q. And what analysis did you undertake with respect to that particular experiment?

A. So that particular experiment is highlighted in the

yellow row there. It was a tablet. The notebook reference is on the left. But the testing apparatus was not USP 2. And we've just heard, USP 2 cannot be substitutable to 7, they're different. So it did not meet that requirement.

Q. And what conclusion did you form, Doctor, as to whether Jazz was actually in possession of a formulation that falls within the scope of Claims 7 and 11?

A. It doesn't.

Q. Now, let's talk about what you analyzed from the Avadel perspective. What conclusion did you form about whether Avadel's patent publication demonstrates possession of the very deficiencies that you identified with regard to the '488 patent specification?

A. So I went through the so-called Avadel '284 on the right-hand side, and I looked at that in the same amount of detail as I did the '488. And within the Avadel patent application, there is description of the multiparticulate formulations -- of multiparticulate formulations. There is a description of formulations using MAMM within a functional coating. And there is a description of dissolution data under the claimed conditions.

So I have put a tick, a green tick next to each of those.

Q. Now, turning to DTX30, what did the Avadel inventors say that they discovered?

A. **We heard from Dr. Megret this morning how she had discovered this novel relationship between the release of oxybate from the formulation and what its performance would be in a human subject, and that's described here in this part of the specification.**

Q. **And looking at table 1d, what does this show a skilled formulator?**

A. **This shows a skilled formulator the presence of MAMM. MAMM is the equivalent of methacrylic acid copolymer type B, highlighted there in yellow.**

Q. **And what quantity is disclosed in table 1d?**

A. **So to work out the quantity of MAMM disclosed, you add up the three coating excipients and then determine the amount of that total amount that is MAMM, and that amount is approximately 27 percent.**

Q. **And what testing does the Avadel application disclose in terms of pertinent to your analysis?**

A. **Yes, this is dissolution data in USP 2 apparatus in deionized water. And this describes the results of that dissolution experiment, and those data meet what is required by the claims.**

Q. **And in what other ways did Avadel inventors test their formulations?**

A. **They tested the formulation here in the laboratory, after they prepared or formulated it. They then went on,**

because of the promising results here, they then tested the formulation in human subjects.

Q. And what ultimately happened to that formulation?

A. Ultimately, that formulation that was tested in human subjects, you heard Dr. Gray this morning talk about the progress through what's called clinical trials. And that's what was then submitted to the Food and Drug Administration, and that's what got approved that is now known as Lumryz.

Q. And so what conclusion did you form as to how -- as to whether Avadel's patent disclosures compare to the deficiencies you identified in the '488 patent specification?

A. There is a marked difference in terms of what the disclosures are.

Q. Now, I'd like to turn to the prosecution history. If you can turn in your binder to JTX9 and JTX807, if you're able to do that.

What are those documents, sir?

MR. CALVOSA: One second, I don't think I have it and I don't think the witness has it either.

(Discussion held between counsel off the record.)

THE WITNESS: So I have got nine. What was the other number?

BY MR. SCHULER:

Q. **Let's do JTX9 for now. What is JTX9?**

A. **Prosecution history.**

MR. SCHULER: Avadel moves for admission of JTX9.

MR. CALVOSA: No objection.

THE COURT: JTX9 is admitted.

(Exhibit admitted.)

BY MR. SCHULER:

Q. **Do you have a binder with PTX807, Doctor?**

A. **Yes.**

Q. **And what is PTX807?**

A. **Further prosecution history.**

MR. SCHULER: We move for admission of PTX807.

MR. CALVOSA: No objection.

THE COURT: PTX807 is admitted.

(Exhibit admitted.)

BY MR. SCHULER:

Q. **So what analysis did you conduct with the prosecution history, Doctor?**

A. **I went through the prosecution history to understand what I could. We just heard earlier this morning that that's a process that occurs. So firstly, I identified in March 2011, this was the initial filing of a patent application by Jazz.**

Q. **And what were those claims directed to, Doctor?**

A. **Those claims were directed to compressed tablets.**

Q. **And what happened next?**

A. **The prosecution process occurs. And there were a set of new claims or amended claims in October 2017, and they were similarly focused on compressed tablets as being the formulation of the invention.**

Q. **And what happened in the application that we're currently looking at?**

A. **What happened is that there was subsequently a new application made, and there was some curious changes in the claims made in the new application.**

Q. **What happened next?**

A. **Oh, it was abandoned, so these -- there was a new application filed.**

Q. **And what was the subject matter of those new claims in July of 2018?**

A. **So, the compressed tablet is no longer described. And then you can see here there is the description of MAMM and a controlled-release portion with dissolution characteristics under prescribed conditions.**

Q. **And how would you characterize the nature and extent of those changes?**

A. **It was an abrupt change.**

Q. **And did you see anything that might have caused that abrupt change?**

A. **Yes, I did.**

Q. **What was that?**

A. **Avadel, in January 2018, so in between one being abandoned and the new application filed in July 2018, Avadel's '284 published in January.**

Q. **And what did that application disclose that was relevant to your analysis?**

A. **That application described immediate-release microparticles, modified-release microparticles, the presence of MAMM, and the description of the USP 2 dissolution conditions in deionized water under those required conditions.**

Q. **And what did you conclude when you compared the information of Avadel's '284 patent application publication to the claims that Jazz sought for the first time in July of 2018?**

A. **I describe them as being strikingly similar.**

Q. **And what did you learn from Jazz's witnesses that may have led to that abrupt change?**

A. **I heard Mr. McGarrigle's deposition testimony this morning and on the video, and he described that when those new claims were being drafted for the July 2018 application, that the attorneys drafting those claims referred to the Avadel, the pre -- the existing Avadel publication.**

Q. **In conclusion, what did you -- what opinion did you**

form from the course of prosecution?

A. It was an abrupt change over time. And these new claims reflect what was in the Avadel '284 publication there.

Q. Now, let's turn to the '782 patent written description and some inventorship.

What did you conclude with respect to whether Jazz's '782 patent specification conveys possession over claim -- full scope of Claim 24.

A. I concluded that it doesn't.

Q. Now, let's look at those claims. Can you explain how the subject matter relates to Claim 14?

A. Yes, Claim 24 describes the unit dose, the unit dose is the amount of drug in the particular dose that's going to be given to the patient. And it says that that unit dose is packaged in a sachet, right, so the patient gets the sachet and refers back to Claim 14 as to the characteristics of what goes in the sachet.

Q. And what does Claim 14 recite?

A. So Claim 14 recites the following: That there is the presence of immediate-release particles, there is the presence of modified-release particles, there is the presence of a viscosity-enhancing agent, that is a thickener, the presence of an acid and the fact that the viscosity-enhancing agent and the acid, they both have to be

separate from the immediate release and modified-release particles.

Q. **What construction did you apply to modified release?**

A. **The construction provided by the Court and that construction says that the modified-release particles that contain the oxybate have a release profile that is different from that -- from the immediate-release particles.**

Q. **What did you conclude about the breadth of Claim 24 in light of Claim 14?**

A. **I concluded that the scope of the claim is very broad.**

Q. **Why?**

A. **For the three reasons that I have listed here on the slide. If you think where it just describes immediate release, microparticles or particles, modified release, acid and the viscosity-enhancing agent, it doesn't say anything about what the formulation technology is. So any formulation technology is encompassed and we'll talk about resinates in a moment but I've simply described that as any formulation technology that can include resinate or nonresinate.**

In terms of the ingredients of the formulation, it can be any pharmaceutical ingredient. And in terms of the modified release profile, it just has to be different to that of the immediate release, so it could be very long or

very different, medium or just a little different. There's no guidance given as to what the modified release profile needs to be.

Q. And what did you conclude about whether the '782 patent specification conveys possession over the full scope of that subject matter?

A. I concluded that it does not.

Q. Why?

A. The three reasons listed on the slide. Firstly, is that the '782 patent only describes resinates. There's no description of so-called "nonresinate" or what is also listed as conventional. And we'll talk about that in a moment. So the only description within the '782 is for resinates.

Secondly, that there are two examples of a resinate that was loaded, not a formulation but a resinate and there is no data to show that that could even modify the release of oxybate.

And then thirdly, there is no guidance given as to why both the acid and the viscosity-enhancing agent need to be separate.

Q. All right. Talking about the first subject, what did you conclude about whether the specification demonstrates possession of these nonresinate technologies?

A. So nonresinate technologies are described in this

part of the specification. It says that the factors complicate -- now, the factors are the difficulty of formulating GHB. So those factors complicate and in many cases, limit conventional approaches for modified release. And in the example, a conventional approach modified release is described there as is "core shell," so that's where there is a shell provided over a core, such as a tablet, for example.

And because of the solubility and the ability, that's the permeability of GHB, it reduces the number of viable approaches to prepare an extended release formulation because of these characteristics of GHB.

Q. Does the specification provide any information about conventional techniques that might solve these limitations?

A. No, it only describes the challenges and the problems inherent in them.

Q. And if the inventors were in possession of nonresinate formulation or techniques for modified release that would address these problems, what would a formulator expect to see?

A. A description of them.

Q. Now, what does Jazz's expert, Dr. Little, rely on as support for these conventional techniques?

A. Dr. Little relies upon an incorporation by reference that we heard earlier today from the patent person, that

Allphin 2012 is incorporated by reference. Allphin 2012 has the same disclosure as the '488 patent, that's the one for coated tablets.

And the challenge, of course, is that the problem is these conventional approaches of a coated tablet. So incorporating the problem certainly doesn't provide a pathway to find a solution.

Q. **Were you here for Mr. Allphin's testimony on Monday?**

A. **Yes, I was.**

Q. **What technology did he describe that was utilized in the '488 patent specification?**

A. **He described such an approach as being a core shell approach.**

Q. **And what does his later '782 patent specification say about the viability of using core shell?**

A. **It's clearly challenging.**

Q. **Now, how did that inform your opinion about whether the specification was talking about the technology -- or, I'm sorry, about whether the specification provides a disclosure that would convey to a person of skill that the inventors were in possession of conventional techniques for modifying the release?**

A. **It doesn't provide that at all.**

Q. **Now, if you could please put up DTX692.**

What is DTX692?

A. **This is an email from Clark Allphin in December 2014.**

Q. **If we could bring up the first --**

A. **Yes, background materials on PLE-2 legacy program.**

Q. **Right.**

And what does Mr. Allphin say in the second sentence?

A. **So this is in the context of the PLE-2 program which is what led to the '488 patent and he's saying here that he's providing some background information on that is Jazz's previously -- or previous unsuccessful attempt that oxybate sustained release referring to the PLE-2 program, which are the coated tablets.**

Q. **And how did that inform your opinion as to whether Jazz had actual possession of a conventional technique for modifying release as of 2014?**

A. **It doesn't demonstrate possession to me.**

Q. **And what would that tell you as to -- about whether Jazz's incorporation of that PLE-2 technology description would convey to a person of ordinary skill the ability to make a successful sustained formulation of oxybate?**

A. **Well, it doesn't. It's described as "unsuccessful." And as I said before, you can't have a solution being a problem all at the same time.**

Q. **All right. If we can go back to the presentation. Can we turn to DDX 65.**

Now, what did you conclude, Doctor, about whether resinates are a material part of the scope of the claim?

A. **Yes, resinates are a substantial part of the scope of the claim. This is my attempt at a representation as to some of the different approaches with regard to modified release and resinates are an important part of that specification.**

Q. **Now, could you explain your opinion about item No. 2?**

A. **Yes. Resinates can be loaded with oxybate, but loading doesn't mean you get release. It doesn't tell you anything about the release. So unless there's data to demonstrate that a loaded resin provides modified release, you can't conclude that there is modification of release. You need data.**

Q. **Now, what are ion exchange matrix resins, Doctor?**

A. **So, another diagram. An ion exchange resin is an ingredient. It's typically polymeric and it has a positive charge on its surface and that's represented by the dots on the purple.**

A drug with a negative charge, such as oxybate, can be loaded on to it. And the way it gets loaded, it's a bit like a north and south magnet, right, it sort of sticks to the surface. Then what happens -- so that's a loaded resin and then what happens, if there are other negative

charge ions come along, they then remove the oxybate that was otherwise previously loaded.

Q. Now, Doctor, what were the scientists at Jazz expressing internally about the viability of using such resinate technology around the time of the filing of the original patent application around 2015, 2016?

A. There was skepticism within the company.

Q. If we could put up DTX1675.

And for context, what is DTX1675?

A. This is an email from December 2017.

Q. And if we could go to DTX1675.2.

What does the last bullet point here -- I'm sorry, first of all, what is Project Tau?

A. Project Tau is the resinate project.

Q. And what does the last bullet point of this embodiment say?

A. The last bullet point says, "Ion exchange resin approach is distinct from the current JZP 324 formulation approaches; however, this is the important part -- "the probability of success remains low, approximately 10 percent," and this is in 2017.

Q. What does that tell you about whether Jazz was in possession of an invention involving resinate technology to modify the release of oxybate as of 2016?

A. It's consistent with my opinion that they did not

have possession of that.

Q. If we could go back to the presentation.

Now, turning back to the disclosures of the specification, in light of all the recognized difficulties with oxybate, what would a formulator expect to see in conjunction with a claim to modified-release technology?

A. Well, also on the slide, this is what we had before, this is the chemistry lesson, same drug, you'd expect to see the same problems described and they are being described similarly in that part of the '782 specification and, of course, they are the same because it's the same drug.

Q. And what would a formulator expect to see if -- to convey that an inventor had possession over a formulation that could modify the release of oxybate?

A. As we said for the '488, because of the challenge here, you'd expect to see examples that that challenge had been met, that there was a way to do it, there would be data and a demonstration that that challenge had been met or there was a successful outcome.

Q. Now, does the specification of the '782 patent have any data showing that resinates formulations can modify the release of oxybate?

A. No.

Q. How many examples are there?

A. There are seven examples in the '782 patent.

Examples 3-7 are described as "prophetic," hypothetical, they weren't done.

The two experiments that did support -- the experiments that supported the two examples are shown here and that is actual data in example 1 and in example 2.

Q. **What do examples 1 and 2 show?**

A. **The only data in each of these two examples is a description of how oxybate could be loaded on to two different resins, right. Remember, the purple resins, so this describes two different resins, how oxybate was loaded, but it doesn't say anything about what the release profile of oxybate was from that. It stopped only at the loading.**

Q. **Why doesn't the fact that you can load a resin with some sodium oxybate demonstrate to a formulator that it will also modify the release?**

A. **Loading and release are separate events. You don't know what the release profile will be. You need data to demonstrate what the release profile would be. Loading, you need, but it is insufficient to demonstrate release, sort of pretty obvious, I guess.**

Q. **Let's talk about actual possession, if you would turn in your first binder to DTX44.**

THE COURT: So, Mr. Schuler, just, ladies and gentlemen of the jury, I'm going to give you just a minute to stand in place. I know it's the afternoon, we've been

going for a while. Just to wake up.

All right.

MR. SCHULER: Thank you, Your Honor.

BY MR. SCHULER:

Q. Were you able to locate DTX44? In your first binder.

A. 44?

Q. Yeah.

A. I'm sorry. I'm having trouble finding it.

THE COURT: In volume 1.

THE WITNESS: Here we go. The standing up didn't help me. Yes, got it.

BY MR. SCHULER:

Q. What is DTX44?

A. DTX44 is a Jazz document from February 2019.

MR. SCHULER: We move for admission of DTX44, Your Honor.

MR. CALVOSA: No objection, Your Honor.

THE COURT: DTX44 is admitted.

(Exhibit admitted.)

MR. SCHULER: If we could publish that.

BY MR. SCHULER:

Q. And there's a mention of a company named -- a mention of the words "Tris." Who is Tris?

A. Tris is a company that had expertise in resinate technology that was contracted by Jazz to undertake the

development of a resinate approach for oxybate.

Q. And what did Jazz and Tris investigate to evaluate the release of resinates from a formulation?

A. There's some PK data. This is the pharmacokinetic data described here, and this is -- the third bullet point that is highlighted, the conclusion is that the data -- this is in human subjects -- the data are indicative of immediate release of the majority of the dose.

Q. And how does that compare to the definition of modified release that you were asked to apply?

A. Well, it's certainly not meeting the requirements.

Q. And what year was this?

A. This was 2019.

Q. And what does that tell you about whether loading a resin is sufficient to tell a formulator that it will relieve or modify the release?

A. It's consistent with my opinion that loading won't tell you what the release profile will be, and this is the release profile in human subjects.

Q. If you would turn in your binder to JTX217.

A. Yes.

Q. What is it?

A. This is a Jazz document from June 2021 entitled Jazz/Tris Collaboration Recommended Alliance Exit Termination.

MR. CALVOSA: Your Honor, at this time we move to seal the courtroom if we're going to get any further into Tris.

THE COURT: Okay. If anyone is not a --

MR. CALVOSA: I think it's going to be brief --

MR. SCHULER: It's going to be brief, and I was just conferring to see if I could avoid the need if I just tell him what I'm going to show the witness.

(Discussion held between counsel off the record.)

MR. SCHULER: Your Honor, we won't publish. We'll just have Dr. Charman read the --

THE COURT: Read it --

MR. SCHULER: -- conclusions.

THE COURT: -- without putting it on the screen.

MR. SCHULER: Correct.

THE COURT: Okay.

BY MR. SCHULER:

Q. **Doctor, if you would turn to the page 217.8.**

A. **Yes.**

Q. **The title is Pilot PK Study. Can you remind us what a PK study is?**

A. **A PK study is a study of a formulation in human subjects where you measure the amount of drug appearing in the blood.**

Q. **And what type of formulations were being tested?**

A. **Resinate formulations.**

Q. **And in the 2017 pilot study, what is listed in the results and issues column?**

A. **There is a comment here that the profile of the formulation when tested in human subjects -- it says the profile of oxybate, the profile was not at all an extended release.**

Q. **And what about December of 2018, what does it say in the results and issues that was pertinent to your analysis?**

A. **The second bullet point says -- the conclusion is: "Suggests immediate release of majority of dose."**

Q. **And what did you conclude about this information in terms of whether Jazz actually possessed a resinate formulation back in 2016 that could modify the release of oxybate?**

A. **It's consistent with my opinion that they did not.**

Q. **All right. Now if we could go back to the presentation. The last issue you identified is lack of a disclosure of separate acid and separate viscosity-enhancing agent. What does the specification say about acids?**

A. **Acids are listed throughout the specification for the different purposes that acids can provide.**

Q. **And what direction does the specification provide to a formulator as to where to place the acid?**

A. **There is no specific guidance as to where the acid should be placed within the formulation.**

Q. **Let's talk about the viscosity-enhancing agent. Is it mentioned in the specification?**

A. **The word is mentioned once, and there are some examples of potential viscosity agents listed.**

Q. **And what, if anything, does the specification tell a formulator about where to place that agent in relation to the particles?**

A. **There is no guidance provided.**

Q. **Now, the claim here says that both the viscosity-enhancing agent and the acid are separate. What disclosure did you see in the specification, if any, that would guide a formulator to that combination?**

A. **There was no guidance to guide a formulator to that combination.**

Q. **Now, let's talk about possession and turn to Avadel's patent. What did you conclude about who was in possession of a formulation as claimed in the '782 patent, Claim 24?**

A. **Yes, this is an example of the composition from the '866 patent. The presence of the modified-release microparticles, immediate release, an acid listed that's separate to those components, suspending agents -- that's viscosity agent -- they are listed as separate to those components, so it reflects the separate nature of those two**

components in the presence of the modified-release particle and the immediate-release particle.

Q. Now, how does it tell a formulator that they're separate?

A. This is the finished composition. This is the qualitative aspects, and it identifies the microparticles that are separate -- sorry, the modified-release microparticles separate from the immediate-release microparticles, separate from those other components, the acid and the three suspending agents or viscosity agents.

Q. And does Avadel's patent disclose which particular acid to use?

A. It discloses here the use of malic acid.

Q. And would a formulator know -- is there a broader list of acids?

A. There is a broader list of acids, yes.

Q. And would a formulator know which acid to select from the group?

A. Acids, for the function that they're fulfilling, are almost interchangable because of the function that's there.

Q. Now, what does the Avadel '866 patent tell a skilled formulator about the preferred packaging?

A. This is taken from the specification. The heading of this section is called "Packaging," and you can see the words there where it says, "The modified-release formulation

is preferably supplied in sachets or stick-packs." That's where the sachet concept is described.

Q. And what did you conclude about whether the '866 patent demonstrates possession of a formulation that falls within the scope of Claim 24 of the '782 patent?

A. I determined that it does.

Q. Did you review any other information on the issue of possession of such a formulation?

A. Yes, I did.

Q. What was it?

A. As I had access to internal Jazz documents, I similarly had access to internal Avadel documents. And I've reviewed those, and I have seen formulation reports and the rationale, the approach they've taken, the results from that development program that led to that invention.

Q. And we spoke about the difficulties in formulating oxybate. What did you learn in the course of your review about how the Avadel inventors were able to overcome those difficulties to achieve Lumryz?

A. I learned the way in which these microparticles are prepared, the challenges that they have addressed, the dissolution data from that final formulation, the pharmacokinetic data show it works in humans. That ultimately became the approved product by the FDA that I know as Lumryz. As a formulator, I find this to be a very

impressive piece of work.

Q. And who did you conclude was in possession of a formulation falling within Claim 24 first?

A. Scientists from Avadel.

Q. Now, let's turn to the prosecution history.

MR. SCHULER: And if we could get -- we need JTX12 and 11 and then DTX1644.

BY MR. SCHULER:

Q. All right. Doctor, do you have JTX11 and 12?

A. Yes, I do.

Q. What are they?

A. Prosecution history documentation.

MR. SCHULER: Your Honor, we move for admission of JTX11 and JTX12.

MR. CALVOSA: No objection.

THE COURT: JTX11 and JTX12 are admitted.

(Exhibits admitted.)

BY MR. SCHULER:

Q. And if you can find DTX1644 and 1645.

A. Yes, I found those.

Q. And what are those?

A. Part of the prosecution history documents.

MR. SCHULER: And we move for admission of DTX1644 and 1645.

MR. CALVOSA: No objection.

THE COURT: DTX1644 and DTX1645 admitted.

(Exhibits admitted.)

BY MR. SCHULER:

Q. **When was the first application filed relating to the '782 patent?**

A. **In February 2016.**

Q. **And what were the claims of that application directed to?**

A. **As highlighted here in the yellow, they were directed to ion exchange resins.**

Q. **And what happened next?**

A. **There was the prosecution process and there was advancement in claims in 2019.**

Q. **What were those claims directed to?**

A. **Similarly to ion exchange resins.**

Q. **And what happened next from the Jazz perspective?**

A. **There was a curious change from those ion exchange resins in September 2019 to these claims that were submitted in that application in March 2021, and those claims described no longer the ion exchange resin but the immediate-release portion, modified-release portion, viscosity agent, and an acid where the two of those are separate from the other components.**

Q. **And how would you describe the nature of that change?**

A. **As abrupt.**

Q. **And did you see anything that may have led to that change?**

A. **Yes, the Avadel '866 issued intermediate between September 2019 and March 2021.**

Q. **And what did you depict on DDX-WC0.085?**

A. **So what I've done here is to -- on the left-hand side, this is the '866 Avadel patent that issued in August 2020. And then on the right-hand side is what was filed by Jazz in March 2021, and I'm just going to walk through what the key elements are.**

Firstly, is that each now, or each demonstrates the presence of an immediate-release portion and a modified-release portion of oxybate. Each demonstrates the presence of a suspending or viscosity-enhancing agent, and there are examples of what those agents are. It then moves on to show the presence of an acidifying agent or an acid, and there are examples of those acids listed, and interestingly, the order of those are identical in terms of the listing of the acids. And, importantly, the fact that the acid and the suspending agent both need to be separate from the immediate-release and modified-release particles.

Q. **And what did you conclude based on the language alone?**

A. **They're nearly identical.**

Q. **And did Jazz see Avadel's patent?**

A. **Yes, as we heard this morning from the video deposition testimony from Mr. McGarrigle, the Jazz patent attorney, he highlighted or described how the drafting of those new '782 claims -- sorry, the new claims in the '782 application, that the patent attorneys referred to the Avadel patent as they were drafting those new claims.**

Q. **And what did you conclude about who first had possession of a formulation falling within the scope of Claim 24?**

A. **I concluded that Avadel first had possession of that invention.**

Q. **Now, let's talk about Claim 19 of the Jazz '782 patent. What does it involve?**

A. **Claim 19 of this patent, as highlighted here in yellow, describes a unit dose of Claim 14 -- that's the formulation in the sachet -- wherein eight hours after administration of the formulation -- so that's after administering that formulation to a subject -- that there were blood concentrations of oxybate ranging from 15 to 30, as described there.**

So take the formulation, give it to a subject, and at eight hours, these are the concentrations of oxybate in the blood.

Q. **Does Jazz's '782 patent specification support a unit dose of oxybate that achieves such blood levels after**

eight hours?

A. **No.**

Q. **And does Avadel's 08 -- I'm sorry, '866 patent show possession of a formulation that can achieve that range?**

A. **Yes. On the left-hand side there are data from the Avadel patent, and those are data from human subjects that had been administered the formulation and where the blood concentration of oxybate at eight hours was, in fact, measured, and those data are described on the left-hand side there.**

Q. **Now, I want to talk to -- talk to you about nonenablement. What conclusion did you form on enablement of the two patents at issue?**

A. **That neither are enabled.**

Q. **And what standard did you apply in evaluating the issue of enablement?**

A. **That the specification needs to be able to demonstrate to a person of skill in the art the way in which to practice the full scope of the invention.**

MR. SCHULER: If you could go to DDX90, Mr. Jarrett. No, DDX.

BY MR. SCHULER:

Q. **All right. What specific criteria were you asked to evaluate in discerning whether or not enablement was satisfied?**

A. **Yes, there's a framework that I followed, they are called Wands factors, each of those Wands factors are described in those green boxes. And I assessed each of those factors with respect to each of the patents as to whether or not that part of the Wands factor was satisfied.**

Q. **All right. What did you conclude -- the first is scope of the claims. What did you conclude about the scope -- the breadth of the scope of the claims of the '488 patent?**

A. **A bit of a revision. This is the '488 patent slide that we had. This is just demonstrating how broad it is, it's -- or the breadth of that encompassed with the scope of the claims.**

Q. **And what did you conclude about the breadth of the '782 patent claims?**

A. **Further revision. This is what we saw before with regard to the '782 patent and how broad those claims are.**

Q. **Now, the next is nature of the invention. What is the nature of the invention here, Doctor?**

A. **The nature of the invention is working with a difficult-to-formulate drug, high-dose, solubility, permeability, those issues. So a difficult-to-formulate drug and the nature of the invention is to formulate that difficult-to-formulate drug into a medicine or an extended-release or modified-release formulation that would,**

in fact, modify the release of the drug for the benefit of the patient.

Q. **And is there information in the -- either of the patent specifications that would allow a formulator to reliably predict whether a given formulation would have the desired release profile?**

A. **Yes.**

Q. **Next, the level of skill in the art and the state of the art. What was the state of the art as of 2011, when the original filing -- the original application was filed for the '488 patent?**

A. **The commercial formulation of oxybate that was available in the marketplace was Xyrem, the solution formulation, that's what the state of the art was at the time.**

Q. **How had it changed, if at all, by 2016 when the '782 patent was filed?**

A. **It was still dissolution formulation. There were no other examples of extended-release formulations available. So the state of the art was basically the same.**

Q. **And how does that inform your opinion on enablement?**

A. **The challenge is as significant as we have described, there was no guidance from the state of the art as to what to do.**

Q. **Next is teachings in the patent. You've talked about**

that a lot. What did you conclude about whether there are teachings in the patent sufficient of both specifications to teach a person how to make and use the full scope of what's claimed?

A. Yes. Not to go through everything we've been through; the teachings in the '488 and the teachings in the '782 are insufficient to inform a formulator as to what to do with regard to the preparation of specification within that scope of the claim.

Q. And what did you conclude as to whether there was a common thread teaching in the '488 specification that would guide a formulator to be able to predict whether a particular formulation would be able to sustain release?

A. I concluded that there wasn't a common thread in either formulation that could provide that guidance.

Q. What about MAMM, why isn't MAMM a common thread that would allow a formulator to predict that a formulation would, in fact, sustain release?

A. MAMM, if it's used, right, and it comes with these warnings. But it's one ingredient. There are so many more other ingredients that are necessary within a formulation in order to provide for the modification of release, so I don't consider that as a common thread.

Q. And what did you consider as to whether there was some common thread in the '782 patent specification that

would enable a formulator to reliably predict whether a particular formulation would or would not modify release?

A. I could not identify a common thread being present.

Q. What did you conclude about the quantity of experimentation that would be required to practice the full scope of the claims?

A. It would be excessive. There's a lot of experimentation that would have to be done in an attempt to formulate a material such that it might meet that is -- as is described in the claims.

Q. Just as a practical matter, what would a formulator have to do to attempt to make a formulation to see whether it could modify or sustain release?

A. Well, you'd have to understand the challenge, come up with the appropriate approaches in terms of following what teachings are available and indicated the limited. They'd have to make the formulation. They would then have to test it. They would have to make another one and test it. Just making it, if you can, doesn't tell you whether it's going to work. So it's, a right trial and error process.

Q. And, sir, what did you see -- you evaluated a couple of Jazz programs in the course of your work, is that fair?

A. Yes.

Q. What were they called?

A. The programs, the '488 program and the '782 program,

one was the sustained-release tablets and the other was the resinate program.

Q. Right. If we go back to DTX692. How did Jazz describe that PLE-2 program?

A. It described it as an unsuccessful attempt at oxybate sustained release.

Q. And if we put up JTX217.2. What did Jazz conclude in the first two bullet points about its resinate effort?

MR. CALVOSA: Objection, Your Honor, can't just have the expert witness read the documents in, he has to give an opinion on how it affected his opinion.

MR. SCHULER: He will.

MR. CALVOSA: Not the last one, you just had him read it.

MR. SCHULER: I'll read it and I'll ask him his opinions, that's fine.

BY MR. SCHULER:

Q. Here it says, "Failure to meet PK criteria after three and a half years and eight formulations, lack of scientific and formulation success."

What did you conclude, Doctor, as to whether an ordinary person, ordinary formulator could succeed where Jazz indicates that it could not?

A. After that amount of time, that number of formulations and the experience and expertise Jazz has had

with oxybate over the years, it really wasn't formulation that was meeting an outcome here.

Q. And what did you conclude about whether an ordinary formulator would be able to succeed, given that level of effort by Jazz?

A. Not possible.

MR. CALVOSA: Objection, Your Honor, it's asked and answered three times now. He's not getting the answer he wants.

THE COURT: Okay. That's the last time he'll ask it.

MR. SCHULER: No further questions.

THE COURT: All right. Cross-examination.

MR. CERRITO: May I approach, Your Honor?

THE COURT: Yes.

CROSS-EXAMINATION

BY MR. CALVOSA:

Q. Dr. Charman, good to see you again, how are you?

A. I'm well. Thank you.

Q. A birthday in the family -- or have a birthday in the family coming up on Friday, right?

A. You have a good memory.

Q. I have a great memory.

I'd like to start on -- I'm going to work off your slides, just so it's easier.

MR. CALVOSA: Could we pull up DDX62, please, Mr. Lewis.

BY MR. CALVOSA:

Q. **And you had mentioned before the incorporation by reference of the published application of the '488 patent specification in Allphin 2012, right?**

A. **Yes.**

Q. **And you said how the '782 patent discussed some of the same problems -- or I guess the same three categories of problems that were discussed in the '488 patent, right?**

A. **The three categories, what do you mean?**

Q. **Well, you have them if you go to slide 68, I believe. Yep.**

A. **Oh, the properties of oxybate, yes.**

Q. **Yes. And if you go back to the beginning, when you discussed it in the context of the '488 patent, and we look at what you put on slides 11-16, and you called out different portions of the '488 patent specification, and you had pictures there corresponding to the three problems, you didn't tell the jury what the bottom of that paragraph says, right?**

MR. CALVOSA: And, Mr. Lewis, can you please call out the bottom three lines.

BY MR. CALVOSA:

Q. **And right there, the inventor in the '488 patent**

discloses that "despite the challenges noted, formulations and unit dosage forms providing controlled release of GHB are described herein," right?

A. **Yes, it does.**

Q. **And a POSA would have read that, right?**

A. **Pardon?**

Q. **A POSA would have read that, right, you did not read that portion to the jury?**

A. **I'm happy to read it now, no.**

Q. **You said that Avadel's Lumryz product is a microparticle formulation, right?**

A. **Relatively speaking, yes.**

Q. **If we could go to your slide DDX19, you had some information up here and you talked about how a powder is not a microparticle formulation, right?**

A. **Yes.**

Q. **Okay. And that's why there were no microparticles disclosed, you said, even for the immediate-release portion, right?**

A. **That was one of the reasons, yes.**

Q. **Okay. We'll come back to that, I promise. I think I have kept my word when I said I would come back to things this week, so I'll do it.**

A. **Okay. Thank you.**

Q. **You had talked about how loading on a resinate**

doesn't guarantee modified release of a resinate, right?
A. Yes.
Q. And you don't disagree with me that the '782 patent describes how to load GHB on to a resinate, right?
A. That's correct.
Q. And it gives different binding affinities for GHB depending which molecule GHB substitutes in for on the resinate, right?
A. There's a description of relative finding affinities, yes.
Q. And it gives information about how you do that and you do multiple washes and equilibrium to get the most loading on that resinate, right?
A. Yes, there's an example.
Q. But you just think that binding a resinate doesn't equal releasing a resinate, right?
A. No, it doesn't.
Q. Okay. Now, you've never personally prepared any formulations for resinate, correct?
A. That's correct.
Q. And you have not worked with your own hands on the use of resins for the control on drug release, right?
A. I have worked with resins for other purposes but not personally for the control of drug release, that's correct.
Q. And control of drug release is what we're here

talking about this week, right?
A. Yes, it is the concept in my report, of course.
Q. And you've never published on using resins to control a release of any drug formulation, right?
A. That's correct.
Q. And you don't have any products related to control and the release of drug patents with resins, right?
A. That's correct.
Q. The challenges we looked at for GHB and then the ones the inventor said they overcame, the inventors actually had hands-on experience working with GHB, right?
A. Yes, they did.
Q. You've never worked hands on in the formulation of GHB, have you?
A. No, I haven't.
Q. And you've never published on the formulation of GHB, correct?
A. That's correct.
Q. And none of your patents talk about the formulation of GHB; is that right?
A. Correct.
Q. You mentioned before that -- when counsel asked you about the transition from tablets to microparticles, that you tried it and was unsuccessful. Did I hear that right?
A. I described how I was working with a team of

experienced formulators and we were unsuccessful and unable to go from a coated tablet to coated microparticles of the same medicine.

Q. **You have formulated both a tablet and a microparticle modified-release formulation of the same active ingredient, right?**

A. **Yes, I have.**

Q. **And that's what you told me at your deposition, right?**

A. **Yes, that's right.**

Q. **We looked at a lot of internal Jazz documents for your possession opinions earlier, right?**

A. **Yes.**

Q. **And we looked at a lot of Avadel internal documents for your possession opinions earlier, right?**

A. **Yes.**

Q. **And with respect to the Jazz documents, you actually prepared something called Appendix E to your expert report as part of your work in this case, right?**

A. **That's correct.**

Q. **Now, Appendix E was just a selection of documents that Jazz provided to Avadel in discovery in this case, right?**

A. **They were included in this -- in the documents that I reviewed in Appendix E, I can't remember every reference**

that I cited in Appendix E, but they were documents from Jazz, yes.

Q. And the way you got those documents to prepare Appendix E, is that they were selected by Avadel's counsel, right?

A. They were provided to me by Avadel's counsel, yes.

Q. Sir, they were selected by Avadel's counsel, correct?

A. I guess they had to select them to provide them, yes.

Q. They didn't provide you with every document that Jazz produced to them?

A. No. No.

Q. Okay. And you didn't ask Avadel's counsel for any specific documents for the preparation of your Appendix E when you were preparing your opinions, right?

A. The documents that I had been provided, I went through them and those that I felt were relevant to the opinions and the description I was given, they are, then, referenced in the reference list in the back.

Q. Sir, that wasn't my question.

A. Sorry.

Q. We established that counsel selected the documents for you.

A. Yes.

Q. My next question, what I asked, and please, I'm on limited time, I'll get yelled at, just yes-or-no answers if

you can.

You didn't ask Avadel's lawyers for any specific documents for preparation of Appendix E?

A. No, there was no specific document asked for. I had what I felt that I needed to prepare Appendix E.

Q. But you wouldn't know what else was relevant unless counsel gave you the documents, right, you didn't have the universe to look at?

A. From Jazz itself, no, I didn't.

Q. And the same was true with respect to deposition transcripts that you reviewed before you prepared your expert report and heard all the facts in this case, right?

A. There was some deposition transcripts that I had reviewed and they were provided to me, yes.

Q. And they were selected for you by counsel for Avadel, right?

A. They identified what they wanted me to review and then provided them to me.

Q. As part of your work in this case, you reviewed the file history of the '782 patent, right?

A. Yes.

Q. And that's the one we're here about today, correct?

A. Well, we're here for both, right? '782 and '488.

Q. '782 and '488, so it's one of the ones we're here for today.

A. **Yes.**

Q. **There was also another related patent, the '079 patent, correct?**

A. **Yes.**

Q. **And counsel actually gave you the '079 patent's file history before in those big voluminous binders?**

A. **I didn't go through each of the pages that were in there. When I was asked what they were, I described them as prosecution history, I didn't look to see which of the different patents it referred to. It was prosecution history material, I think I described it as "prosecution history documents."**

Q. **Can you turn to JTX5 in your binder, it should be the first one.**

A. **Yes.**

Q. **That's the '079 patent, right?**

A. **Yes, it is.**

MR. SCHULER: Objection, Your Honor, sidebar.

(Whereupon, a discussion was held at sidebar as follows:)

MR. SCHULER: Objection. This has been dropped from the case. It's not relevant to any issue that I'm aware of. Why are we going --

MR. CALVOSA: You marked the file history for the '079 patent.

MR. SCHULER: I didn't ask any questions.

MR. CALVOSA: You entered it into evidence for what purpose? Regardless, I asked him, in his '079 patent specification, substantially said, "Are any of your opinions different between the '079 specification and the '782 specification?" He said, "No," so then I used the '079 patent specification during the deposition.

MR. SCHULER: Patent specification during the deposition, I'm just trying to establish that now, so that way, if there's an issue where impeachment comes up, I can use the '079 patent as well.

THE COURT: That's fine.

MR. SCHULER: I was just going to say I may have asked you about this --

MR. CALVOSA: It's just a line and the close-up numbers are different. I don't want to get into a situation where she's saying that's not what it says.

(Whereupon, the discussion held at sidebar concluded.)

BY MR. CALVOSA:

Q. **You recognize the JTX035 as the '079 patent, right?**

A. **Yes.**

MR. CALVOSA: And, Your Honor, I'd like to enter the '079 patent, JTX05 for evidence at this time.

MR. SCHULER: Limited purpose for which it was

offered, no objection.

THE COURT: All right. It's limited for the limited purposes to discuss --

(Exhibit admitted.)

BY MR. CALVOSA:

Q. I didn't want to break my promise so my colleague over here brought me JTX87, which is the Lumryz label.

A. Yes.

Q. And you've seen this before, right?

A. Yes, I have.

MR. CALVOSA: Okay, Your Honor, I'd move to admit JTX87.

MR. SCHULER: No objection.

THE COURT: JTX87 is admitted.

(Exhibit admitted.)

BY MR. CALVOSA:

Q. And we were talking about before how the Lumryz is the microparticle formulation and how in your opinion a powder is not a microparticle, right?

A. Yes.

Q. Can you --

A. As described in that part of the specification, but yes.

Q. Just that part of the specification?

A. No, no, I said before, more broadly as well, but

that's the anchor point in terms of the comments that I made here to the question that I was given.

Q. Can you turn to page 3 of JTX87.

MR. CALVOSA: And, Mr. Lewis, if you could blow up section 3, dosage forms and strengths.

BY MR. CALVOSA:

Q. It says right here that Lumryz is a white to off-white powder, correct?

A. Yes.

Q. Okay. So...

MR. CALVOSA: You can bring that down.

BY MR. CALVOSA:

Q. Back to the '079 patent and how it's related to the '782 patent. You agree that the specification of the '079 patent is substantially similar to the specification of the '782 patent, right?

A. There's two or three paragraphs different, so if that means "substantially similar," yes.

Q. None of the changes between the specification of the '079 patent and the '782 patent affect your opinions, right?

A. Opinions with respect to what?

Q. With respect to any of the opinions you offered here today?

A. I don't believe so.

Q. Do you recall telling me at your deposition no, they

don't?
A. That was a long time ago, I'm just trying to think how much you've got stacked up in there.
Q. All right. Why don't we turn to your deposition transcript. Volume 2, page 287.
A. Where do I find that?
Q. It's at the very end of your binder.
A. Oh, sorry, volume 2, 287.
Q. 287:23-288:1. And I'll ask you again, Dr. Charman.
"QUESTION: Do any of the changes between the '079 patent specification and the '782 patent specification affect your opinions?" --
A. Yes, I said that, "No, they don't." And the reason I didn't give you that exact answer then is that I had not looked at the '079 for a little while.
Q. -- I'm not trying to call you a liar. I'm just trying to establish that they are the same.
A. Yes.
Q. You reviewed the file histories for the '079 and the '782 patent, right?
A. Yes.
Q. And that's back and forth with the Patent Office that Jazz had, correct?
A. Correct.
Q. And you don't know whether the examiner did a

substantive written description analysis for the '079 patent's claims, right?

MR. SCHULER: Now I do object, Your Honor.

MR. CALVOSA: I'm happy to explain why.

(Whereupon, a discussion was held at sidebar as follows:)

THE COURT: Speak one at a time. You need to speak one at a time. Speak to me. No double-teaming.

MR. SCHULER: My objection is that he's now asking about the claim and subject matter, of course, any review under 112 would be with respect to what was the claimed subject matter. That's different from the '079 patent and the '782 patent that they are now asserting.

MR. CALVOSA: It's the overlapping sachet element, Your Honor. The examiner did a substantive description analysis specific to the sachet element in the '079 and Dr. Charman didn't consider that, and that's relevant because the specification of the '782 patent, as I just established, is substantially the same as the '079 and none of the changes affect his written description.

MR. SCHULER: They had a chance to examine for two days. They could have asked him about Claim 24, the claim they are asserting, and asked him questions about what the examiner did or didn't consider. They didn't do that.

MR. CALVOSA: The examiner considered -- in the

context of the '079, it was the same examiner. It was literally days apart. It was what they're saying she went through, both patents' file histories, she was doing things for both. She did the sachet in the '079. She did other elements in the -- and once the examiner did it for the '079, as my colleague pointed out, then there's no reason to do it for the '782.

MR. SCHULER: Your Honor, he offered it for a limited purpose. He said --

MR. CALVOSA: You entered the entire file history.

(Reporter clarification.)

THE COURT: Speak to me.

MR. SCHULER: He offered it for the limited purpose he said --

(Simultaneous talking.)

MR. SCHULER: My impeachment is that I asked him about the '079 specification and I said for that limited purpose I understand. But now he's asking about the claimed subject matter, which is different.

MR. CALVOSA: Your Honor, it's the entire file history that he entered into evidence --

(Simultaneous talking.)

MR. CALVOSA: I can use that. He entered it into evidence.

THE COURT: And so she only did one analysis of the sachet, you're saying, the analysis would have applied to the '488 patent and this patent?

MR. CALVOSA: The '782 patent.

THE COURT: So what's your response to that?

MR. SCHULER: That is a large logical leap that this witness will not be competent to comment on.

MR. CALVOSA: I'm not going to ask him if he knows the examiner did a substantive review. He already answered no. That's all I'm getting to. It's two to three questions, Your Honor. I'm not going to go into the file history.

MR. SCHULER: Again, the limited purpose was I asked my questions at deposition and they were about the '079 specification.

MR. CALVOSA: That was about -- about the patent. He entered the entire file history. He's trying to confuse -- I'm wasting a ton of time here.

MR. SCHULER: My point is one question after a limited purpose. We now jump to the limited purpose. He's now asking about the claimed subject matter rather than his impeachment.

(Simultaneous talking.)

MR. CERRITO: To be fair, that was a limited purpose to that question that was then pending. If he

enters the file history and we can't ask questions about that, that seems a little unfair.

THE COURT: All right. I'm going to allow no more than three questions.

MR. CALVOSA: Thank you, Your Honor.

(Whereupon, the discussion held at sidebar concluded.)

BY MR. CALVOSA:

Q. You don't know whether the examiner did a substantive written description analysis for the '079 patent's claims, correct?

A. I have reviewed the prosecution history. I don't recall seeing that term within it, but there were many pages and I did that some time ago.

Q. And you don't know whether the examiner did a substantive written description analysis for the '782 patent claims, right?

A. Same answer for that, yes.

Q. You only read through the file histories of those patents in what you termed "quickly," right?

A. Quickly doesn't mean ignoring the key parts. I went -- there's many pages for the different parts, so I was looking at it section by section. So if that's what you describe as "quickly," that's what I did, but I was looking for headings, and if the heading wasn't relevant, I then

didn't read all the material that came after that.

THE COURT: So, Dr. Charman, did you use the term "quickly" in your response to Mr. Calvosa's question? That's all he was asking you.

THE WITNESS: Oh, I was trying -- well --

THE COURT: Your counsel will get a chance to redirect and allow you to explain what quickly means, but he's just simply asking you: Did you use the term "quickly"?

THE WITNESS: When I was reviewing them -- I'm sorry. I'm --

BY MR. CALVOSA:

Q. I'll ask the question again.

A. Yes.

Q. Dr. Charman, you only read through the file histories of the '079, '782 patents in what you called "quickly," correct?

A. Quickly and carefully, but...

Q. Dr. Charman, when I asked you at your deposition, you only said "quickly," right?

A. I don't -- well, if that's what I said, yes, I'm providing you some context here today.

Q. Your counsel can ask for context on redirect.

A. Okay, okay.

Q. I'm on a limited clock. Please --

A. **Yes.**

MR. CALVOSA: Your Honor, would you like to take a break at this time?

THE COURT: Yes. How much longer do you think you have?

MR. CALVOSA: 20, 30 minutes.

THE COURT: Okay. All right.

All right. Ladies and gentlemen of the jury, we're going to take the afternoon break at this time.

(Whereupon, the jury left the courtroom.)

THE COURT: All right. Take a ten-minute break then back.

MR. SILVER: Your Honor, can we talk on the record before the jury comes back in after the break?

THE COURT: Yes. But do you want to do it now before we --

MR. SILVER: We still have --

MR. CALVOSA: May I be excused, Your Honor? Do a little prep work, see if I can cut it down? Thank you.

MR. SILVER: So, Your Honor -- thank you, Your Honor. So the way this is playing out, it appears that we will be in a position to close our case this afternoon. Under the circumstances that we've already discussed with regard to Dr. Meyer and her condition, I don't --

MR. SCHULER: Dr. Charman, you want a break?

THE WITNESS: Sure.

THE COURT: Dr. Charman, you're still under oath, so you can't talk to your counsel until you finish.

THE WITNESS: I understand. Thank you.

MR. SILVER: So, Your Honor, with regard to Dr. Meyer and her condition, the way it's shaping up is we are not planning to call her and we'll just rest our case after this witness.

However, under the circumstances, we were inclined to ask Your Honor for some sort of instruction, but after conferring with counsel, we have agreed that neither side will reference during closing that Dr. Meyer had an issue that precluded her from testifying or that Avadel didn't present a damages witness. We just want to make sure that the playing field remains level in the light of the way things transpired.

THE COURT: Okay. All right.

MS. THOMPSON: Yes, we have no objection to that --

THE COURT: All right.

MS. THOMPSON: -- that we won't be referencing Avadel not presenting an expert witness on damages or Dr. Meyer at all.

THE COURT: All right. All right. Sounds like both parties are in agreement and agree to not reference the

fact that Avadel has not presented a damages expert and will make no reference to Dr. Meyer at all. All right.

So we'll come back at 4:15.

MR. SILVER: Thank you, Your Honor.

(Break taken.)

MR. CERRITO: Your Honor, we've been talking about just time management and where this is going to land. Obviously upon the close of their case, I wanted to make my Rule 50 motion, but instead of wasting the jury's time and Your Honor's time, obviously, if we could do a short submission, they'll oppose, Your Honor will rule, and we think that that would allow us to finish the case, hopefully, by the lunch break on Thursday, have the charge conference, and be ready to close Friday morning.

THE COURT: All right. So you'll submit your written submission tonight --

MR. CERRITO: Yeah.

THE COURT: -- and they'll respond and then --

MR. CERRITO: Nine o'clock, Your Honor.

THE COURT: Yeah -- and then I can rule in the morning on it.

MR. CERRITO: Well, when you rule for us, yes, it'll be -- it would be really nice. Yeah, I don't want to waste the jury's time --

THE COURT: Right. Well, the jury wasn't going

to hear --

MR. CERRITO: No, no, but they'd have to wait while --

THE COURT: Well, I was going to let them go.

MR. CERRITO: Oh.

THE COURT: By the time we get finished, it's probably going to be close to 5:30 anyway, but I'm willing to -- if both sides are willing to get their submission in by -- you do yours by what time?

MR. CERRITO: Nine o'clock -- nine o'clock, Your Honor.

THE COURT: Let me hear from you.

MS. DURIE: Could we -- could we just chat about it for one moment, Your Honor.

THE COURT: All right. If Defendant could get theirs in, let's say, by 6:00 a.m.

MS. DURIE: That seems unduly --

MR. CALVOSA: It seems unfair to them.

(Discussion held between counsel off the record.)

MS. DURIE: We'll just do it on the record.

THE COURT: Okay. We'll go on the record.

All right. So what we'll do is we'll do those first thing in the morning, so we'll finish with this. That should take us to 5:00.

MR. CALVOSA: I'm hopeful for shorter than that, Your Honor.

THE COURT: Okay. You're going to have some redirect, I assume, maybe.

All right. And then -- so we'll see where we are at. Let's get the jury.

(Whereupon, the jury entered the room.)

BY MR. CALVOSA:

Q. **Dr. Charman, I want to talk about your inventorship opinions, quickly.**

You're not offering an opinion that the '488 patent is invalid for improper inventorship or derivation if the '488 patent has support in the March 24th, 2011, application to which it claims priority, right?

A. **I have not offered opinions about that.**

Q. **And you're not offering an opinion that the '782 patent is invalid for improper inventorship if the '782 patent has support in the February 18, 2016, application to which it claims priority, right?**

A. **I have not offered that opinion.**

MR. CALVOSA: Mr. Lewis, could we pull up his Slide No. 39.

BY MR. CALVOSA:

Q. **And, Dr. Charman, you had some opinions about some dissolution data that Mr. Allphin talked about earlier this**

week, right?

A. **Yes.**

Q. **And you made it a point for the third from the bottom to point out that it wasn't done in USP 2, right?**

A. **Yes, I did.**

Q. **And you heard Mr. Allphin say that he at the time understood that he would get similar results in USP Apparatus 2 as USP Apparatus 7, correct?**

A. **I did hear him say that, yes.**

Q. **Did you think he was lying?**

A. **I don't agree with him.**

Q. **You just don't agree with him?**

A. **I don't agree with him.**

Q. **Now, you did not conduct any experimentation with gamma-hydroxybutyrate to see if there was any difference dissolving it in USP 2 versus USP 7, correct?**

A. **No, I haven't.**

Q. **And you relied on Ms. Gray for her dissolution opinions, correct, right?**

A. **In part, yes, as well as my own assessment of the situation.**

Q. **And we heard Ms. Gray also say she did not do any testing, right?**

A. **That's correct.**

Q. **And do you remember that Ms. Gray put up that table,**

and there's a lot of red up there, and said not deionized water for all the examples in the '488 patent?

A. Yes, I remember a slide with different boxes and different amounts of red on it, yes.

Q. You also relied on another expert for Avadel in this case, correct, a Dr. Scharf?

A. Yes, I believe I have in terms of earlier reports, yes.

Q. Dr. Scharf is not with us this week, is he?

A. I don't know. I haven't been here for all the testimony of different witnesses.

MR. SCHULER: Your Honor, sidebar.

(Whereupon, a discussion was held at sidebar as follows:)

MR. SCHULER: He didn't offer any opinions in this examination that he relied on Dr. Scharf, so I don't see any relevance.

MR. CALVOSA: I couldn't hear what he said. I'm sorry.

THE COURT: He didn't offer any opinions during his testimony that he relied on Dr. Scharf.

MR. CALVOSA: But he is offering opinions on whether it's USP 2 and USP 7, and he's relying on Ms. Gray for that, and he's also relying on her discussion of whether the testing of the patent itself, which is both USP 2 and

USP 7, was done in deionized water. Remember the red chart, he similarly relied on Dr. Scharf, and Dr. Scharf said the opposite of what Ms. Gray said.

MR. SCHULER: I think Dr. Scharf testified about once-nightly, right?

MR. CALVOSA: I'm just going to show the report.

MR. SCHULER: It says.

(Simultaneous talking.)

MR. SCHULER: Once-nightly.

MR. CALVOSA: No --

(Simultaneous talking.)

MR. SCHULER: You offered --

(Simultaneous talking.)

THE COURT: One at a time.

MR. SCHULER: Your Honor made a ruling motion in limine. We respect it. We did not call Dr. Scharf for that reason.

THE COURT: Yeah, so I'm going to -- just so that we don't even have an issue, I'm going to sustain the objection.

(Whereupon, the discussion held at sidebar concluded.)

BY MR. CALVOSA:

Q. **Dr. Charman, do you recall whether any other expert you relied upon in this case informed your opinion that the**

dissolution testing and examples 2-9 --

MR. SCHULER: Objection, Your Honor.

THE COURT: Sustained.

MR. CALVOSA: If we could pull up Dr. Charman's slide 25, please.

BY MR. CALVOSA:

Q. And you note that there were 13-plus pore formers in Jazz's '488 patent, right?

A. Yes.

Q. Only the three pore formers on the right are enteric pore formers, correct?

A. Correct.

Q. And you didn't mention it, but if we go to JTX003.23, at column 13, beginning at line 35-47. The '488 patent specification teaches that the percent by weight for the methacrylic acid-methyl methacrylate is from about 20 percent to about 50 percent by weight of the coating composition, right?

A. I see the 20-50 percent. Where does it say "MAMM"?

Q. It says, "Where included, the amount and nature of the pore former included in the functional coating composition can be adjusted to obtain the desired release rate characteristics for a given drug substance," right?

A. Yes, it describes pore former, yes.

Q. And the MAMM is a pore former, correct?

A. **MAMM is listed in the section describing pore formers, yes.**

Q. **And one of only three enteric pore formers, correct?**

A. **That's right.**

Q. **You mentioned some what you call downsides of using MAMM.**

A. **Yes.**

Q. **Do you remember that?**

A. **In the context of the tablet formulations, yes.**

Q. **And you agree with me that the '488 patent teaches that where a start up lag time is desired, the use of enteric pore formers would impart a start up lag time, correct?**

A. **There is some language in column 19 about that.**

Q. **A POSA would have known what a lag time was before reading Jazz's patent, correct?**

A. **The term "lag time" would be familiar to a POSA, but it's the specificity of the description of lag time here that would then inform the POSA as to what was meant by that particular term.**

Q. **And you had no opinion on whether a POSA would have known of benefits of having a lag time for a sustained-release dosage form, correct?**

A. **Could you say that again, please.**

Q. **You have no opinions of whether a POSA would have**

known of any benefits for using a lag time with a sustained-release formulation, right?

A. No, I don't provide that opinion.

Q. I'd like to pull up your slide No. 49. And here you were talking about the claims as originally filed in Jazz's '369 priority application that led to the '488 patent, correct?

A. That's linked to the date on the left there; is that right?

Q. March 2011?

A. Yeah, yeah.

Q. That's what you said on your direct?

A. Yes, I'm just trying -- there's slides with claims and different patents that it's linked to, so I just wanted to confirm that's the one it was linked to, thank you.

Q. You have the '369 application in front of you?

A. In one of those big binders, yes.

Q. Can you please pull that up and go to the page 1034 of that.

A. Which exhibit number is that, please?

Q. It is PTX807.

MR. SCHULER: Sorry, where is it in the binder?

(Discussion held between counsel off the record.)

THE WITNESS: I have got PTX0807.

BY MR. CALVOSA:

Q. **And can you please turn to where you said where the claims originally filed in March 2011 that you said were limited to tablets, page 1034 of that?**

MR. SCHULER: Objection, Your Honor, that's not what was on the screen.

MR. CALVOSA: Yes, it was.

MR. SCHULER: What was on the screen was the second set --

MR. CALVOSA: He testified that that was from March 2011. This is not -- if he wants to redirect him, he's perfectly welcome to, but that's what he testified, Your Honor.

THE COURT: PTX807, this was testified to.

MR. CALVOSA: Yes, Your Honor, this is DDX-WC.049 of Dr. Charman's presentation.

And if we pull up PTX807.1034.

BY MR. CALVOSA:

Q. **Do you see at the top it says, "Reply to office action" dated April 4, 2017?**

A. **Yes, I'm just looking for the page in here.**

Q. **You're free to look up there.**

Do you see these claims that are limited to tablets were filed April 4, 2017?

A. **I see that's the date on the top of that.**

Q. **Let's go back to the claims that were actually filed, the original claims, on March 24, 2011. That's going to be all the way at the beginning of PTX --**

MR. SCHULER: Your Honor, this didn't get admitted into evidence.

THE COURT: He's not --

MR. CALVOSA: Your Honor, he put it on the screen and admitted it into evidence.

MR. SCHULER: I did not offer this exhibit.

MR. CALVOSA: It's in his slides, Your Honor.

THE COURT: It was referenced in your slide.

BY MR. CALVOSA:

Q. **Let's please go to the actual claims filed on March 24, 2011, page 2, all the way at the beginning.**

If you look at Claim 1, is that in any way limited to a tablet, sir?

A. **This is PTX0807.2, is that the page?**

Q. **Correct. And Claim 1 does not recite a tablet formulation, correct, sir?**

A. **Yes, that's correct.**

Q. **Now, I'd like to pull up DDX72. And you were testifying about the viscosity-enhancing agent and the acid being separate from the GHB particles, correct?**

A. **Yes.**

Q. **And I couldn't help but notice, you said that there**

was no guidance to do those two in combination, did I hear that right?

A. No. I don't believe you did.

Q. Okay.

A. My comment was that they were both to be separate.

Q. Correct. And you agree with me that the '782 patent teaches a POSA that in certain embodiments where the compositions of the present invention are provided as liquid compositions, such as suspensions, thickeners can be used, right?

A. Yes, I believe there's part of the specification that describes that.

Q. And "thickener" is another word for viscosity-enhancing agent, right?

A. Yes.

Q. And in the suspension embodiment in the '782 patent, the thickener would be there with the formulation dissolved in a liquid to impart viscosity to it, correct?

A. There were a lot of words. I'm sorry, could you restate that, please.

Is this with reference to the specification or just --

Q. Correct. In the embodiment here in the '782 patent, where it's describing a composition being provided as a suspension, a thickener would be there within the

formulation dissolved in a liquid to impart a viscosity to it, correct?

A. If you're reading from the specification, yes, that would be correct.

Q. I'm reading from your deposition, sir.

A. I can't remember what's in there either. So you're talking about my deposition?

Q. Correct, sir.

A. That's what I said, yes, that's correct.

Q. Okay. And the thickener would not work to impart the viscosity that you commented on to the suspension if it was included within the GHB particles, correct?

A. Oh, I remember this conversation now.

Within the modified-release particle, our conversation was that it would not be able to impart a thickening, but it could be within the immediate-release particle.

Q. I'll ask you again, Dr. Charman, a thickener could not work to enhance the viscosity of the suspension if it was included within the GHB-containing particles, correct?

A. My answer at deposition was that it would be uncommon.

Q. Not traditional?

A. That's right.

Q. And unlikely?

A. **I remember uncommon and not traditional.**

Q. **You don't recall saying "or it's unlikely"?**

A. **No, there's a lot to remember, I got the two words. But you have the transcript there and I will stand by what I said then.**

Q. **And with respect to the discussion of an acid in the '782 patent, it's your opinion that a POSA would understand that the use of the acids referenced in the '782 specification is to stabilize the composition of the formulation and likely counteract the change in pH that would occur when the GHB from the immediate-release component dissolves when the formulation is mixed with water, or supplied as a liquid suspension prior to ingestion by the patient, right?**

A. **Yes, you are reading from the specification?**

Q. **I'm reading from your opinion, sir.**

A. **Yes, that's correct.**

Q. **And it's your opinion that the acid could be separate from the GHB-containing particles in the suspension, correct?**

A. **That it could be separate, yes.**

MR. CALVOSA: Can we please go to DDX85, please. And can you blow this up.

BY MR. CALVOSA:

Q. **And here you were commenting on Jazz's curious**

claiming?

A. Which one?

Q. I believe "curious" was your word, sir, was it?

A. Yes, "curious" was my word.

Okay, this is '866 and '782, yes.

Q. And we can look first.

MR. CALVOSA: If you could blow up the bottom left one, Mr. Lewis, please.

Both sides of the bottom left one, both Avadel's claim and Jazz's claim.

BY MR. CALVOSA:

Q. You don't highlight every acid that's in Avadel's claim compared to Jazz's claim, correct?

A. No, I was comparing those that were present in the Jazz claim that were listed in the Avadel patent.

Q. You've never reviewed Jazz's '219 patent to see if Jazz had previously used these same acids that they claim here on the right with oxybate, correct?

A. I don't recall the '211 patent issue you're referring to.

Q. '219 patent, sir.

A. '211?

Q. '219.

A. I don't recall what that is.

Q. Okay. Now -- actually... and you testified earlier,

but you don't remember any substantive written description analysis from the '782 patent file history, correct?

A. Of the patent examiner saying he or she had done that?

Q. Correct.

A. Yes. No, I don't recall that through my analysis of the prosecution history.

Q. Okay. Then let's move on to the blood concentrations. Slide 87.

Can you pull up slide 87, please. And if we could blow that up.

Jazz claims the numbers 15-30 in its claim, right?

A. Yes.

Q. And the beginning range in Avadel's patent disclosure is 13-40.3, correct?

A. Yes, the lowest number on the left-hand side there of the Avadel patent, yes, 13.0 and the highest is 40.3.

Q. So they --

A. 40.3.

Q. So they have 13 to 40.3, right?

A. Yes.

Q. Jazz has 15-30?

A. Yes.

Q. As part of your work in this case, you reviewed and

cited throughout your report Avadel's final invalidity contentions, correct?

A. Yes, I did.

Q. And there was a discussion of the Claim 19 in the '782 patent in Avadel's final invalidity contentions, correct?

A. I don't recall, but if you say it was there, yes.

Q. What I just handed you, PTX1851, is an abridged version of that so I don't give you the voluminous document but that is Avadel's final invalidity contentions that you reviewed, correct?

A. I would have, yes.

Q. Okay. And if you turn to --

MR. CALVOSA: And, Your Honor, I'm happy to offer the whole document into evidence, but given its volume and other issues not in the case, is it possible to offer just the abridged version as evidence?

MR. SCHULER: It depends on the purpose, Your Honor. If he's trying to make an argument that depends upon potentially other disclosures in our contentions and try -- I don't know what he's trying to do.

MR. CALVOSA: This specific claim.

MR. SCHULER: I know there's other contentions that are assessed --

THE COURT: So why don't you, why don't you

publish it, ask the questions you want to ask and then we'll see whether Avadel will agree to admit the truncated version.

MR. CALVOSA: Okay, thank you, Your Honor.

BY MR. CALVOSA:

Q. If you could go to page 183, Claim 19.

And it says Claim 19, which depends from Claim 14, and it gives that 8-hour blood concentration, the 15-30 there, right?

A. Yes.

Q. And it says, "This claim limitation is also recited in Claim 12."

A. Yes.

Q. If we go back up a couple of pages to Claim 12, on page 199, it has -- 177, I apologize. Right there, under Claim 12, it has that same 8-hour 15-30 blood concentration, right?

A. Yes, that's listed there, yes.

Q. And do you see down there it says, "This claim limitation -- "

MR. SCHULER: Why are we publishing this?

MR. CALVOSA: Your Honor permitted it.

THE COURT: So --

MR. SCHULER: You didn't move to admit it.

THE COURT: Let's take it down for now. Let's

come to sidebar.

MR. CALVOSA: Okay. I apologize, Your Honor.

(Whereupon, a discussion was held at sidebar as follows:)

MR. SCHULER: Is this is going to obviousness which is not asserted we dropped this, so what is this relevant to?

MR. CALVOSA: It's relevant to inventorship, Your Honor, they are saying for Claim 19 that Clark Allphin didn't have this blood concentration in their invalidity contentions which Dr. Charman relied upon. It says, this claim limitation, the one they are saying he didn't have, is disclosed in Allphin 2012. And as Dr. Charman, Allphin 2012 is the published application for Mr. Allphin's which is incorporated by reference to the '782 patent.

MR. SCHULER: The all obviousness theory.

MR. CALVOSA: I'm happy to put the full document in it.

MR. CERRITO: They raised 19 and say we can't respond to it.

THE COURT: He can respond to it, yes. So the question is what -- whether you want a truncated version of this document or the full document.

MR. SCHULER: I'd rather have the full document in evidence then.

MR. CALVOSA: Sure.

THE COURT: Let's put the full document in.

MR. CALVOSA: Thank you, Your Honor.

(Whereupon, the discussion held at sidebar concluded.)

MR. SCHULER: We will address what the scope of the document will be later.

THE COURT: Okay. Thank you.

MR. CALVOSA: Mr. Lewis, if you could put that back on the screen and let me step back to where we were.

BY MR. CALVOSA:

Q. **What Jazz is saying -- what Avadel is saying, Mr. Allphin didn't have that blood concentration in Claim 19 which refer back to Claim 12 here, same limitation, 8 hours, 15-30 number.**

Here, in their invalidity contentions, Avadel said, "This claim limitation is disclosed in Allphin 2012," correct?

A. **That's what it says, yes.**

Q. **And Allphin 2012 is the '488 patent published specification that's incorporated by reference into the '782 patent, correct?**

A. **Yes.**

Q. **And if we continue down a couple of pages, it gives -- if you continue scrolling down, figures 12, that's**

from the '488 patent as well?

A. I believe so, yes.

Q. And figure 14 also from the '488 patent, sir?

A. I believe so, yes.

Q. And then right underneath that -- if we could blow that up, Avadel says, "By comparing figure 12 and figure 14, one would understand that at least for treatment E, treatment group with a daily dosage of 8-gram, the plasma concentration of sodium oxybate 8-hours after administration is 15 micrograms per milliliter or 15 milligrams per liter just as in Claim 19 of the '782 patent," correct, sir?

A. You have read that correctly, yes.

Q. And that's the number that's in Claim 19 of Jazz's '782 patent, sir, right?

A. That's one of the numbers, there were two numbers, weren't there?

Q. Correct.

And then, thus, a POSA would have understood that the claimed range of plasma concentrations, that's that 15-30, is disclosed in Allphin's 2012, right, sir?

A. That's what it says, yes.

Q. And if we could scroll down to page 272.

The names here, this is submitted by Avadel's attorneys sitting right here today, correct?

A. Yes, I recognize some of those names.

Q. **And as you continue scrolling down, that's Avadel's team sitting right here today, right?**

A. **I don't know if they are all sitting here, but, yes, that's representing the group.**

MR. CALVOSA: No further questions, Your Honor.

THE COURT: All right. Redirect?

MR. SCHULER: Briefly.

REDIRECT EXAMINATION

BY MR. SCHULER:

Q. **Dr. Charman, do you recognize what this is?**

A. **Yes, I do.**

Q. **What is it?**

A. **It's placebo particles representing the Lumryz formulation, so they are particles and they are the ones that -- there was a Lumryz sachet that I had but it was placebo, there's no drug in it.**

So what I did was, you cut the top of the sachet and then I tipped the particles, the microparticles that were in the sachet into that bottle, so they don't contain drug, but they do represent the character of the immediate release and modified-release particles with the viscosity agent and the acid separate from them.

Q. **Now, from a patient's perspective, what does it look like?**

MR. CALVOSA: Objection, Your Honor, outside of

the scope of --

(Simultaneous talking.)

MR. CALVOSA: I just did.

MR. SCHULER: It's going to his very first point that he made about powders, what does that look like?

MR. CALVOSA: He's not a doctor. He's talking about patient's perspective. He's not qualified for that.

THE COURT: Overruled. He can answer the question.

THE WITNESS: I am a pharmacist and I am well-experienced in preparing formulations for patients so from that standpoint, I'm able to comment as to what this looks like and they look like particles.

BY MR. SCHULER:

Q. **And from a formulators perspective, what is in Lumryz?**

A. **The composition that we've discussed which are the two types of particles, plus those two agents that are separate from the particles.**

Q. **Could you put up DDX 19, again.**

And, sir, why did you conclude that this passage with a reference to powders in an IR component did not disclose the subject matter of a powder or multiparticulate formulation for the sustained release portion?

A. **The highlighted comment, or highlighted words in**

terms of powder is in the context only of the immediate-release portion. It's got nothing to do obviously with the nonimmediate-release portion and it describes, again, as we said previously, of the powder, then being compressed into the final coated tablet or capsule.

MR. SCHULER: No further questions.

THE COURT: All right.

All right. Dr. Charman, you may step down, thank you, sir.

All right. Avadel.

MS. DURIE: Thank you, Your Honor. With that, Avadel rests.

THE COURT: All right. Avadel has rested its case.

All right. So ladies and gentlemen of the jury, I'm going to take you out of the courtroom for a couple of minutes. It may be that we let you leave early tonight because I may need to hear -- deal with some issues outside your presence, so give me 5 minutes or so and I'll let you know.

In the event that you do leave, remember the instructions, no independent research, don't talk to anyone about the case, don't review any TV or other stories about this case and leave your jury notebooks in the jury room, all right?

(Whereupon, the jury left the courtroom.)

THE COURT: All right. We're going to hear JMOL motions.

All right. I'm going to let the jury go for the evening.

MR. CERRITO: Yes, Your Honor, thank you. This time Jazz moves for a Rule 50 judgment. Let me just start -- try to be as brief as possible and try to -- and let's just start on that last issue, Claim 19.

You just saw and heard from this witness how Avadel admitted that they met the -- the limitations of Claim 19 were met, that the claim is not invalid. They showed that to you right at the last break -- right before the last break.

Also, with regard to enablement, I think we heard Dr. Charman say that both -- for both patents, '488 and '782, that the experimentation necessary would be extensive. Under the case law, that's not good enough. He did not say it would be undue experimentation. Extensive experimentation simply does not meet their burden.

So both for enablement in Claim 19, defendants have not met their burdens, and judgement should be entered.

Let me go down the list for Your Honor just so the record is complete.

For infringement, they've obviously admitted

infringement on the '782. For infringement of the '488, as I walked through a little earlier this morning in response to defendant's motion, with regard to the '062 patent, Dr. Little walked through tables 1a and 1b, made it pretty clear why they have a core, a drug-containing core.

Doctor Klibanov's response didn't change that fact, again he looked at the same pictures, ignored the evidence that was before him, which, quite frankly, was overwhelming. I think that the testimony concerning Avadel's SEC filing and the structure that was proposed there was unrebutted. Dr. Klibanov didn't talk about it, said nothing on it. And it shows the structures -- both the structures from the core, as described in Legrand and the Micropump technologies that this Court and the jury heard about this week. Again, nothing, unrebutted from Dr. Klibanov.

When I mentioned Mr. Vaughn earlier this Monday -- morning, Avadel's 30(b)(6) witness, when questioned, I quote, "The core of the MR particles was in the IR microparticles? That's what Avadel told the Patent Office in the '616 application that led to the patent-in-suit, the patent that we have been talking about here?

"Answer: Yes, that's what it says, yes."

That's an admission, Your Honor. It's an

admission of infringement.

With regard to the DI water, Dr. Little provided substantial testimony and evidence on that fact. You heard almost nothing from Dr. Klibanov on that matter. You've also heard from Dr. Guillard how he did three tests on DI water, averaged the numbers out, averaged the numbers out, put it in this patent. That's all that's necessary for infringement on that claim. I think the plaintiffs have more than carried their burden of by preponderance of the evidence.

For invalidity on written description for the '488 patent, I won't bore Your Honor with the law, Your Honor is well aware of the law in this area. But my point is Avadel has not met its high burden and no reasonable juror could find in Avadel's favor.

Written description requirements may be satisfied by a combination of words, structures, figures, diagrams, formulas, experiment or data contained in the patent's application, these are often, as we know, called place marks.

Place marks guide the readers through the specifications forest, if you will, towards the claims. And with respect to the asserted claims of the '488 patent, Avadel has not shown and a reasonable jury would have no evidentiary basis to find those place marks are missing in

the clear and convincing evidence.

Perhaps, what was most telling in the testimony of Dr. Charman, we just heard about the MAMM pore former, which he identified if you have lag time it's there, there's only three identified, that's a pretty good place mark.

For this, among other reasons, Avadel has not proved by clear and convincing evidentiary basis on which a jury could conclude that the asserted claims of the '488 patent lack written description, again by clear and convincing evidence.

The same argument with regard to the -- sorry, the '782's written description. Claim 24, no reasonable jury could find for Avadel on this defense either. They failed to prove by clear and convincing evidence that Claim 24 of the patent is invalid for written description.

I did enablement for both the patents a moment ago; no enablement, never testified there was undue experimentation, simply said "excessive." Case law is pretty clear on that, said that's not good enough.

With regard to inventorship, inventorship for the '488 and '782. For the '488, Avadel must provide sufficient evidentiary basis on which the jury could conclude its former employees conceived of the subject matter of the asserted claims before Mr. Allphin and Mr. Pfeiffer. Avadel has not provided that evidence.

Mr. Allphin clearly testified that he did the work underlying the claims of the inventions in September of 2009. Those laboratory records are in evidence. The evidence also shows he filed a patent application on that work in 2011.

Dr. Guillard has testified and was shown that patent application where he admitted that Jazz did it first. Why did he admit that, because Dr. Guillard admitted that he had not applied MAMM functional coatings to GHB formulations until 2012. After the filing of the patent by Jazz. And he did not carry out the deionized water testing that Jazz claimed until 2015. How could they have invented it first? Not possible.

He didn't carry out that testing until he saw it in Jazz's patent filings. There's no evidentiary basis, let alone clear and convincing evidentiary basis, on which a jury could find Avadel conceived of the claimed inventions before Jazz or that Jazz inventors did not conceive of those inventions at all.

Avadel has not provided sufficient evidentiary basis for this jury to conclude that Claim 24 lacks proper inventorship, and although Avadel pursued several different theories against the '782 patent, they all failed.

First, Avadel has taken the position Mr. Allphin and Mr. Bura are not proper inventors because they never --

they never even conceived of the claimed subject matter, but there is no basis on which a jury could make that finding. Mr. Allphin walked the jury through the work he did in the 2015/2016 timeframe. He testified how he conceived of the modified-release GHB formulations --

(Reporter clarification.)

MR. CERRITO: He testified how he conceived of the modified-release GHB formulation further comprised of a separate acid and viscosity-enhancing agent to solve several administerability problems that he and his co-inventor, Mr. Bura, had identified. There's no doubt that Mr. Allphin conceived of the formulations that he claimed.

Second, Avadel has taken the position that Mr. Allphin and Mr. Bura are not the proper inventors because Avadel filed a patent on the claim, but there is no dispute that Jazz filed its application that eventually matured into the '782 patent in February of 2016, months before Avadel filed their patent application.

The '782 patent is adjudicated, as we know, under the American Invents Act. It was an AIA patent. And all that matters is who filed first. Clearly, the record shows evidence is there, Jazz filed first.

With regard to derivation on the '488 patent, Avadel has also asserted that the claims of the '488 patent and only the '488 patent are invalid because they were

allegedly derived from Avadel's public patent filings. No reasonable jury could come to that determination, simply not enough evidence, simply no evidence.

Avadel did not file the publicized patent application at issue until years after Mr. Allphin did the work that underlies Claim 7 and 11 of the '488 patent, if anything, the evidence shows Dr. Guillard derived crucial aspects of his patent filing from Jazz. Specifically, again, the deionized water testing.

The jury cannot find that Jazz derived from Avadel when Dr. Guillard clearly admitted he took the limitation of the claimed invention from Jazz. Jazz did it first.

As to damages, the evidence demonstrates that the jury could not -- could reach only the conclusion that Jazz is entitled to a 27 percent royalty rate for past infringement for reasons that we all know. They're obviously not going to hear and have not heard anything to rebut that. Jazz's experts Dr. Rainey opined that Jazz and Avadel would accept a 27 percent royalty rate as part of a three-tiered royalty structure because such a rate would make Avadel better off and Jazz not worse off.

Jazz and Avadel are direct competitors. Avadel has aimed to expected -- and expected that patients would switch from its product, Jazz's product, to Lumryz, and

Lumryz specifically -- Avadel specifically targeted that switch that Avadel linked its once-nightly to the formulation -- or should I say once at bedtime, sorry -- that Avadel linked its once-at-bedtime to the formulation he's promoting, its once-at-bedtime formulation. That the FDA linked its ODE to the convenience of the once-at-bedtime formulation was linked to those patents.

So Dr. Rainey expressly testified that the patent inventions drive the value of Lumryz because of its once-at-bedtime formulation is what constitutes an improvement over the twice-nightly oxybate products and that the formulation would not exist absent the patented features. Indeed, as we saw, no noninfringement alternatives exist. You won't hear -- the jury won't hear about any at this trial.

Obviously, the jury saw that Avadel did not cross Dr. Rainey on the appropriateness of the royalty rate, and thus, a reasonable jury could conclude that only a reasonable royalty of 27 percent is proper for past infringement. Thank you, Your Honor.

THE COURT: Thank you.

MS. DURIE: Thank you, Your Honor. I will just take those points in order. With respect to Claim 19, Avadel is entitled to pursue theories of obviousness and invalidity under section 112 in the alternative as part of

the pretrial process.

In addition, the standards that apply to invalidity under section 102 and 103 are different from the standards that apply to written description and enablement.

In addition, the data that is set forth in Allphin 2012 with respect to blood plasma levels that was referenced has been shown in the course of this trial to be unreliable in that the actual data was only partially provided to the Patent and Trademark Office. And the data critical to the interpretation of the data that was provided was withheld, rendering that data unreliable for purposes of Jazz's effort to demonstrate possession of the invention.

With respect to section -- the other claims of the '782 patent and the '488 patent, which were dealt with collectively and generally, Dr. Charman's testimony that there would be extensive experimentation required, I think at one point it was extensive and at another point was excessive, more than meets the standard for whether experimentation is undue.

The legal test does not require the expert to recite the word "undue." The legal test requires the expert to provide substantive evidence. With respect to the amount of experimentation required, including merely rote and conventional experimentation, which can be deemed undue under controlling Federal Circuit law, it is a question of

fact for the jury ultimately to make a determination as to whether the amount of experimentation that was described constitutes undue experimentation for purposes of enablement.

With respect to infringement of the '488 patent, the Court and the jury have seen ample evidence that Avadel's product has a core and that Avadel's product does not have drug within that core.

That conclusion is buttressed not only by the expert testimony that the Court has heard, but also by the figures and texts in Avadel's patent, which clearly demarcate the difference between the core that contains drug -- sorry, the core that does not contain drug that is inert and the drug that surrounds that core.

The purported admission that Jazz repeatedly cites is nothing more than an admission that the figure and the text in the patent and the table in the patent together accurately describe the composition of the formulation, which they do, with respect to both the presence of drug and the presence of the neutral core.

The fact that we agree that that, in fact, covers Avadel's product does not translate that into an admission that the core in Avadel's product has somehow gone away -- the inert core in Avadel's product has somehow gone away.

And as Dr. Klibanov explained, at most there's a failure explicitly to recite that the IR microparticle that forms part of the CR microparticle contains sodium oxybate as well as the inert core, a conclusion that is extremely self-evident from reading the patent specification and the weight that is ascribed to the IR microparticle, which is the combination of the inert core and the drug. That is what makes up the total weight.

With respect to invalidity of the '488, a similar argument was made with respect to the amount of experimentation required. The response is the same, an excessive amount of experimentation is undue, that is a determination for the jury.

With respect to inventorship, Jazz indicates that their contention is that Mr. Allphin conceived of the invention in September of 2009. The documentation to which they refer is not present in the patent. It is up to the jury to make a credibility determination whether that was, in fact, a conception of an invention or whether those were experiments with respect to a material that Mr. Allphin deemed not desirable, experiments that he then concluded were unsuccessful and made a decision not to include in the patent precisely because they were different from what he contended to be his invention. The experiments were a pH trigger and his invention was not. His invention was a

tablet that had, in lieu of a pH trigger, a slow release.

The fact that Mr. Allphin may have done some work first does not mean that he conceived of the invention first. It does not mean that he ever possessed the invention, and the fact that Mr. Guillard admitted that Mr. Allphin had done some work first is far from admission that he was the true inventor.

With respect to inventorship, certainly the jury is also entitled to credit Mr. Allphin's admission that he did not consider himself to be the inventor of Claim 1 of the '782 patent and also to credit his admission that he did not know why the separate acid was even present as a limitation in the claim. In other words, the jury is entitled to credit that the rote copying of that language from Avadel's patent application also supports the notion that Avadel is the true inventor of that subject matter and that there is not support in the February 2016 application for those claims as they were later presented to the Patent Office.

The fact that Jazz filed first under the AIA is not the only dispositive question. Inventorship is still a defense post-AIA, and it is to the jury to make a determination under the evidence that has been presented as to who the true inventors of that subject matter are.

With respect to derivation with respect to the

'488 patent, the legal analysis with respect to inventorship is essentially the same, although pre-AIA, there was ample evidence that the inventors of the subject matter of a claim with methacrylic acid-methyl methacrylate, subject to a particular dissolution test under particular conditions, was an invention that was made by the Avadel inventors.

Jazz has been unable throughout the course of this trial to point to any work that it did that satisfied those precise testing conditions, and has not pointed to a single experiment that falls within the ultimate scope of the claims as issued. Although, such an experiment would not be conclusive with respect to who is the inventor of that subject matter.

And, again, with respect to conception of the invention for purposes of derivation, it is again to the jury to make a determination as to whether there was an earlier conception of an invention meeting all the requirements of the claims, or whether that invention only came about upon a review of, as an initial matter, the publication of Avadel's data in 2014, and then later the publication of Avadel's patent application listing the precise parameters that later wind up in the Jazz patent claims.

With respect to damages, Mr. Rainey's opinion was that depending upon the period of time, damages might be

anywhere from 3.5 to 27 percent. He conceded that 3.5 percent was an appropriate royalty for a period of time during which the patents at issue in this case were in force, but a period of time in which other Jazz patents were no longer in force.

We would suggest that actually conclusively demonstrates that 3.5 percent is the correct royalty and that Jazz cannot rely on the value attributable to other patents in order to satisfy its burden with respect to damages.

Jazz made the assertion that there are no noninfringing alternatives. As a matter of law, the question is not whether in view of the FDA's regulatory requirements Avadel had a viable option to switch its formulation at the point of first infringement; the question for the damages experts and ultimately for the jury is the incremental value of the patented invention as applied to Avadel's product. There was no testimony from Dr. Rainey on that subject, certainly nothing that would unambiguously support such an award, and the proposition that we did not cross him with respect to what would constitute a reasonable royalty is wrong. There was testimony on the fact the 27 percent royalty is predicated on other patents not at issue in this case. The 3.5 percent is the only royalty number predicated on these patents.

And to the extent that it was not otherwise clear with respect to the motion as it pertains to written description, Avadel provided extensive testimony that -- through Dr. Charman and through others that the specification of both the '488 patent as originally filed in 2011 and the specification of the '782 patent as originally filed in 2016, respectively, do not describe the inventions as they were ultimately claimed.

With respect to the '488 patent, the 2011 specification does not describe an invention that includes MAMM. It lists MAMM on a list of a very long number of potential excipients that would result in an enormous multitude of formulations, but it does not provide any place marks specifically to MAMM as a desired component of a formulation and to the contrary teaches away from the use of it by indicating in multiple places the undesirability of a formulation that is triggered by a change in pH where MAMM is an ingredient that would cause such a change in the pH and, therefore, a pH-triggered formulation, were it to be used.

In addition, the '488 patent is all about tablets. It extensively discusses the invention as being about tablets. There are many Jazz internal documents that refer to that patent and its disclosure as being about patents. The word "microparticle" does not appear in the

'488 specification. And its teachings are not translatable, either on their face as a matter of written description, or as a function of the amount of experimentation that would be required for purposes of enablement to allow you to go from a tablet to a microparticle. Every weight range, everything else that's in the patent specification pertains to tablets and tablets only.

With respect to the '782 patent, for written description purposes, the only data that is provided in there provides -- is -- relates to a resinate formulation. There is not even a disclosure of any release of the drug from that resinate. And, of course, the claims are directed to immediate-release and controlled-release.

There is no description of that release. There is no description of a separate acid. There is no description of a formulation that is not a resinate. And there is no description of a multiparticulate formulation that is comprised of a substance like MAMM that allows for a pH-triggered release as is the Lumryz, the accused product.

If I may have one moment, Your Honor.

I think that probably will suffice as a response, thank you.

THE COURT: All right. The Court will take the JMOL motions under advisement and will render a decision in the morning. We're adjourned. We're going to adjourn for

the day. So what -- before we do that, what's the plan for tomorrow morning after the Court rules on JMOL motions?

MR. CERRITO: We'll begin our rebuttal case, Your Honor. Robert Stoll will be our first witness.

THE COURT: Okay. All right. Any idea how many witnesses you plan to call?

MR. CERRITO: We're trying to, you know, obviously, limit it as much as possible. If Your Honor would indulge me until the morning, I can give you a better --

MS. DURIE: And will we roll straight from that into the charge conference?

THE COURT: Yes.

MS. DURIE: Okay.

THE COURT: All right. So we will adjourn.

MR. CERRITO: Your Honor, I apologize for interrupting. Just one question in view of the question we just heard. I assume, then, pushing the charging conference and then close Friday morning and give it to the jury in the afternoon instructions?

THE COURT: Most likely, yes, most likely. I wouldn't want one side to have a closing and not be able to follow with the other side, so...

MR. CERRITO: I agree.

THE COURT: Yeah, we will likely not start

closings until Friday morning, you know. In the event we get done super early and, you know, we got time for both closings, you know, we'll do that, but most likely, we won't do closings until Friday morning.

MR. CERRITO: Thank you, Your Honor.

MS. DURIE: Thank you.

THE COURT: All right. Anything else?

MR. CERRITO: Not from Plaintiffs, Your Honor.

THE COURT: All right.

MS. DURIE: I'm sorry, Your Honor. I apologize.

THE COURT: Okay. All right. All right. We will be adjourned until tomorrow morning.

(Whereupon, the following proceeding concluded at 5:19 p.m.)

I hereby certify the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Michele L. Rolfe, RPR, CRR
U.S. District Court