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
Friday, March 1, 2024
Trial Day 5

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

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Michele L. Rolfe, RPR, CRR

APPEARANCES:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
BY: JEREMY A. TIGAN, ESQ.

-and-

QUINN EMANUEL URQUHART & SULLIVAN, LLP
BY: F. DOMINIC CERRITO
FRANK C. CALVOSA, ESQ.
ELLYDE THOMPSON, ESQ.
The Plaintiff

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BY: DANIEL M. SILVER, ESQ.

-and-

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For Defendant

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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 9:00 a.m.)

THE COURT: Good morning. Are we ready to

proceed.

MS. SAWYER: Yes, Your Honor. We have a couple of quick housekeeping matters that we'd like to address.

THE COURT: All right. Remind me your name again.

MS. SAWYER: Audra Sawyer for Avadel, Your Honor. We have a proposed correction to the Court's list of admitted exhibits. We have two exhibits that should be added. They are DTX1275 and JTX217. And I believe there is no objection to adding either of those, although we would ask that JTX217 be placed under seal.

THE COURT: All right.

MR. CALVOSA: No objection, Your Honor.

THE COURT: Okay. DTX1275 is admitted. JTX217 is admitted under seal.

(Exhibits admitted.)

MS. SAWYER: And I'd also like to ask that a few exhibits be placed under seal because they contain sensitive Avadel financial information. Those exhibits are JTX119, JTX122, JTX129, JTX130, JTX259, and PTX486.

MR. CALVOSA: And we have no objection to that, Your Honor. We did have one additional document to place under seal.

THE COURT: All right. I'll deal with that after this. So let me admit JTX119, 122 -- they're already

admitted but admit under seal, JTX119, 122, 129, 130, 259, PTX486.

(Exhibits admitted.)

THE COURT: Mr. Calvosa, you had one to go under seal?

MR. CALVOSA: Yes, Your Honor, JTX147.

THE COURT: JTX147. All sealed.

MS. SAWYER: No objection.

(Exhibit admitted.)

THE COURT: That's is it?

MS. SAWYER: That's it. Thank you, Your Honor.

THE COURT: All right. All right. Any agreements on any of the jury instructions that -- no further agreements.

MS. THOMPSON: No, Your Honor. No, we were not able to reach an agreement on adding anything.

THE COURT: Okay.

MS. THOMPSON: So we'll stick with what the Court had at the end of the day yesterday.

THE COURT: All right. Let's get the jury.

(Whereupon, the jury entered the room.)

THE COURT: All right. Good morning, ladies and gentlemen of the jury. We're going to begin today with the closing arguments, both sides. Plaintiff will go first, then Defendant will go, and then Plaintiff will get the last

word.

All right. Then the Court will charge you, give you the jury instructions, and then you will begin your deliberations.

All right.

MR. CALVOSA: Permission to approach, Your Honor?

THE COURT: Yes, you may. You may begin.

MR. CERRITO: Thank you, Your Honor. May it please the Court.

Ladies and gentlemen, it's been a long week. You've heard a lot of evidence, saw some really excellent witnesses up there. I tend to think Jazz's were a little better. I tend to think they were a little bit more honest.

My wife reached out to me today to talk about good luck. She always does. Reminded me of something she says to me all the time. You know, I tell her about our cases. I argue my case in front of her. Usually pretty convincing. Just on my work stuff. The other stuff, not so much. But her response to me is always, So what are they going to say? And I say, They're going to say something. You're going to hear something, and that something is going to be a story, a story that's not accurate, a story that's not supported by the evidence, and a story that just doesn't add up.

I'm going to walk you through the facts, the evidence that we heard this week, try to put it together for you, little pieces so you can take it back in that jury room when you deliberate, think about it. Now, I'll go, then she goes, and I get the last word. So we're going to talk about misdirection a lot and let's see if it comes true.

The evidence showed this week that Jazz is an industry leader. It's a company dedicated to bringing new medicines to patients as quickly and as safely as possible. It has seven FDA-approved products. It's constantly improving and innovating. You don't have to take my word for it. Avadel holds us out as the industry leader. That's their words.

The evidence shows that Jazz did this first. Remember, I told you early on in the case the dates were important. They're important. Let me show you why.

The first time anyone used -- ever used the MAMM copolymers as a pore former to sustain the release of GHB, that was Mr. Allphin in 2009. That's what the evidence of this case shows. Avadel never achieved sustained-release GHB before. Mr. Allphin did it first. What did Avadel do? It followed Jazz. It followed Jazz when it relied on Jazz's clinical data to file the Lumryz NDA. It's going to follow Jazz when it seek FDA approval for idiopathic hypersomnia. It's going to follow Jazz to seek FDA approval to treat

pediatric patients, and it's going to follow Jazz to seek FDA approval for that low-sodium product, that Xywav I told you about.

And those are the basic facts of this case: Jazz got it first, Avadel followed. As I said, I hope it doesn't happen, but I think what you're going to hear is misdirection, misleading from my opponent.

Remember when Ms. Durie told you during the opening that Jazz wanted to buy Lumryz at that time because it was so much better? Didn't they also show you that 43 other companies took a pass on it? They got approval, that's great, but it wasn't such a hit. 43 companies passed on it.

Let's talk about the difference in the burdens of proof you'll be asked to use for this case. For infringement, that's Jazz's burden, just over 50 percent, preponderance of the evidence, 50.1, just a smidge more. That's all we have to use to prove infringement. With regard to invalidity, the law is clear and convincing evidence. It's a much higher standard. And that's because patents are presumed valid. The Patent Office did their work. They're presumed to have done their job, so they have a higher standard. That tilts the scale a lot more. A lot more. That's their burden in proving all of their issues including validity, inventorship. That's their burden.

So let's talk about what the evidence showed for two patents in suit. And let's start with the '782, even though it's later in time. This one's is easy. You don't have to decide. They infringe it. They admit they infringe it. That's an easy -- easy shot there.

So then what's left? Avadel has asserted three defenses. When it comes to the '782 patent, Avadel has failed to establish by clear and convincing evidence, no doubt in their mind here, that the '782 patent lacks written description, it is enabled, and they haven't shown improper inventorship. Proof of -- proof of inventorship is a patent application that has written description and enablement support. So what does that mean? It means if you determine the '782 patent has written description and enablement support, as of its priority date -- and we talked about this a lot, and we'll talk about it again, that priority date being February 18th, 2016 -- then you must also find that there's proper inventorship.

So, again, why are we focused on this 2016 date? Because if you find Claim 24 is described and enabled by the application that Jazz filed February 18th, 2016, then Jazz wins on all three issues. Did it first; filed it first; if there's written description and enablement, that means there's inventorship. That means Jazz wins on all three issues.

Before you even start thinking about this issue, remember the '782, the Patent Office, the examiner did this very analysis. Patent Office already did this before the patent issued. Did this analysis on written description and enablement. She reviewed the specification, she found the support. She found the '782 could claim -- could claim priority to the application back, the one filed in 2016.

Both sides' experts testified that a priority analysis is simply a written description and enablement analysis. That's how you get back to your original date because you had all the information there. That means the examiner, before the '782 patent issued, viewed the specification, found the February 18th, 2016 date application to have written description and enablement support for Claim 24 of the '782 patent.

Avadel wants you to believe the examiner missed something. Not sure what, but they're saying they missed something. At the time of her priority determination, the examiner had their patent, had it in her hand. We know that. Jazz submitted the '866 patent to the Patent Office. The examiner considered that reference as part of her analysis, looked at their work. She had to, and she looked at it, and she initialled her name against it. They want you to think that it was buried in a -- they put up all these patents. Oh, my God, this thing was buried. Where

was it? It was number one. That didn't escape them. The examiner saw it. She did her job.

The law presumes that the Patent Office acted correctly, so the examiner's priority determination on February 18th, 2016, is presumed to be correct. Avadel hasn't presented any evidence that the examiner was wrong, that she messed up. Didn't hear that. Dr. Charman didn't even look at the file history, didn't even look at it. He's telling you there's no written description, no enablement. Didn't even look at it. Strange. And, remember, the patent examiner is presumed to have acted correctly. That's why they have a higher burden. That's why their burden is higher, because somebody already looked at this.

The parties presented expert testimony of written description and enablement. You heard from Jazz's expert, Dr. Little, and you heard from Avadel's expert, Dr. Charman. I'm going to walk you through some of Dr. Little's opinions for written description and enablement for the '782 patent. Dr. Charman had three reasons why the '782 patent lacked written description support, meaning basically he's saying, There's three things that were missing here, I'm not seeing here; therefore, it lacks written description. The examiner found it, but he found there was a problem.

First, he said there was no disclosure of

nonresonate microparticles. Dr. Little showed you he was wrong. He showed you the microparticles. Then he said, Oh, wait, wait. He said that there was no description of modified-release resins either. Dr. Little showed you again Dr. Charman was wrong. He showed you the modified-release resinate microparticles. Who are you going to believe here? Dr. Charman, who has never had experience with modified-release resinates, or Dr. Little, who works with these particles every day?

Third, Dr. Charman said the acids and viscosity-enhancing agents were not described either. Guess what I'm going to say? Charman was wrong again. 0 for 3, 0 for 3. They're disclosed. Dr. Little showed you they were disclosed. The examiner saw it, Dr. Little saw it, a POSA sees it.

And then on cross Dr. Charman admitted that the viscosity-enhancing agent and the acid were both outside the particles. He admitted that. That's all you need.

And you heard from Dr. Little how these claims are enabled, just like the examiner found. There was no undue experimentation. You heard us going back and forth about undue and excessive.

A person skilled in the art knew how to modify the release of these particles. Dr. Charman never said "undue experimentation." That's what the law requires. You

didn't hear that from him.

Avadel has no clear and convincing evidence of inadequate written description and enablement. Avadel has the burden here. They have not given you enough evidence. It just simply doesn't exist. Avadel only presented the expert testimony of Dr. Charman; that was it. Obviously much more support on Jazz's side for this. Not only do I think we're 100 percent right; there's no way they could meet their burden on this one, simply cannot.

Because Avadel fails to show lack of written description and enablement, because they fail on that, inventorship also fails. That's why I sort of merge those two together. Avadel's expert only claims that there's improper inventorship if Claim 24 is found to have no written description or enablement support. That means if you agree with the examiner and find that Claim 24 relates back to February 2016 date, Dr. Charman has no opinion, none, as to whether the inventorship is improper.

You heard about claim copying. It's a strange thing. Let me get to it in a second, but it was strange. The idea that claim copying or referring to someone's claims is somehow -- takes away from the inventorship of Claim 24 is misguided, it's misleading, it's wrong. You heard both Patent Office experts testify that it's acceptable practice to copy claims to cover a competitor's product so long as

there is support.

In fact, Mr. Stoll testified he does this as part of his normal practice. Let me take a second on Mr. Stoll. That's a guy who was in the Patent Office for almost 30 years. He was the commissioner of the office. He ran all the prosecutors, everybody who's doing the examination process. He did examination process for 12 years. Their expert, Mr. Matal, is a lawyer. He represented an agency in court. He never prosecuted a patent in his life.

Mr. Stoll said that it is -- Mr. Stoll testified that he does this as a part of his practice. He said this is fair because, and I quote, "If you're the first inventor to provide the information to the public, you should be able to claim it in any manner that you see fit." Mr. Matal said, "If there is support, you would be entitled to copying claims."

Mr. Stoll testified that the claim copying is permitted as long as you have support in your application. Mr. Matal did not dispute that claim copying is permitted in that case. He just said there was a duty to tell the examiner that you did that. I think Mr. Stoll made it quite clear why there was no duty.

Avadel relies on alleged duty of disclosure for claim copying. It's a misdirection. As we told you, Avadel

is trying to misdirect you by citing MPEP sections that only related to pre-AIA, American Invents Act, patents. '782 is post, that is the AIA patent. The things he was citing you, the regulations he was citing you go backwards, not forwards.

Mr. Stoll said that the MPEP section does not have anything to do with AIA patents. Under Patent Office procedure, the requirements to the examiner about the source of copy claims came from 37 CFR, the section that's cited there, a rule that is only related to pre-AIA proceedings. The requirement does not apply to Claim 24 of the '782 patent.

Here's the part where I -- sort of threw me off on this whole copying thing. Avadel's expert, Mr. Matal, did not opine, never said Claim 24 was copied. He didn't say that. Because it wasn't. It wasn't referred to, it wasn't close, wasn't -- whatever word you want to use, it wasn't.

So why are we talking about this? Because they are trying to misdirect you. Trying to make us, Jazz, look like bad actors, that's the only reason. He didn't say we copied it, because we didn't.

Misdirection, misguiding, that's what they are doing.

The evidence presented to you this week shows

that Claim 24 of the '782 patent has written description and enablement support as of February 18, 2016.

Written description and enablement support, as we just discussed, equals proof of inventorship. We, Jazz, invented it first. And under the AIA, the first inventor to file, that's the rule change, first inventor to file is awarded the patent. We got there first 5 months before they did. I don't care what they did. We got to the Patent Office first.

Here, Jazz filed first and should be awarded its patents.

At the end of these closings, you're going to get a verdict form, something for you to fill out, and they'll ask you a series of questions and also to write down your judgment in this case. It's going to look like this: Questions 6-8 deal with Avadel's invalidity defenses, the ones we just talked about against the '782 patent. I'll ask you to select "no" for each of those.

And this is important: If you find for Jazz, you must select "no" to all the invalidity defenses. You can't divide them up because if you divide them up, they would win on their invalidity defense. You have to check "no" to all of them. Side with Jazz, that's the way to go.

So let's turn to the '488 patent, start with infringement. There were two disputed issues. Remember in

opening I said there was one about the DI water, the dissolution, and another about core. DI water fell off the floor, we didn't hear about that, nobody testified about it, they gave up on it.

One issue the core, we heard quite a bit about that, spent a lot of time with that one. They didn't cross Dr. Little on DI water. Dr. Klibanov didn't talk about it. Nobody talked about it. So core is the only issue remaining for you to decide about.

The next -- the reason they dropped that, quite frankly, was that -- because the evidence clearly shows that Dr. Guillard took that testing from Jazz.

In 2015, he knew about Jazz's patents and he did that testing because he saw it in the Jazz patent first. That testing shows infringement, that's why he dropped it.

So let's turn to that core element now. What the claim requires is a sustained-release portion has a functional coating deposited over the core and that core contains a GHB drug, oxybate drug. What the parties dispute is whether the core of the sustained-release portion of Lumryz has GHB.

So let's look at what Avadel told and said before this case started, before there was an infringement action on them and they weren't paying attention to every word, every concern, and they weren't defending themselves

in a court of law where they had to tell the truth to the United States Security and Exchange Commission. What did they say?

They told the SEC that the core of its product contains the active ingredient which they called later "the core." That's what they said before this case started.

Also before this case started, under oath to the United States Patent Office, they said that the drug-containing IR microparticles, the immediate-release particles, are the core of the sustained releases. Just take those immediate release and put the coating on it, this is the core. That's what they said. That's what they told the Patent Office under oath.

Avadel's own lawyers admitted this, that the core of the modified-release microparticles contains the drug. Remember the testimony about this document? Mr. Calvosa was doing it. This is written by Avadel's team of lawyers early in this litigation, the same team you see behind me. These are the exchanges between the parties. They have 30 days to respond to these. These are well-thought-out, well-reasoned, a lot of lawyering going into these. They didn't quibble, they didn't make excuses, they admitted it. Can't say it any plainer than that.

And now they are telling you something different, trying to mislead you, trying to mislead you.

Even though Avadel is telling you something different at this trial, the evidence showed otherwise. Dr. Little told you, "the drug is in the core." Avadel wants you to only look at the one picture, they showed you that picture over and over and over. They even put that big board in front of you so they can show you, "Look at this picture." I had to sit over there. Move back. Move the board, this whole thing. Same picture over and over again.

But Dr. Little told you that a POSA would look at the picture and the words, not just the picture. Both. The picture and the words. Those tables underneath it, that's what it's describing.

And what does the evidence tell a POSA? That this is a drug-layered core. It's the words that they used in that SEC document. The core of the modified-release particle is the entire IR particle, which includes the drug, that's called drug layering. It's exactly what they testified to.

And Dr. Klibanov admitted Lumryz is made by drug layering, he said that. And like Dr. Little told you, everything under the functional coating is the drug-layered core.

Now, Dr. Klibanov, God bless him, I think he tried to mislead you there. He shouted, not at you, but just in general, regardless of how many POSAs would think a

drug layering -- he kept saying that's not Lumryz, that's not Lumryz. Okay. But that's not how Avadel characterized it, not in its product before this case, before this patent infringement trial started. And that's not how a POSA thinks of drug-layering cores. He never rebutted that Avadel's SEC submission, that first one that I showed you, the colored one. Why didn't -- he didn't talk about that at all, did you notice that? Why? Shows that Lumryz has a drug layered core and he had no answer to that.

When he was talking about the patent, he's -- he -- he said there's missing words, I think the word he actually used was "oversight," that they didn't describe it with all the words, it was an "oversight." Okay.

So Avadel goes back to the Patent Office to correct their oversight? No, it's under a sworn statement to the United States Patent Office. It wasn't an oversight, that's exactly what they meant.

So, again, I'm going to show you that verdict form. It's going to look like this when it comes to the '488. Question 1 deals with infringement: Do you believe infringement has been established, again, our burden of proof, preponderance of the evidence, just a little bit more than even? And since the evidence shows that Avadel infringes, I'll ask you to check "yes" for the each of the claims, Questions 7 and 11.

So let's talk about everything you need to consider with respect to the '488 patent, validity issues there. United States Patent Office was required to evaluate each of the allegations Avadel was making in this case, they already looked at all of this. The Judge is therefore going to instruct you that the law presumes the patent claims are valid, presumes it.

The law presumes the Patent Office acted correctly, did their job at issuing the patents. That's why they have that heavier burden. That's why they go high up. They didn't say, We bamboozled the Patent Office. They didn't say, We didn't submit the prior art references. They didn't hide anything. Then you have Claim 24, which we never said we copied. The Patent Office -- same thing that they are saying today, Patent Office looked at it already. There's nothing missing. It's all there.

During opening, Ms. Durie actually said something I agree with. Every once in a while we agree on things, why not?

Was this something -- I think she said, Was this something they copied and didn't invent until 2018? Remember, she threw that date out there? Or was this an invention they had all along, an invention they made back in 2011. The question you have to decide for the '488 patent is whether Mr. Allphin had the invention all along,

something he actually made back in 2011. And the reason I agree with Ms. Durie on this one is because the '488 patent is judged under the old law. It's a pre-AIA patent. The law changed between the patents and the question is: Who was first to invent it? Who came up with the idea first? That's all that matters.

Happened to be that Jazz got to the Patent Office first too. The evidence shows Jazz did it first.

Remember, the evidence showed Mr. Allphin was first. He discovered he could control the release of GHB by using MAMM as a pore former. Back in 2009 -- we showed you those exhibits of his work in the laboratory notebooks from 2009. Dr. Guillard didn't do that work until 2012, and he only did it after he saw that testing in our patent. I'm going to get to inventorship in a minute, but how could he be the inventor if he took it from us? It's not possible.

He didn't do that testing until he saw it in Mr. Allphin's patent. Dr. Mégret told you about the different kinds of tests she ran, nothing on dissolution, nothing on DI water, we didn't hear anything about that.

Mr. Allphin did the work first. He looked you in the eye and he told you, "the sustained release with MAMM pore formers." That's what he told you. He was earnest, he was honest, he talked about his work.

And, again, don't take my word for it, it's all

right there. That document doesn't lie. A date doesn't lie. The work doesn't lie. It's all right there. They show that Mr. Allphin did the work in September of 2009. Remember, Avadel didn't start until 2012.

Let's talk about what exactly Mr. Allphin's laboratory records show, that his MAMM pore former formulations sustained the release of GHB, they work. Do you remember we showed you these graphs? Here, the data doesn't lie, Mr. Allphin was first. Avadel knows that Mr. Allphin used MAMM pore formers with GHB before they did. They -- they obviously know that, they know the dates, so they tried to misdirect here. They tried to change the story.

They tried to tell you that Mr. Allphin didn't actually disclose his invention to the patent -- in the patent specification, that document we have been looking at. What did Dr. Moreton tell you? He told you that the MAMM copolymers are specifically mentioned, called out in the patent specification. So whenever he tries to misdirect you again, the specification says, MAMM, but MAMM isn't -- isn't any -- they -- sorry.

So Avadel tries to misdirect you again on a slightly different issue here, the specification may say MAMM but it's not in any of the examples.

Okay. Mr. Allphin's dissolution curves aren't

part of that patent. But what did Mr. -- sorry -- what did Dr. Moreton tell you? Dr. Moreton explained to you that a POSA would understand the difference between MAMM pore former formulations and the nonenteric formulations with something called a "lag time." Remember, start-up lag time, that little period of time, something that would delay the start, the release of the SR portion about an hour.

So let's look at what happened when we moved the nonenteric pore former from figure 1 to Mr. Allphin's data. We showed you this earlier yesterday. What you see, once you move it, you reset it, it's off by about an hour. That's the lag time. That isn't there with the nonenteric pore former. But let's see, again, when you shift it by 1 hour, move that 1 hour, that lag time over, matches right up. It's the invention. Matches right up.

And by the way, these two different tests, one was an Apparatus 7, one was an Apparatus 2, look how they were, almost identical, it doesn't matter which apparatus, nonsense.

So, again, how did they respond to all of this? They try to misdirect you again. And Avadel argues and says, well, Mr. Allphin did his testing and dissolution 7 apparatus, and the claims say you should use dissolution 2, I just showed you on the 7, they match up, doesn't matter, they are the same, that's what Mr. Allphin figured out.

But what did Dr. Moreton tell you on this? He told you these devices yield a very similar dissolution profile, we just saw it, very similar, they are equivalent. Avadel called Ms. Gray to the stand to try to tell you something different and try to call Allphin's data into question. But Ms. Gray didn't do any of the testing of her own to call the data into questioning. She didn't test it. She could have, she could have gotten samples. It's her client, they could have just gotten it from Avadel.

She didn't show you the two dissolution apparatuses that would yield different results, she didn't show you how that would be, she just said it. She didn't do any testing to prove it. Mr. Allphin did it, showed you how they matched up.

And that's their burden to show. We don't have to show anything. It's their burden to show all issues on validity, their burden, clear and convincing.

To prove by that clear and convincing evidence that the data doesn't line up, Avadel could have done its own test. They had lots of experts. They brought the woman who wrote the book. Why didn't they just do it, prove us wrong? Because they know we're not wrong. They're just trying to misdirect you.

And it's not like Dr. Gray relied on one of Avadel's other experts. As I said, none of them did any

testing either. That's not clear and convincing evidence. They have to prove us wrong, and they didn't. They have to do it by clear and convincing evidence, heavy burden, simply didn't, didn't come close.

And Ms. Gray did not even know what a -- MAMM copolymers were before she got involved in this case. She never heard of them. And yet, zero testing to support the conclusions.

So what happened next? Avadel tried some more misdirection. Avadel's experts argue that the specification doesn't give a POSA any reason to choose MAMM formulation with a lag time, and so these claims are invalid for that reason. Okay.

What did Dr. Moreton tell you? There are advantages to choosing these kind of formulations, depending on the circumstances. Why you would want that lag time, those advantages, he told you that. Dr. Charman didn't say otherwise. No expert rebutted that.

Think about what else Dr. Moreton told you. The specification teaches you if you want a lag time, use an enteric pore former. It says that, and there's only three in there, and MAMM is one of them. The specification says you have three choices if you want to make one of these lag time formulations, and that's written description under the law. It's a limited, limited universe, three.

Not all those charts that Avadel put up to try to make you believe there's hundreds of choices, you're going to have to -- not true.

Getting -- sounding a bit repetitive, but what happened next? Another misdirection. They next argued, well, your MAMM lag time formulations are limited to tablets. Remember that whole discussion about tablets? You don't describe microparticles.

What did Dr. Moreton tell you? That the specification tells you that a POSA uses a special machine that's only really used, very rare instances in other places, to make microparticles. It's called a Wurster coater. One of the first cases I ever had was about a Wurster coaters, it's a special place in my heart. I know quite a little bit about these machines.

The patent tells a POSA to use the very same machine Avadel uses when it decided to make its microparticles. The patent tells a POSA to use the very same machine, and Avadel uses that machine to make its microparticles.

So, Dr. Charman originally told you that Allphin's '488 patent was limited to tablets. When you look at the claims Mr. Allphin filed way back in 2011, the original claims, and Dr. Charman's testimony on cross, these claims aren't limited to tablets. The claims have written

description support.

Remember what Dr. Charman told you, these claims have written description support. And he has no inventorship position. What does that mean? He agreed that if he find Mr. Allphin did the work in 2009 and put it in his patent application, the one that's filed in 2011, and he's on our side and he agrees with us. So we've seen that Allphin has done the work first. We've seen that Allphin described his invention.

The last question is where Allphin enabled others to make and use his invention. And how do you know Mr. Allphin's patent describes enough to enable a POSA to practice the claims? Because Dr. Guillard and Dr. Mégret did their own DI water testing, according to the Jazz patent, that's how we know. That's consistent with what -- Dr. Moreton's opinion. He reviewed the Allphin laboratory records and saw an extensive amount of work there.

So we check all the boxes here. Where does Avadel go next? In opening, Avadel's lawyer told you that Dr. Allphin didn't file his patent until 2018. Remember that? I probably made a face, I probably shouldn't have. I was like, what are you talking about 2018?

Why did you think -- that's when we first filed, you saw those claims and you saw they were originally filed in 2011 before Avadel started their work. Jazz did it

first.

So you're going to see the verdict form again on this issue. You're going to get questions 2-5. We'll ask you to give your judgment on whether the '488 patent claims are invalid and ask you to check "no" for each one of those. And, again, very important, we ask you to check it across the board. Check one of those, then the patent is invalid no matter which one, but we ask you to go with Jazz on all of those issues.

So let's talk briefly about damages. You heard Avadel admitted to infringement of the '782 patent. For the '488 patent, I think we've proven well beyond our burden here that they infringe that, too.

So what's the result? Under the U.S. Patent laws, Avadel is required to pay Jazz damages for its infringement. Avadel has clearly made and used the inventions of the patents. Doesn't matter that Jazz doesn't have its own once-nightly product on the market. I told you that in the beginning, I'll tell you that again, they're going to tell you it probably five more times. It is irrelevant. She can't deny that.

We have a patent, that's what matters. We contributed to the science here. We gave the platform technology for everybody else, including Avadel, to use, but it's not free, it's not what we do.

How has Avadel made use of the invention, you ask? Well, obviously they made Lumryz. And Avadel has targeted Jazz patients to get them to switch, convert off of Lumryz -- off of our product onto Lumryz. It's in their materials, they tell the doctors what they should be doing.

The parties also knew in a hypothetical negotiation, remember that's how this works, that Avadel planned to expand its use, right. That's what -- by expanding use, we talk about the pediatric labeling, so they can give it to under-18-year-old children with idiopathic hypersomnia. And maybe other areas, as we said, low-sodium product. And they use it just like Jazz uses it.

And what did Avadel expect from using Jazz's patent? They expected Lumryz to be a commercial success. Avadel was telling its own board of directors, as well as its investors, that it expected to make on Lumryz over a billion dollars annually, one billion. It's a big number. It's a big number.

It also expected Lumryz to take 50 or 60 percent of the oxybate market share. That's a big number, too. And you saw from Avadel's January 2024 investor slides, they are still saying it today.

There's no customary royalty for this technology in Jazz's patents. There's no place, no chart you can go look at and say, Oh, this is how much that costs. It just

isn't. They won't tell you there was one, because there isn't.

But Dr. Rainey put himself in the shoes of both Jazz and Avadel to figure out what a hypothetical license, if they sat down and had a talk at the time of infringement, what it would look like in the May, June 2023 timeframe when Avadel began infringing Jazz's patents.

He considered all the facts that both Jazz and Avadel would know walking into that hypothetical negotiation. And he determined that the parties would agree to a 27 percent running royalty rate for past damages. That's the only evidence you heard about this. That's the only thing you heard. It's only fair.

If you think about it, what the math works out to on this, and it's shown on the slide we saw the -- at the time these were prepared, about $32 million worth of product. 27 percent royalty rate gets you over $8 million in damages. Again, this is only fair.

Jazz and Avadel are direct competitors. We're the market leaders but we're direct competitors. Dr. Rainey concluded that Jazz would have been no worse off by entering the hypothetical negotiation. We wouldn't have done it, but had we to do it. We would be no worse off. Avadel would be much, much, much better off by entering into this hypothetical license.

So when you go to -- when you go to -- go back in the verdict form, you're going to see -- are going to ask you about the damages, we ask you to write in the 27 percent reasonable royalty. We ask you to write in the numbers that you see there as damages for Avadel's use of our patents.

You'll hear from Avadel's counsel on this. It believes the parties would agree to a 3 and a half percent royalty for the entirety of the hypothetical license, but there's no evidence in the record that Jazz would agree to a 3 and a half percent royalty in these hypothetical negotiations, none. You didn't hear any. Didn't exist.

As Dr. Rainey explained, Jazz would lose millions of dollars if the royalty rate were 3.5 percent of the entire license here, of the entire license term. It would be economically irrational for Jazz to enter into a license at a rate that would cost them millions and millions of dollars, they just wouldn't do it. But the hypothetical negotiation assumes that both parties would act rationally, that's what you have to do in this hypothetical negotiations.

So Avadel's theory is just wrong. And, therefore, again, on the verdict form, we're going to ask you to write in a 27 percent royalty rate, and for past sales of the $32 million number we saw, 32,519,345 for the record, and damages in the amount of $8,780,223 for the

amount of past damages from Avadel.

Now I'm going to turn the podium over to my adversary and she's going to talk to you for a bit. And I get to come back and get the last word in, I'm going to be short there, so I'll talk to you in a minute.

MS. DURIE: Thank you. Thank you, Your Honor, and ladies and gentlemen, good morning.

At its heart, this is a case about inventorship. It's a case about who made the inventions that are at issue in this case.

What we see here on the left is the claim that the United States Patent and Trademark Office awarded to us on our invention. What we see on the right is the claim that Jazz got. Now, you don't have to decide in this case whether the United States Patent and Trademark Office made a mistake, and that's because we know that they made a mistake, because they issued the same claim on the same invention to two different sets of people.

So we know there was a mistake, the only question is which one of these was the mistake; was it a mistake to give the patent to us in the first place or was it a mistake to give the patent on the same claims to Jazz?

Now, we showed you this, this is Claim 1 and Claim 1. And during the course of the trial, Jazz -- you heard Jazz complain, Well, the claim at issue in this case

is Claim 24, not Claim 1. That's fair; but Claim 24 has the same requirements.

If we go through and we compare our claim with the claim that Jazz is asserting in this case, those requirements still line up. There's a little bit of our invention that's missing, but those requirements still line up.

And I want you to keep in mind the Patent Office gave us a patent on that invention first. We filed for this patent in 2019. The Patent Office gave us a patent on those claims, determining that was our invention in 2020. Jazz didn't even try to get a patent on these claims until 2021. That patent issued later.

Now, you just heard Jazz's counsel tell you that Jazz did not copy our invention. And I want you to look at this and ask yourself, Is that credible? Because one thing that I agree with is that a lot of this case is about credibility. It's about who's trying to give it to you straight. Is it credible that this was just a coincidence? Or is it perfectly obvious from looking at that language that Jazz copied our claims.

Now, you heard that Mr. Matal didn't have an opinion about copying. That's because that's for you to decide. It's not up to any of the experts to tell you whether Jazz copied. That's a decision for you to make.

And I would note, nobody from Jazz came here and told you that they didn't. Instead, we heard you and we presented to you testimony from Phil McGarrigle. Remember, he's a Jazz lawyer, he works at Jazz. He was the person that we got to ask questions to about whether this was copied. And you may remember he sort of twisted himself into pretzels to try to avoid admitting that that's what happened.

(Video played for the jury.)

MS. DURIE: So they won't admit to copying. They do admit that they referred to our claims. It's up to you to decide whether those claims were copied. They then presented to you testimony from Mr. Stoll, their expert on Patent Office procedure. He had access to this entire record, including Mr. McGarrigle's deposition testimony, including the claims. He looked at that and said having read that testimony, having looked at the claims, he had not seen anything that convinced him that there was copying by Jazz. Again, I would ask you, is that credible?

So why is Jazz refusing to admit what seems pretty obvious, which is that they copied our claims? The reason they're refusing to admit that is because of the consequences of that copying. You heard Mr. Matal and Mr. Stoll talk about this provision, part of the rules that govern the patent examination process. And what it says on its face, when claims are copied or substantially copied,

you need to disclose it and that that information is material information. It's something the Patent Office would want to know, and failure inform the Patent Office may violate the duty of disclosure.

That's why Jazz doesn't want to admit to copying. Mr. Matal -- who, remember, was the director, he was the most senior guy at the Patent Office -- said if you copy the claims, under that rule you have to tell the Patent Office. Jazz did not tell the Patent Office that it copied the claims. And, in fact, Jazz invoked a special procedure to be able to keep its claims a secret from the world and from us until the day they issued and the day that we got sued.

Now, Mr. Stoll, the guy who saw no evidence of copying, took the stand and said he disagreed. He said he doesn't think that provision means what it says on its face and that it doesn't apply anymore. So a couple of things about that that I want you to keep in mind.

One, Mr. Matal explained to you when provisions get revoked or the law changes, it says so, and he showed you that where it says, This only applies to patents that are pre-AIA. This provision doesn't say that.

But the second thing, assume that both of these guys have reasonable positions. Right? Assume that there's actually a legit debate about whether you have to disclose.

We don't think there is, but assume there is. What would you do if you didn't have anything to hide? You would disclose.

So even if Mr. Stoll is right that some people think there's not a requirement that you disclose, when there's a rule that on its face says you should disclose and when the former director of the Patent Office says you should disclose, don't you think you would just disclose? Unless you had something to hide and you didn't want to tell the Patent Office that you had copied the claims.

So why wouldn't you want to tell the Patent Office that? Remember what Mr. Stoll said? There are over 600,000 applications a year and there are 9,000 examiners. That was his testimony. I did a little math. If you figure there are about 260 working days in a year, that's about 66 applications per examiner per year. That's about 32 hours per application. Not knocking the work the examiners do at all, but that's not a lot of time. And it's especially not a lot of time when you saw the volume of information that they get presented with.

You saw this was a single information disclosure statement that Jazz presented with 332 references on it that the patent examiner was supposed to review. This was the first one they sent in, and then in a subsequent one, they sent in the one that had our patent on it. So, again, no

knock on the Patent Office, but there's a reason that there are rules that you have to affirmatively tell the examiner things because the volume of work is overwhelming and it's really easy for stuff to get lost.

And that's why you heard in the patent video back a week ago -- which probably seems like a long time ago, it does to me -- that there is the possibility that mistakes were made. This is why you're here, right? If the Patent Office always got it right, we wouldn't need you. The reason we ask you to take a week out of your lives and do this job is because you're the ones who get to make this decision. And as you heard, examiners have a lot of work to do and no process is perfect and mistakes get made, and as I said, we know here that a mistake got made. It's just a question of which mistake.

Now, something for you to keep in mind, something else that you heard in the patent video, that whole patent examination process happens in secret, right? We didn't get to participate. So when Jazz was telling the Patent Office, Here are our claims, here's our invention, we didn't get to come to them and say, Excuse me, that was actually our invention. You are the first people who hear that.

And if you think back to opening statements on Monday, Jazz's lawyers got to talk to you first, and at the

end of their opening statement, you probably thought they had a pretty good case because you only heard one side of the story. That's the position the patent examiner is in. The patent examiner only heard from them. We didn't have a chance to get up and give the other side of the story. And I'm hoping that now that you've heard our evidence, you see there are two sides to the story. Information that the patent examiner did not have.

And one of the instructions that you're going to hear from the Court is that when the Patent Office did not have all the material facts in front of it, our burden to prove invalidity is easier. And that makes sense, right? Because the Patent Office can't consider something that it doesn't know. And here, Jazz didn't tell the Patent Office they had copied claims. That's not information the Patent Office had. And if you agree that it sure looks like those claims were copied, that is material information that makes it easier for us to show that that claim was invalid.

Now, I'm going to spend a whole lot of time talking about the evidence in the case, and I'm going to show you a lot of that evidence. There have been a lot of accusations that I just heard about misdirection, and as I said, I agree that credibility in this case is really important. So I want to show you the evidence, and I especially want to show you what people were saying about

that evidence back in the day, not what the experts are saying now, but what people actually said back then.

But before we get to that, I want to address a couple of things that I think are not relevant to what you're being asked to decide.

Now, we heard a little in the case about Xyrem, right? That was Jazz's immediate-release product approved in 2002. And there's been a consistent theme, I think, throughout the case, and it's actually reflected in this document from Jazz, that Jazz wants to be the master of all things oxybate. They had the first drug. It was Xyrem. They should get to have the oxybate market. It's their franchise.

They may want that, but that doesn't mean they have a right to that. Because, as is also undisputed and in Jazz's own documents, this is a really old drug. It was developed back in the 1960s, and part of what that means is there is no innovator company. Jazz -- Jazz didn't discover oxybate. They don't have the rights to oxybate. And that means they are not allowed to keep people from competing with them with oxybate drugs unless they actually have a valid patent that allows them to do that.

Now, you heard a lot of testimony about this 505(b)(2) pathway and you may have been wondering, What does this have to do with anything? It doesn't, and let me try

to explain why. 505(b)(2), as Mr. Divis explained, is a pathway created by the Food and Drug Administration, and what it allows you to do is not to repeat certain studies that have already been done before. This was a policy decision by FDA that says, If we already know that a drug is safe or not toxic, we're not going to make you go redo studies and test it on people to see whether it's toxic because we know the answer to that question.

FDA has an interest in getting drugs to patients as quickly and efficiently as possible, and it's a waste of time and a waste of resources to have people redo studies that have already been done. So this FDA pathway allows companies like us to use public data that is out there to support our application, and we're supposed to do that in order to get our application approved and get our drug into the hands of patients.

Now, you heard a lot of suggestion that Avadel got a benefit from that, and I think the point of that was to try to suggest that even if we don't infringe, maybe Jazz should get some compensation, right, because we used their data so they deserve something. This is a patent infringement case. Your job is to decide whether there are valid patents. This is not about compensating Jazz for the use of that data, and you know what? There is no requirement that we compensate Jazz for use of that data.

If the FDA wanted to put that into place, they could, but they didn't. What we did was absolutely fair and square. It's not germane to the issues in this case. It was just designed to make you think they deserved some compensation.

Now, you heard Mr. Divis testify about this. He's our CEO. He's been here for the whole trial. He sat in that chair. He answered their questions. Where's Jazz's CEO? You haven't heard from him. He didn't come in. You didn't even hear him by video. And I want you to keep that in mind when you're thinking, again, about the credibility of the testimony that has been present to you.

Now, you saw in opening this slide from Jazz. And what Jazz tried to suggest to you is that whole once-nightly thing was just about convenience. They didn't think it was that important. They prioritized safety, that's why they came up with their low-sodium product.

And, indeed, Jazz's very first witness was PJ Honerkamp. He was the guy who went to Harvard Law School, not a doctor. But he came in and he said the reason Jazz doesn't sell a once-nightly product is because it prioritized low-sodium, and he said it's not that big a deal. People may have expressed concern with taking it twice a night, but once they took it, they felt comfortable with it. And he said that somebody told him, Once nightly is a concept dreamt of by non-narcoleptics. So it doesn't

matter. You're waking up at night all the time anyway, no big deal. That's not what the Food and Drug Administration wrote.

This is Exhibit 112, and I tried to blow up some of these exhibit numbers in case you want to take notes because you're going to have copies of the exhibits back in the jury room, and I encourage you to look through them and see that evidence for yourself. And this exhibit, Exhibit 112, is one that I think is important because this is the letter from FDA where FDA said Lumryz is clinically superior to both Xywav and Xyrem, and it explained why.

And it actually says -- I'm not going to read all of this, but it says this is true even for a lot of patients who are sensitive to sodium, that the benefits of being able to sleep through the night are more important than the additional sodium burden. So JTX112, you can go look at that for yourselves, but suffice it to say the FDA disagreed with Mr. Honerkamp and said that having this once-nightly treatment is important.

And we brought you a doctor. We brought you Dr. Corser, who prescribes Xyrem, has worked with both companies, and what did he say? He said there are a lot of people who never get on oxybate because of twice-nightly dosing who would benefit from it; that once-nightly dosing is important for a lot of patients, it's a real benefit; and

that Xyrem, a high-sodium product, has been around for 20 years and they haven't really seen problems with sodium, with the sodium in sodium oxybate over those 20 years.

Did Jazz bring you a doctor to say that Dr. Corser was wrong about any of that? No. His testimony is in this case unrebutted. That's the record, because it's true. And they couldn't bring in anyone who was actually a doctor to contradict him.

Now, I want to talk a little bit about Mr. Allphin. Because I want to be clear about something. We're not trying to take away from Mr. Allphin the fact that he did good work. He did. I think he's a nice guy. I think he's mostly a pretty credible guy. He said that he was one of the people who developed Xywav, and I'll credit him for that. It's good for patients to have choices. We agree that there are patients for whom low sodium is a good option, and he should be justly proud of that work. You also heard Mr. Allphin say, In science, sometimes things work, sometimes they don't. Xywav project was a success. The once-nightly program at Jazz was not.

This is also a significant document, it's DTX236. And this is a technical memo that Mr. Allphin wrote summarizing the history of Jazz's efforts to develop a once-nightly program. And it's got this chart that just sort of summarizes all of those efforts.

You just saw a timeline that said Mr. Allphin did some work in 2009, and then he took a break to work on Xywav and then came to once-nightly in 2015 or 2014, there was sort of this big gap. This document is Jazz's own summary of their efforts to try to develop once-nightly. And it starts in 2002 and it goes through all of these different efforts, up to 2009. This, 2009 PLE-2, (indicating) we're going to talk more about this, this was the product that led to the '488 patent, but it continued.

2011, they tried a soft gel; they tried this thing called GBL; they tried a prodrug; they tried this, like, sipper device thing that would sort of give it to you slowly overnight; they tried this inhibition strategy; they had more trials in 2014; they were trying to solve this problem the whole time. And they went from thing to thing to thing to thing because none of it was working.

And then, in 2015, they did pick it back up. As we're going to see, once they saw that we had been successful and went back and realized that maybe we had the right strategy all along.

This is a document from Mr. Allphin, it's Exhibit 1412, this is from 2019. So this is years after Jazz says that Mr. Allphin had made these inventions and what is he saying in 2019? "I have seen so many oxybate once-nightly program and everybody thinks theirs will work,"

and then he lists them. PLE-2 (SR tablets), that's the work that led to the '488 patent; our work, he was still skeptical even at that point, that we would be successful; Tris resinate, the resinate program that ultimately got handed off to Tris but that was the program that led to the '782 patent.

And what does he say? "There's still a lot of work to be done between concept and reality, formulation is often taken as assured but seldom is."

In 2019, are these the words of someone who has already invented it? They're not. Right? Their invention had not yet happened.

Now the Court is going to instruct you about inventorship. And one of the jury instructions that you're going hear is that the patent has to name the true inventors, only the true inventors and all of the true inventors. And if you make any contribution to the invention that is claimed in a patent, you get to be named as one of those inventors.

And that's where I want to start, because we brought you testimony from our inventors, took the stand, and explained to you how they came up with this invention. Dr. Mégret explained that she studied the pharmacokinetics of sodium oxybate and how it interacts with the body and this idea that it gets cleared by the liver, right. And the

point of that was, because it gets cleared by the liver, if you give someone a small, steady dose, it's going to get cleared by the liver and it's never going to hit your bloodstream.

So what she realized is, you need to overwhelm the liver. You need to give a really big dose so that some of it will get past that clearance mechanism in the liver and make it to your bloodstream and to be able to be effective. And that was what then caused her insight, that the right way to make this drug was to have these two waves of this drug, very rapid to overcome the liver. Big release right at the beginning when you're going to sleep and then after a delay, a second big release that you would get during the middle of the night that would allow you to sleep through the night. She called it this "pulsatile profile," because it was two pulses, pulse, pulse.

And so the way this works for Lumryz, you take it, you get a release in the stomach, but those blue particles, those modified-release particles don't release in the stomach because they have a pH -triggered release and they don't release in the stomach which is really acidic. So they keep going down during the night, down into your intestine and then once they hit your intestine in the night, they release their drug because of that pH change and that was the invention that our inventors made.

And they were able to accomplish that using Avadel's Micropump platform, which goes back to 2001, which is a way to coat microparticles with this pH-sensitive coating that will allow for this delayed release. And you heard that Lumryz takes advantage of that Avadel platform technology, to have these delayed-release beads with a core that is inert, made up of something called MCC, but a little MCC core that you can buy a bag of, a drug layer layered on top of that, sodium oxybate, and then this Micropump coating that, in this case, includes methacrylic acid-methyl methacrylate that is designed to keep that thing intact until it hits your intestine, until it hits that higher pH and then release there during the night.

Now, Avadel appreciated early on, back in 2010, that the technology was a good fit for sodium oxybate. And you saw that we actually presented that to Jazz back in 2010 and said, we thought this would be a good idea. Mr. Allphin was on these communications back in 2010. And explained that we thought the Micropump system was the perfect fit for sodium oxybate because you could have this double-trigger mechanism based on pH, so you could have one release in the stomach and one release in the intestine because of that pH trigger. This is DTX1361.

Jazz had a whole different idea. This is an internal Jazz document from 2009. And what was their way of

thinking? Two pulse is not attractive. They thought that was a bad idea. Instead, they wanted, it says, "zero order release to 5 hours." What that means is a slow and steady release over a five-hour period of time, because they didn't understand what Dr. Mégret had figured out about the liver and about the clearance. So they thought, if you want to stay asleep all night, give people a slow and steady amount of the drug overnight.

So their idea was tablets, we're going to talk more about this, and it's tablets that were not triggered by pH, they would just slowly release the drug over time. So over the course of the night, you would get this slow consistent release of drug. Seems like a reasonable idea, but it didn't work for sodium oxybate because of the way that sodium oxybate interacts with the body.

But Jazz did file a patent on that idea. That is the application they filed in 2011. And as we're going to see, it's all about tablets, it's about sustained-release tablets. And what it is saying is that this idea of having a pH trigger is bad. They think what you want instead is this slow, steady release.

Then in 2014, Flamel publishes its results that there's been a positive first-in-man clinical trial with Micropump sodium oxybate. And I want to pause here for a minute and say, we did do clinical trials. We relied on

some Jazz safety data, that's true, as we're supposed to under the FDA regulations. We also did a massive clinical trial and published interim results from that clinical trial in 2014. And we said that our formulation was Micropump-based microparticles.

So, what was Jazz's reaction? This is an e-mail from Mr. Allphin, October 12th, 2014, after seeing those Flamel results. DTX248. He says, "I looked at the PK data on PLE-2 again" -- we're going to talk about that, but he went back and looked at the data they got on that tablet program, he says, "Every time I do so, it's a little less painful. It's still smarts though." But he says, "In doing so, my thinking on what happened has changed a little bit and I have to assign a greater chance of success for Flamel's or any concept that involves beads versus tablets."

He had been working on tablets. He saw that we had used beads. He saw that we were successful and he thought maybe beads are a better idea than I thought after all.

And then there's a big presentation at Jazz about, you now, how to think about Flamel. Flamel market intelligence, once-nightly sodium oxybate Micropump formulation. This is DTX250; this is a really important document. Because if you read through it, there's a lot of information here about how they were evaluating what Flamel

had done. You'll see one thing they said is, What we know, Jazz has been attempting to develop once-nightly sodium oxybate for many years and has not been successful. That's their own words. This is 4 years after they filed that 2011 patent application. They had been trying for a lot of years, they had not been successful. And they saw Flamel. So what was their reaction?

Flamel appears to be naive about the technical challenges of sodium oxybate. Essentially, sodium oxybate is incredibly hard to work with. You heard a lot of witnesses talk about that. It deliquesces anyway, it's really hard to work with. They thought that we didn't understand all those problems. They also said we still had technological, clinical and regulatory challenges. Fair enough. So what were their next steps? Maintain a high awareness of what we were doing, wait until there was more data and then consider when/if corporate development discussions are desirable.

Corporate development discussions means talks with us about whether to buy us, fundamentally, but they wanted to wait to see whether what we had proved up. So they did. They also went back to the lab, because you saw that Mr. Allphin said, Maybe those beads are a better idea than I thought. And Mr. Allphin started doing some initial experiments with resinate bead technology.

Now, remember, we published in 2014 our results, that it was using Micropump and that it was beads, but we didn't publish all the details of our formulation at that point in time. So Mr. Allphin was trying to figure out, how do I make beads? And he did some early experiments trying to make these resinate beads, so we're going to talk a little bit more about that. But then, very quickly, Jazz filed this patent application on those resinate beads. Then -- and that's the project that you saw went up to Tris, then they tried to partner with Tris and then that didn't go well.

Then in 2018, our patent application publishes and that patent application has all the details of our formulation and that is what provokes Project Zeta. Now, these are the corporate development discussions, and Jazz approaches us with an offer to buy the rights to FT218, to Lumryz. And they offer to pay us 50 million upfront and $100 million in development milestones and royalties for the rights to our products. And I would just ask you to think: If they thought this was something they'd already invented, why were they offering to buy it from us? They were offering to buy it from us because they didn't have it.

We made a counteroffer. We thought our product was more valuable than Jazz's price. And it's important to remember, in these discussions, and you heard it right out

of Mark Rainey, their damage expert's mouth, the entire premises of these discussions, Avadel was the inventor, we were the inventor of the product, Jazz was going to be promoting it, they were going to be selling it, but we were the inventor and that is reflected in the term sheet.

So if you look at the term sheet, it's JTX200, you're going to see there is a provision in it about scope of licenses and exclusivity, the license grant. What it says is, they were going to get rights to our intellectual property, to our patents. There was nothing in there saying that we needed any licenses or rights to any of their intellectual property or that they had any intellectual property that was relevant or any patents that was relevant to FT218.

And you heard Mr. Divis take the stand and testify, he was asked, When Project Zeta ended, did Jazz tell you you would need a license to its patent if you didn't do the deal with them? He said no. That's undisputed. Nobody from Jazz got up there and said he was wrong about that. Oh, yes, we did say that after all. They didn't say anything about patents. And I think I heard something over the course of the trial that was a suggestion, Well, we didn't say anything about the patents because the patents hadn't been -- we didn't have the patents yet. Well, that's exactly the point.

If they had already made the invention back in 2011 and 2016 and they had filed for patents on those inventions back in 2011 and 2016, they would have said so, right? They would have said, We've already filed for patents on this, you're going to need rights to our patents. They didn't say that, because it didn't occur to them that they could try to claim to have made this invention until after these negotiations fell apart, when they didn't want to pay the price and they tried to figure out what to do to protect their franchise.

That brings me to the '488 patent. Now, again, I'm going to go through the evidence in slightly excruciating detail, but, again, there's been a lot of talk about misdirection and I want to make sure you see that evidence yourself and I want to start by talking about noninfringement.

So the Court is going to instruct you about infringement and how infringement works. And the Court's instructions will explain: You compare each asserted claim separately against the Lumryz product to see whether all elements, each and every requirement is present.

What does that mean? Imagine that I invent the ginger cookie, and I get a patent on a cookie that has flour, sugar, butter and ginger. In order for a patent to infringe, that's how I write my patent claim, a patent has

to have flour, sugar, butter and ginger.

If somebody else comes along with a chocolate chip cookie and it's got flour, sugar, butter and no ginger but chocolate chips instead, there's no infringement. And that's true even though there's flour, even though there's butter, even though there's sugar, because for infringement, every single requirement has to be met.

That's the way the law works; you get to write patent claims to define your property, and then people, if it's not within the scope of your patent claim, what you've defined as your property, other people get to use it.

They wrote the claims, they said, This was our invention. Every single element has to be present, and that's just the way the law works.

You can think of it as a little bit like a deed to a piece of land. If I'm walking down the street in front of -- on the sidewalk in front of your house, I'm not trespassing on your property. I might be really close, I might be 2 feet away, but I'm not on your property. If I step over into your property, and you haven't given me permission to do that, now I'm trespassing.

And patents work the same way, there's a boundary, you're either in or out. In order to be in, every requirement has to be present.

So let's take a look at what their patent

requires. One of the things that their patent requires, this is part of Claim 1, is that you have to have a drug, you have got to have a functional coating, you've got to have a core, and the core has to comprise -- that means include -- at least one pharmaceutically active ingredient.

So why would Jazz have included this requirement? They copied our invention, why would they include this? So they copied it, but they sort of copied it badly, is what I said to you in the opening. And the reason for that is that this patent is all about tablets. And in the patent, when it's talking about this core, it's talking about the core of a tablet, it's a coated tablet having a controlled-release CR core that includes at least one drug substance.

So in the context of a tablet, that makes total sense. So if you think about a tablet, a coated tablet, it's got a tablet, the drug is throughout the tablet, and then there's a coating on top of it.

So in the context of a tablet, that totally makes sense. And that's exactly what they described in their patent specification. They've got a sodium oxybate tablet core, it's got sodium oxybate in it, it accounts for 95 percent of the weight of the finished tablet. And then there's a little coating that they are going to put on top.

So that's why -- I mean, it doesn't actually

matter as to why, but that is why there is this requirement in the patent that you have a core and that there has to be drug inside the core.

That's not what we have. As we talked about in opening with the example of the baseball, we have a core that is inert, it's MCC. Again, as I said, you buy it, there's no drug in there. We have drugs sprayed onto it. And then we have a coating that is on top of both that core and of that drug layer.

And if you take a look, one of our other patents, we're sort of talking about this very explicitly, an inert core, a coating and a layer. That's just -- it's unambiguous, right, that's what our product is.

And, again, as I explained in opening, you cut open a baseball, you can see the core, you can see stuff around it, that would be equivalent to the drug substance, and there's the leather that wraps around the whole thing. The patent is about having the drug and everything else that's inside all mixed together.

So what's the evidence about our product and whether it has a core? It's our patent. And both sides agree, our patent accurately describes the product. You read our patent, that is the evidence about how our product works. Now, I say "our patent," I mean the whole thing, I don't mean pulling one little thing out of context. I mean

you read the patent and you understand how our product works.

And I will say, I think Jazz's argument on this is really word games. They don't actually dispute how our product works because they can't, and so it really is word games. Because this figure is -- there's no room for ambiguity here.

On the left, there's the immediate-release particle, it's got a core, no drug in there, everyone agrees with that, it's got a drug layer surrounding it. On the right, the modified-release particles. Same core, same drug layer, now we've got a coating on top.

And you heard, when Dr. Little was asked questions about this, he said, Well, it's two-dimensional. I mean, yes, it's a cross section, it's two-dimensional. But there's no dispute that this accurately represents our product. Nobody got up here and said that figure is misleading, that's not actually how Lumryz works.

And if that is actually how Lumryz works, I mean, there's -- there should not be any possible room for doubt here, it's got a neutral core.

So what is Jazz's argument? Jazz says, well, there's table 1a and there's table 1b and they correspond to the two figures. So table 1a, it's the composition of the IR microparticle. And we see it says there's a

microcrystalline cellulose sphere, that's the core, and there's sodium oxybate, that's the drug substance. Couldn't be more clear.

And then we go to figure 1b and they say, ah-ha, it says IR microparticles, and they are performing the function of the core of the MR microparticle.

Now, as you heard, that's true insofar as it goes, because there is a core in there that is providing the function of being the core. What it doesn't say explicitly is that there's also sodium oxybate as part of that IR microparticle, it's performing the function of a core, it's also performing the function of having a drug.

Now, I think Jazz's point -- and then there's a coating.

Now, I think Jazz's point is, if you look to figure 1b in isolation, you might think, huh, the entire IR microparticle is the core. But if you read it in the context of the patent, this is not remotely debatable. The patent makes it entirely clear there's drug in there, too. The patent makes it entirely clear the core and the drug are separate, that's figure 1b, it shows it, right.

And the fact -- the fact that the drug substance is not explicitly called out in table 1b does not mean that there is not drug substance in there. And that is confirmed by other portions of our patent.

You go look at table 1d, it's the finished composition, what does it say? Sodium oxybate is the drug substance, MCC spheres are the core, various coating excipients. According to Dr. Little, this is impossible. He doesn't have any explanation for how this could be correct.

He takes 1b, he looks only at 1b, he doesn't look at the figures, he doesn't look at this, and he says, ah-ha, I see ambiguity in figure 1b. There's no ambiguity when you look at the patent as a whole.

There's a core, there's a drug layer, there's a coating, table 1b tells you so. And there are documents and documents and documents, we only try to show you a small number of them, that again make this plain. This is what we submitted to FDA, there's a neutral core, there's a drug layer, there's a coating. This is from Jazz's own documents. There's a neutral core, there's a drug-loaded layer, there's a coating.

Now, we heard a criticism of this, I think that they are saying, oh, it's showing the same figure over and over again. Well, yes, because that's the figure that shows how our product actually works. The reason that that's what we're telling FDA, the reason that's what Jazz is telling itself is because it's the truth; this is our product works, we have a neutral core, we have drug around it, we have a

coating around that.

And this is what we told our investors, this is now more a three-dimensional picture, but you can see there's an inert core, there's a drug layer. Consistently we explained the way our technology works. There should not be any question that the centermost thing in our modified-release particles is an inert MCC core.

So what does Dr. Little say? He says, Well, there's coating, so anything that's underneath the coating is the core and there's drug under there, so that's got to part of the core.

That's just flatly inconsistent with figure 1. He's got no response to that. It's not the way that our product is described. It doesn't make sense. But he's got no way to address figure 1b other than saying it's two-dimensional, which really isn't the point.

So what else do they do? They point to this document and they say, ah-ha, this talks about a coating and it talks about a core underneath of the coating. Two things about this that are important: One, this is a document about Flamel's Micropump technology generally. It is not a document that is only specifically about Lumryz. Our Micropump technology is a coating technology, and you can put it on any kind of particle. So you could put it around a particle that had drug mixed inside.

And, to be clear, that's a thing. You heard about extrusion inspiration technology. That Jazz folks played around with that a little bit, but they didn't have the right kind of equipment to do it. But that's technology where you mix the drug up with stuff and you squeeze it out. And then you do have the little spheres that have drug in them that you can coat.

And you could use Micropump coating technology to coat those if you wanted to, or you could use Micropump coating technology to coat our particles, inert core, drug around it.

So when you take a look at our presentation about Micropump coating technology, it's not specific because the coating technology could be used either way.

It also then says core active ingredient, layered core. Jazz is very excited about that, I'm not totally sure why. Because, sure, once -- one option is you've got, in the core, crystals or granulates, or you've got a core with layers on top of it. All of these are options underneath our Micropump coating technology.

So, what are the facts at the end of the day when you sort of strip away the word games, what are the facts? The facts are our immediate-release particles have an inert core and a drug layer, Jazz doesn't disagree with that. Those same immediate-release particles are used to

make our modified-release particles. We put a coating on top.

Jazz's argument is that when we put a coating on top, somehow, kind of magically, that inert core goes away. It doesn't, it's still there. You know, I talked with you in opening about the fact that you've got a baseball, you cut it open, you've got a core in here, right? It's in here.

I could wrap this up with something, you know, I could give it to somebody as a present, put some nice wrapping paper around it, there's still a core in there. Nothing I do out here is going to change what's inside the middle of this. That core doesn't go away just because I put something outside of it.

Jazz's infringement argument would require that it does.

So at the end of the day, we don't infringe the '488 patent because the '488 patent requires that there be drug inside the core. And we have a core that doesn't have drug inside of it. And for that reason, we don't infringe.

Now, I want to talk about invalidity and why the '488 patent is also invalid. Now, again, we've talked about this, the Patent Office makes mistakes.

And there are three related doctrines that the Court is going to instruct you about that are relevant to

what you're going to be asked to decide. One is what is called a written description requirement. If you want to claim to have invented something, you have to describe what you've invented, and you have to describe all of what you invented. That's part of what's called the public notice function.

You have to say to the world, This is my invention. And you can't say, This is my invention, and then come back later and say, This is my invention. At the beginning you've got to define what your invention is and say pubically, This is my invention, and describe all of it. That's written description.

There's also a requirement called enablement. And the enablement requirement is you have to teach people how to make what you invented, and how to make all of what you invented. And that's part of the patent work, because when you apply for a patent, you're applying to get exclusive rights to your invention.

And part of the trade, part of why we have the patent system is because you have to teach how to make that invention, and then everyone is supposed to benefit from that teaching, from that public knowledge.

And then, finally, you have to name the right inventors. And there are two related doctrines that are involved in the '488 patent on this: Inventorship and

derivation. But fundamentally, you've got to name the right inventors. And you're not one of the right inventors if you got the invention from somebody else, that's derivation.

And if you flunk any of those, if you don't describe the full scope of your invention, if you don't teach people how to use the full scope of your invention, if you don't name the right people as inventors, then your patent is invalid.

And here specifically with respect to derivation, you're going to hear, the Court is going to instruct you, the inventors have to be the true inventors, and if -- they're not the true inventors, if they derived the invention from someone else. So I want to start there, which is: Where did the invention that was ultimately claimed in the '488 patent come from?

Now, these claims were submitted by Jazz to the Patent Office in 2018. That's an undisputed fact. Okay. The application was filed in 2018, the claims were submitted in 2018. That was the first time that Jazz sought these claims that are at issue in this case. And that was after Avadel's patent application had published where we describe, for all the world to see, as you're supposed to do, all of the details of our formulation.

And one of the things that Jazz claimed when it submitted these claims in 2018 was a controlled-release

portion that includes methacrylic acid-methyl methacrylate. So they were saying in 2018, Our invention is the use of MAMM. And they submitted claims with this very specific testing protocol for a MAMM formulation, and that's important. They weren't just saying, like, We invented USP 2 or we invented USP 7. Those have been around for a long time. But they were saying, You have this formulation that has MAMM in it, you test it according to this protocol in USP 2, and here are the results that you get. And they said in 2018, That's our invention.

So these microparticles, they're made out of MAMM, which means they're pH-triggered because MAMM is a pH-triggered thing, and you test them in USP 2 to see whether they satisfy the test. So the question becomes where did that invention come from? Was that invention of these pH-triggered MAMM microparticles an invention they had back in 2011, or was that an invention that they derived from, that they copied from us? So I want to talk about the evidence that relates to that.

So first, where did it come from in a most immediate sense? We showed you DTX483. This is a PowerPoint presentation where the folks at Jazz saw our patent application get published, and they copied a bunch of figures from our patent, that's fine, and then they tried to figure out all the details of our formulation. They made

notes on it, that's fine, and broke down all the details of our formulation. So 483, you're going to see them in 2018, March of 2018, studying our formulation in a lot of detail.

And then they filed those patent claims in July. So the question is: Did they get that from that study of our formulation, or is it something that they had actually invented back in 2011 when they filed a patent application to sustained-release tablets -- I'm going to show you this -- when they said that having a pH trigger like MAMM was bad, was a bad idea, and when they did not have any formulation with MAMM that they even could test in this particular kind of testing apparatus?

So I want to talk about what the invention that they made in 2011 actually was. And, again, I want to apologize. I'm saying a lot, and I'm showing you a lot. And I know it is a ton of material, but, again, there's been a lot of accusations of misdirection, and I want to make sure you have the evidence. So I'm going to walk through this evidence about what they actually invented back in 2011 in a fair bit of detail.

Now, the Court is going to instruct you that written description is designed to make sure that the inventor invented the subject matter and was in possession of the full scope of the claimed invention when they filed -- when -- as of their effective filing date, when

they are saying they made the invention. So back in 2011, did they actually have the full scope, were they in possession of the full scope of what they later claimed in 2018? And the Court is going to instruct you the written description requirement ensures that the issued claims correspond to the scope of the description that was provided in the original application. So you look at the claims, you look at the original application. Do they match?

So, first of all, what did Jazz itself say about that 2011 invention? Jazz itself, not now that we're in a lawsuit with each other, but what did they say back in the time. E-mail from Mr. Allphin in 2014, U.S. 2012, that's Allphin 2012, that's the application that led to the '488 patent that we filed for sustained-release film-coated tablets. We're going to come back to what he says about this, but tablets. And that is the way that Jazz consistently described both the project that led to the '488 patent and that 2011 application. We were looking at their summary, right? 236, 2009 PLE-2 sustained-release tablet, former aspect sustained-release tablet.

In 2013, Mr. Allphin is talking about their various failures, what's been tried before, ER film-coated tablet. That's a reference to this 2019 project. And, in fact, I asked him, When did you first believe you first invented any formulation? And he said, Well, the objective

of the PLE-2 program and in the Allphin/Pfeiffer patent was a single daily dose of tablets. Now, remember, that's what he said at his deposition, but that's right. I mean, he was being candid. That was the invention, or at least the desired invention. It was a single daily dose of tablets.

And again in 2019, when he's reviewing the history of the program -- this is 1412. I'm pulling stuff out so you see what I think is important, but you can go back and look at these documents yourself. 1412, Jazz PLE-2 SR tablet. So why were they talking about it as an application on a tablet? Because that's the work that they had done and that's that they thought they had invented.

This is 1423. They're talking about that PLE-2 project, novel formulation design. It's a tablet, and they have this idea for how to make this sustained-release tablet with drug inside with a rate-controlling film. They've got an immediate-release coat. This was their invention, and that's the thing that they filed for patent protection on was this -- what they thought was a novel formulation of a tablet.

Now, one of the other things the Court is going to instruct you, claims may be no broader than the supporting disclosure and a narrow disclosure of the limited claim breadth. What does that mean? If you disclose tablets, your claims have to be limited to tablets. You

can't disclose tablets and then say, Oh, I invented microparticles too. If you try to do that, if you try to claim more broadly than what you said back in the day was your invention and what you disclosed as your invention in the patent, then your patent is invalid.

So what did Jazz say back in the day in the 2011 application? Every single example is about tablets. I'm not going to run through all of them because there are 13 examples, but you can look at them yourself. You've got copies of the patent. Every single one is about tablets. And if you look at what Jazz says in describing its invention in the '488 patent, it talks about coated tablets, it gives lots of weight ranges and things for ways to make these tablets, how much drug do you want to have, how much coating do you want to have. And it says these ranges are useful for tablets of a particular size, and they say, alternatively, if you've got a tablet of a different size, here's how you want to adjust it, if you've got a different-sized tablet.

All of it is about tablets. There's nothing in here that says, And if you want to make a microparticle, here's how you might want to do it. Nothing. It's all about tablets.

And, indeed, if you take a look at the second patent -- this is the '782 patent, so this is the second

patent that was filed in 2016 -- they're talking about the prior art, about the work that had been done before. And they're talking about this earlier program and explaining why their 2016 invention is different from the work they had done back in 2011. And what do they say? "While extended-release oxybate dosage forms are known, such extended-release dosage forms are provided as solids, e.g., as tablets." And those tablets can be quite large and you've got to take a lot of them, and that's a bad thing.

They're criticizing their own prior work in the '488 patent, but the thing that's important for these purposes, they're describing it accurately. It was about tablets. And they're saying in 2016, We did something different because we did microparticles, that earlier work was about tablets.

So they brought you Dr. Moreton to come in and testify about the disclosure of the '488 patent. And what did he say? He said, Well, a person of skill in the art would know. He admitted there's nothing in the patent about microparticles, right, but he said a person of ordinary skill in the art would know.

I want you to just ask yourself, the patent contains pages and pages of explanation about how to make tablets, how to coat tablets, how to adjust coating weights for tablets. It actually does teach you how to make the

tablets. Why does it have that teaching in there? It has that teaching in there because patents are supposed to teach. You can't just turn around and say, Oh, I don't need to provide the teaching because a person of ordinary skill in the art would know. According to Dr. Moreton, a person of ordinary skill in the art would know everything, including everything that's in the patent, right?

So why is there all that teaching in the patent? There's all that teaching in the patent because you have to teach and because the premise of the patent is it's explaining to you how to make these adjustments for tablets. Nothing about microparticles.

In the opening, Jazz's counsel said that our expert was going to say, I don't see it there, which is true. And he said Jazz will take you through it and show you in black and white where it is. And I would ask you to think about whether that happened. Did they pull out the '488 patent and say, in black and white, There's a disclosure of microparticles, there's a disclosure of microparticles with MAMM that are not pH triggered -- or that are pH triggered and why that's a good idea? They didn't.

They brought you Dr. Moreton, who said, Well, the specification doesn't tell it, but a person of ordinary skill in the art -- that's the POSA everyone has been

talking about, a person of ordinary skill in the art -- would know. That's not a disclosure in black and white.

(Reporter clarification.)

MS. DURIE: That is after the fact wishing that you had made an invention that you didn't actually make.

Now, Dr. Moreton also pointed to this part of the patent specification. This is at column 4 of the '488 patent. And it's talking about having an immediate-release part, and what it says is "The immediate release can be a dry powder or a tablet or a liquid or all these other things." So the immediate release could be a powder. Okay, fair enough. And he had confirmed that's talking about the immediate release. That's not talking about controlled release.

And then it says the immediate-release component can be formulated as part of a single dosage form that integrates both. In such an embodiment, the formulation may be provided in the form of the coated tablet or capsule. And he says, Well, it doesn't say it could be a powder or, you know, microparticles, but it says "may." The pharmaceutical formulation may be provided, so it could be anything. Doesn't have to be a tablet, doesn't have to be a capsule. It could be anything.

That's not the way a patent disclosure works, right? The fact that you say it may be provided as a coated

tablet doesn't mean that you're saying you actually invented everything. Again, you have to describe what your invention actually is. This is what they said their invention actually is, and they get held to that. And the reason they get held to that is precisely so they can't come back later after the fact and claim to have invented something they didn't invent. They invented tablets. That's fair. They get tablets. They didn't invent microparticles. They don't get to claim now that they did.

Now, what else did Dr. Moreton say? He said, Well, there's this example in the patent that talks about a Wurster fluid bed film-coating process, and he said that's better for microparticles than it is for tablets. He admitted that you can use it with tablets, but he said it doesn't work very well with tablets.

Okay, fair enough. It may not be optimal, but remember -- and he admitted this and you'll see it when you go look at the patent -- that reference to a Wurster fluid bed coater comes at the end of a long section that's talking all about tablets, the weights for tablets, and then it says -- and how to coat tablets, and then it says you can use a Wurster fluid bed coater for tablets. Again, it may not be the best way to do it, but it's a way to do it. And the fact that they said you can use a Wurster bed coater to coat these tablets does not tell you that they had made some

different invention. And Dr. Moreton confirmed that what I just said and showed you in the patent is correct.

This is kind of interesting. One of the documents that got put into evidence is what we call the file history. It's the back-and-forth with the Patent Office. And this was part of the back-and-forth with the Patent Office when they were trying to get claims in the '488 patent. It's Exhibit 807, and this is page 407. It's a really thick document, so if you want to go look at it, it's page 407.

And what did they say? The Patent Office had said, Hey, we think Liang already made your invention; what's different about what you're doing from what Liang did? Liang was some very early work that involved microparticles. And they said, Oh, in contrast to what we're doing, Liang does not teach or suggest a compressed tablet. We're a tablet, Liang was microparticles, so we're different. Fair enough. But what they're saying is, We're a tablet, we're not microparticles; Liang did microparticles, we do tablets. That was correct, but it's precisely why their invention was about tablets.

So the Court is also going to instruct you that a wish or a plan for obtaining the claimed invention is not adequate written description. In other words, you can only claim to have invented something you actually invented.

It's not an invention to say, I would like to be able to do something, right? You've got to actually be able to do it.

And relatedly -- and I'm going to talk about these concepts together because they are related -- the Court's also going to say that a patent has to disclose sufficient information to enable or teach people to make and use the full scope of the invention without undue experimentation. So you've got to teach people, you've got to say that you invented it, and you've got to teach people how to make it or use it, and it can't just be a wish or a plan.

Jazz had not invented a multiparticulate formulation. It's not in the patent, and the test, to be clear, is whether it's in the patent. It's not in the patent, and the reason it's not in the patent is because it is an invention that they had not made. Now, to be clear, they thought about it. They thought about it, and they rejected it.

This is Exhibit 667. This is from 2009 when they're starting off the program. Multiparticulate beads, pellets can't work, right, they think it's not likely to work, platform rejected.

And then we see in July of 2009, Exhibit 665, platform is rejected without screening, right, they didn't even try to screen it with different tests.

Multiparticulate beads, pellets unlikely to work as film coated for sustained release.

So, again, I said to you, I want to show you the evidence because what really matters is, what were they saying back then? Not what are they saying now when they wished they had invented this because we did, but what were they saying back then, right? And the documents don't lie about what they were saying back then, and this is what they were saying, it wasn't going to work. They thought it wasn't going to work.

And so moving forward, they rejected film-coated beads or pellets as a potential platform because they didn't think it was going to work. And I asked Mr. Allphin about this and he admitted, they didn't even have the equipment in their lab to make pellets, they didn't have the equipment in their lab to coat pellets, so they didn't do any work with pellets.

And fast-forward to 2014, when Mr. Allphin saw our results that we were successful with pellets, he was skeptical. And part of why he was skeptical, he said, There's other companies out there who are really good at making bead formulations and there are really formidable challenges and if this was a doable thing, I think somebody else would have done it or at least tried to do it if there was even a remote chance of being feasible.

He's saying, I think this is so hard to do, that there's, you know, not even a remote chance of it being feasible and, now, Jazz is saying it was something they had already invented. That doesn't make any sense.

Moving forward to 2015, then, Mr. Allphin says: Looking back, much of the work focused on making IR beads -- this is in 2015 when he's now gone back to try and make beads after he saw that we were successful -- unfortunately all attempts were unsuccessful.

So how could they have already invented something that they were unable to do and that their attempts to make were unsuccessful? You can't teach in your patent how to do something that you are not yourself able to do.

And in 2015, again, four years after they say they made this invention, they tried layering on seeds, didn't work, they abandoned the approach, they couldn't figure how to do it. Long story short, that was an invention about tablets. It was not an invention about microparticles. They tried to make -- they thought about making microparticles. They thought it wasn't going to work. They didn't have the equipment to do it. They went back years later, after they saw we were successful, they tried to do it again and their experiments failed. That's not what it means to be an inventor and it's not what it

means to teach an invention. That's tablets.

Second point about this early 2011 invention, their whole idea back in 2011 was that having a pH trigger was a bad idea. So in 2018, their patent claims are all about MAMM. Yay to pH trigger. We wanted ph trigger. Back in 2011, they thought that was a terrible idea.

You saw this document, 2-pulse, that's having a ph trigger that lets you get that second release in the intestine. They thought that was a bad idea. And they say it in the patent itself, right. They're talking about that earlier work, Liang, they say, the delayed-release component, however, function in a pH-dependent manner.

Remember, I asked Mr. Allphin about that, however, he said, Ah, it doesn't mean it was bad. Well, think to yourself: What does it mean when you say "however"? I want to go for a hike, "however," it's raining, right. You don't say, I want to go for a hike, "however," it's a beautiful day, right. "However" means something that isn't great. And that's exactly what it means here. pH trigger, "however," isn't a good idea.

In fact, I asked Mr. Allphin also about this language. He didn't agree that it necessarily meant there was a problem, but he did say, it differs from what we did, which is true. pH trigger is not what they did. And I asked him: You thought having a pH-trigger was less

desirable? He said, "I think that's fair."

And going back to the patent, specifically with respect to methacrylic acid-methyl methacrylate, MAMM, the thing that winds up in the claims, the thing that was in our formulation, the thing we disclosed in 2018, what does the patent say about that?

Not much, only pops up in a couple of places, but what does it say? It's possible to use an enteric component, "enteric" means pH-triggered. It's possible to use it, here's some examples, however, incorporating enteric components may result in delivery characteristics that exhibit some level of sensitivity to gastric and intestinal transit times. "However" does not mean it's a good idea; "however" does not mean it's our invention. It is saying, however, that's probably not a great idea because sensitivity to gastric and intestinal transit times is not good.

And, again, Mr. Allphin, I asked him: You never came to the conclusion that it might be acceptable to have a pH trigger?

"I didn't."

He can't have invented something that he thought was unacceptable. His invention was no pH trigger, he thought that was the way to go. He thought having a pH trigger was a bad idea.

So what about these notebook pages? They showed you a couple of pages from Mr. Allphin's notebooks and he said he did a couple of experiments with MAMM. And he did. Fair enough.

Now, again, I want you to keep in mind, they showed you, like, a couple of pages out of, you know, work that happened over the space of, what, 2 years, 2009 to 2011. Yeah, he did do a couple of experiments with MAMM. He did experiments with a whole bunch of things, trying to come up with the invention. But these experiments that they pointed you to are not in the patent and there's a reason for that. They are not in the patent because this was a pH-sensitive polymer and he never came to the conclusion that that was a good idea or a good thing to use.

And that's why he testified none of the examples in the patent use MAMM. None of the examples would tell you that it would be possible to be successful with MAMM. He didn't know whether that would be true. And it is why in their own internal documents, from back in the day, what are they saying about multiparticulate beads, pellets? Enteric coating not an option. Enteric means pH trigger, not an option. Now they're saying that was their whole invention, was MAMM. What did they say back at the time? Not an option.

Now, you heard Dr. Little's attempt to explain

this. He said: Well, it's not that they didn't include them in the patent because they thought it was a bad idea, they didn't include them in the patent because you can't include everything in the patent because the patent would be so big you wouldn't be able to use it.

Interesting. Go take a look at Exhibit 260, that's our patent, it's 111 pages long. Go take a look at their patent, the '488 patent, it's 32 pages long. There's plenty of room to include those examples, if that was the really the thing that they had invented. They didn't leave it out because it would make the patent too long. They left it out because it wasn't their invention and they thought it was a bad idea. And it wasn't until they saw we had used it successfully, to get that pulsatile release, that they thought was not a good idea, that they wished that had been the invention that they made.

Now, the other thing you heard reference to was that the original claims that were submitted back in 2011 had this reference to polymethacrylates, and they said well, MAMM is a polymethacrylate, so that must mean that we have an idea.

Well, you heard Dr. Moreton, my partner, Adam Brausa, asked him: There are other polymethacrylates that are nonenteric? And he said, "That's right."

So this is a big umbrella term, it includes

stuff that is pH sensitive, it includes stuff that is not pH sensitive. And you heard Dr. Guillard, when he was asked about this, said: Yeah, we used MAMM, it is a specific kind of polymethacrylates but there -- it's a very broad, it's a very general category.

Sure, they claimed a whole bunch of things, very broad categories but there was nothing that said, we think our invention is having a pH trigger, because they thought it was a bad idea.

The other thing I will just say about those claims, they actually abandoned them and then turned around in 2018 and for the first time, said, actually, our whole idea is a pH trigger. It's kind of like in their patent application, they sort of threw in a whole bunch of stuff, a whole bunch of different ingredients that you might use. And if you read the patent, you'll see there's a list -- like a binder, could be a blah-blah-blah, there's a whole long list of things.

And then we came along and we said, this is the way to do it. Use MAMM, use it in these percentages, this is the secret sauce. This is how it's going to work. And they went back and said, well, actually, we had that invention all along because we had those letters there, even though we didn't appreciate which ones you would need to use or in which order and how to do it. Again, that's not how

invention works, invention works when you actually figure out what the code is. We're the ones who actually figured out what the code was.

They did not, back in 2011, have an invention that was MAMM and it was a pH-sensitive thing. If they had that invention, they would have said something back then.

Final points, final points about the '488 patent. Their 2011 invention was not testing in USP a MAMM formulation. First of all, they didn't have a MAMM formulation to test so they couldn't test it in USP because they didn't have the one in the patent and they didn't do that precise testing ever.

Now, where did this come from, where did this requirement come from? So you heard Jazz's counsel say that we copied this idea of doing testing in DI water from them.

So it's true that their patent talks about doing testing in DI water. This is their original patent. It talks about doing Xyrem, it talks about doing testing in DI water. And it's true that we benchmarked against that to say, how does our formulation compare? Which, you're totally allowed to do, everyone agrees you're allowed to do. We explained it, there's nothing wrong with that. And we then included in our patent what those results were. Here's what happened to our formulation under those test conditions.

In their patent claims that they submitted in 2018, after we published that, they copy the precise test conditions for formulation with MAMM and the results. The problem is, that's not a test they've ever done on that particular formulation.

And in order to know whether you're going to meet those test results, you have to do the test.

Mr. Allphin agreed with this. This is from him in 2021. They wanted to see whether any of this stuff they were doing now would fall within the scope of these claims, and they were, like, well, I don't know, you got to test it. Fair enough. That's exactly right. You would have to test it.

And the examiner, as we saw, raised a concern about this and Mr. Allphin submitted a declaration and I want to be clear here, the declaration is not false, as I said before, it was carefully worded, right, but it's very carefully worded. Not by Mr. Allphin, I'm sure this was written by the lawyers, I can't image he wrote it, but it's very carefully worded.

It says that this shows -- Figure A shows the dissolution profile of a sustained-release portion meet ing the limitations of the claims.

You might think reading that, if you're a busy patent examiner, oh, they did a testing under the conditions

of the claims and they got results. That's not actually what it says.

And then they go on to say, The dissolution profile that was tested in a dissolution apparatus -- they don't specify which dissolution apparatus -- blah-blah-blah.

And you heard Mr. Allphin say, Well, look, anyone would know that because it says a dip rate of 30 per minute, that was dissolution Apparatus 7, not dissolution Apparatus 2, even though the claims required dissolution Apparatus 2.

You heard testimony from Vivian Gray, and she said a couple of things that are significant, I think, for your consideration. One, she said it doesn't make any sense the patent examiner would know. This is not a very common apparatus, this is very specialized testing. And, two, the results can be different; if you test the same thing in USP 2 and USP 7, you get different results.

Now, you can decide the credibility of her testimony, that's why you're here, whether you think she knows what she's talking about, whether her testimony made sense. You can also look at the record, because JTX105, this is a memorandum from Mr. Allphin. And he said they had tested some granules in USP 2 and USP 7 and they got remarkably faster dissolution in one than the other, they got very different results.

So when Jazz's counsel says you got the same results, you might get the same results some of the time. I don't disagree with that. You're not going to get the same results all of the time, and we know that because they didn't. That's why it was important to be precise about what testing was being done.

And the thing I would say is this, look, if you wanted to be upfront, why wouldn't you just say in a dissolution Apparatus 7? Why would you keep that information out?

And I just think, in general, as you look at the evidence, I want you to be thinking to yourself, why did it go down this way? Why not just tell the Patent Office we did it in a different apparatus from what's claimed, and let the Patent Office make the decision about whether that discrepancy was important?

That's it for the '488 patent. I'm done.

We think for all of those reasons: It doesn't name the right inventors, they got the invention from us, they didn't have a description of microparticles that are pH sensitive, subject to these testing conditions, back in 2011. That's not an invention -- invention that they had until 2018, when they saw our formula and copied it and then claimed that that was really the thing they had done back in the day.

Now I want to talk about the other patent, which is the '782 patent, which we believe to be invalid as well. Now, you've heard we don't contend that we don't infringe this patent, and that's absolutely right. And the reason that we don't is because they copied it from us, four square, we saw that at the very beginning, right.

Our invention, their invention, they're identical. So, of course, we do it, it's our invention. The question isn't whether we do it, the question is who owns it, right. That's the only question for the '782 patent, who owns it.

Which mistake did the Patent Office make? Was it a mistake to give it to us or was it a mistake to give it to them? And we think the evidence is pretty clear that it was a mistake to give it to them, that the Patent Office got it right the first time when we applied for that invention and we got it.

So, again, the same basic doctrines are relevant here, or at least three out of the four. Written description, enablement, and inventorship. They have to have described -- if they want to say they invented that back in 2016, they have to have said so back in 2016, they have to have taught how to make it back in 2016. And, critically, they have to have named the right inventors, right?

And if they got inventorship wrong, if the people they put on that patent were not the inventors and the only inventors, then the patent is invalid.

So I want to start with this question of inventorship. Again, you can read the claim for yourself and make a decision about whether you think Jazz did or didn't copy this claim from us. I would suggest just looking at the language, it's pretty clear.

And one of the consequences of the claim having been copied is it's not an invention that Mr. Allphin actually made. I asked him about this. I asked him about this at his deposition, and you remember we had a back-and-forth about this, because at his deposition I asked him about what was topic 20. He had been designated to testify on behalf of the company on certain topics.

And I asked him about topic 20, which was Claim 1 of the '782 patent. And I asked him, "Do you consider yourself to be an inventor of the formulation that is described in topic 20?"

And topic 20, you can see here, I read it into the record when I was questioning him, topic 20 was, "experiments conducted on a formulation of GHB with immediate-release, modified-release, viscosity-enhancing agent and acid wherein they're separate."

Topic 20 was literally the exact same language

we see in Claim 14, right, which is then incorporated within Claim 24. So that's what I was asking him about, were you an inventor of that. This is what he said.

(Video clip was played for the jury.)

MS. DURIE: I think that was a candid response. He didn't know whether he was an inventor of that because that was not an invention that he ever that thought he had made. It was, in fact, an invention that was copied from us.

Now, on the stand he tried to take it back. And he was asked some questions by Jazz's counsel on redirect, and he was asked, "Would you like to explain why you said you didn't know if you were the inventor of experiments conducted on everything I just read at your deposition, because topic 20 was experiments conducted on a formulation?"

And Mr. Allphin said, "Well, experiments conducted, you don't invent experiments so I was confused about what exactly was being asked of me."

You can evaluate whether he seemed confused when I asked him that question. But, again, my question was not about experiments, my question was pretty straightforward: Do you consider yourself to be an inventor of the formulation that is described in topic 20?

And his answer to that question was -- as Jazz's

corporate representative, after two and a half days of preparing for that deposition with their lawyers, his answer was "I don't know."

That wasn't the only thing. I also asked him when he first thought about that formulation and whether it was before or after he acquired a general understanding that Avadel had filed for patent claims on such a formulation.

"Did you think about that before or after you saw our patent claims?"

"I don't recall."

What about his coinventor, Mr. Bura, because Mr. Allphin and Mr. Bura are the two inventors on that patent. What did he have to say about whether he thought he made that invention?

(Video clip played for the jury.)

MS. DURIE: So what is the invention of the '782 patent really? Let's talk about that. I said that in March of 2010, Flamel, you know, then Avadel provided to Jazz thoughts on how to use Micropump technology to make a sodium oxybate formulation.

And if you look at what we told them, we said immediate-release particles; we said you could have modified-release particles; we said you could have a suspending agent, that's a viscosity agent; and we said it would make sense to put in it a sachet. We said all of

those things back in March 2010, that's not the invention that's in this claim.

The invention that's in this claim, which is an invention that we made, is this idea of having an acid and that the acid is separate from the immediate-release and modified-release particles. That's what's new. Everything else was in that 2010 publication, right -- or presentation. This is what's new.

What did Mr. Allphin have to say about that?

"At the time of your deposition, you didn't know what the purpose of having an acid in the formulation even was, right?"

His answer, "I couldn't recall, my memory was fuzzy..."

It's the thing in the claim that's new. That's it, that's the invention. It's the thing in the claim that's new. And he couldn't recall why it was there. And the reason he couldn't recall why it was there was because that's not an invention that he made. It's also not an invention that's described in the patent.

What is the patent? Does the patent say, '782 patent, Jazz, say, you should have an acid that is separate? It does not. What it says -- and this is what Jazz points to for support. What it says is any excipient, salt, acid, buffering compound, blah-blah-blah, basically anything, or

anything else could be packaged with sodium oxybate or packaged separately from sodium oxybate. Anything could be separate or together.

And that's what they're pointing to as support for the idea that they had invented the idea of having a separate acid back in 2016. That's not what that says. That's not remotely what that says.

Now, why did we make this invention and why is this important to us and not an invention that they made? That understand -- that requires understanding the point of having the separate acid be there.

So Jazz, remember, was working on these resinate beads, ion exchange technology, it's not pH sensitive. So they will release without regard to the pH that they are in. So what that means is when you take that Jazz formulation, that resinate formulation, and you put immediate release and modified release into a glass of water because you're going to take the formulation, immediate-release oxybate will release, it's very basic.

In other words, it's not at all acidic, it will make that whole solution less acidic. Doesn't matter. The modified-release beads are still there, they are not pH sensitive, you drink it, all good, you don't need to do anything, it's fine.

However, our invention is different. And as

Dr. Guillard explained, we needed the acid to stabilize the solution because of the particular way that Lumryz works. You see this in our development documents.

This is one of our development documents, it's JTX230, and it talks explicitly about why you need to have that separate acid and why you need to have it there to stabilize during the reconstitution step, that's when you dump your Lumryz into water before you drink it.

So why do we need to have a separate acid? Because if you took Lumryz and there wasn't any separate acid in there, just the modified-release and immediate-release particles, and you dumped it into a glass of water to take it, the immediate-release would release sodium oxybate. I said sodium oxybate is really basic. We have a pH-triggered formulation.

As the pH shifts, as the sodium oxybate gets released, that would cause our modified-release particles to start releasing. And all of a sudden you would get an overdose of the drug because you would be getting the drug in the immediate release and the drug in the modified release at the same time because of that pH trigger.

So what was our solution to make sure this didn't happen because we have a pH-trigger? Include an acid in the formulation separately. So when you open Lumryz and you put it in, there's both kinds of beads, but there's an

acid there too.

The immediate release releases, but it's not a problem because the acid holds the pH at an acidic level. And remember, the whole point of our modified release, it doesn't release an acid, it doesn't release in the stomach, that's the point. So you keep it acidic, it keeps the modified release intact, you don't get the overdose. You drink it, passes through your stomach, gets to your intestines, you get that second wave.

That's why we need the separate acid. It's why they don't need the separate acid. That's why we invented the separate acid. It's why it didn't make any sense for them. It's why Mr. Allphin didn't understand what it was there for, because it's not something they needed. It is something that we needed because of the specifics of our formulation. And it doesn't matter, just to be clear, what acid you use, because the point is having an acid there to hold that pH at an acidic level.

So what is it that Jazz actually invented in 2016? It was ion exchange resins. It was a very small set of experiments. They made these ion exchange resins. We're going to see they didn't actually even show release -- you hear Dr. Charman talk about that -- but they had the actual resin itself, and that's what they filed for a patent on back in 2016. Different from our approach.

Then in 2020, our patent issues, and shortly after that, Jazz files claims in 2021 that are carbon copies of our claims. And remember, they then went through that special procedure to keep those claims a secret so that we wouldn't know they had copied our claims and were trying to get those claims until the claims issued and they could sue us.

So remember, this project back in 2016 got started when they learned about us and our success in 2014. And Mr. Allphin said, looking at Flamel's results, that he actually had to assign a greater chance of success than he thought to beads versus tablets, so he want back to the lab and started investigating beads. 2015, started doing experiments with resins. What did he figure out? Resins are a lot more complicated than they seem at first glance, and there's a decent chance this isn't going to work.

Kept doing some experiments. Interestingly here, way before they filed the patent application, he's thinking about an acid, but it's a totally different reason. He's thinking that they're going to be putting so much basic sodium oxybate into your stomach that it's going to mess up with your stomach pH. So he's thinking maybe we need an acid in there to acidify the stomach. And what does he say about having a separate acid? You can't do that, you can't do it as a loose powder in the sachet because it would be

unpalatable. It has to dissolve in the stomach.

His idea right before he files the 2016 patent is the exact opposite of us. He's not thinking, I need an acid to keep it from dissolving and releasing sodium oxybate in the glass. He's thinking, I need to keep things acidic in the stomach and I can't have a separate acid to do that because it would taste terrible because you would need so much of it.

And then after they filed that patent application, he keeps doing experiments. Now, to be clear, if you file a patent application and you say, I invented this on February 18th, 2016, you have to have actually invented it on February 18, 2016. You don't get to backfill. You don't get to do more stuff and then go back and say, I ought to get the benefit of that earlier date.

And even after that, what is his view? Applying these techniques to pellets -- a nonenteric means a release -- is really hard. And in April, the consultant they're working with is rating the chance of success as less than 1 percent and only because he didn't want to seem overly pessimistic on the call. This was not an invention that they had. They were working on something that they thought, even at the time after they filed the patent application, was extremely unlikely to work.

They continued to evaluate oxybates. What does

he say in June of 2016? It pushes the boundaries of technology, it's hard to see how it would mitigate the failure of conventional beads. Dr. Charman testified it would take an excessive amount of experimentation to go from what they had, early experiments that were not working, to an actual successful formulation. You don't have to take his word for it. They couldn't do it, right? They couldn't do it, and you can't teach other people how to do what you don't know how to do yourself.

So what does Dr. Little say about this? He admits there's no data in the '782 patent that really shows much of anything. Doesn't show release, doesn't show anything. They put in some of these initial experiments that they could make a resin. They didn't even show release of the drug from the resin. He didn't really fight that. Instead, what he said is, Oh, there's an example of that in the '488 patent. So you can go back to the '488 patent. The support is there. And he points to the fact that the '488 patent is incorporated by reference. This is the '782, and he lists a whole bunch of patents that he's incorporating by reference. And he says, One of them is the '488 patent, the support's all back there.

Now, one initial comment about that, Mr. Allphin told you that his invention in the '488 patent was what he kept calling core/shell. I don't know if you remember that

phrase. But he said, My '488 invention is core/shell. Do you know what the '782 patent, the second patent says about that core/shell technology? It actually says it was bad, didn't work, that's why we're now trying to do something different. He said, Those skilled in the art will appreciate that these factors complicate and, in many cases, limit conventional approaches for modified release, such as core/shell -- so saying, What we did back in the '488 patent was conventional core/shell technology -- as the high solubility and mobility of sodium oxybate would tend to significantly reduce the number of viable approaches using such conventional tech solutions. In other words, that core/shell stuff was conventional. It didn't work very well. That's why we have a new invention now.

Okay. In any event, going back to the '488 patent and what it actually discloses, Dr. Moreton told you none of those examples involve microparticles, so they can't teach microparticles. It doesn't mention microparticles, and here's what's really significant about that. If you agree that the '488 patent is about tablets and it's not about microparticles, their entire argument for the '782 patent goes away because they are relying -- they admit '782 patent doesn't teach you anything except these little resinate formulations, doesn't teach release. They're relying on the '488 patent for that. The '488 patent is

just about tablets, and the entire thing falls apart because then there is no support for the idea that they had a microparticle invention in either 2011 or in 2016.

Now, I went to take a little bit about Claim 19 specifically. And this is the claim that's about particular blood levels, and I want to be very clear about something. You saw something flash up on the screen during Dr. Charman's examination where we had said that this was found that there was support for this in the '488 patent application, right, you remember that? And I want to be really clear. We thought that at the beginning of the case. We thought that the '488 patent application had some teachings about blood levels. And then we did discovery in this case, and we came to the conclusion that that was wrong, and I want to show you why. Because it was portrayed as a change in a position, and in some ways it was, but I want to explain to you why we changed our views about that.

So the '782 patent itself doesn't have any support for blood levels. This is the only thing in there that provides any support. This is example 3. It's the one about the fasted beagle dogs, and you heard this is not an experiment they actually did. There's no results here, and the reason there's no results is because it's not an experiment they did. It was what Mr. Allphin called a prophetic example, which is to say how they would do it if

they did it but not something they actually did.

So I think a common ground between the two of us is the '782 patent itself, nothing about blood levels. And that's why Jazz is saying, well, it's not in the '782 patent, but the '488 patent is incorporated by reference and it's in the '488 patent, so good enough. And, again, Mr. Allphin admitted there's no data in the '782 about blood levels.

So let's go back to the '488 patent. What does it actually say? So the '488 patent has data. We talked about this data. There's a table and there's some figures, you'll see them in there, and they report on studies of what happened when they gave these tablets to people and then measured the levels of sodium oxybate in their blood over time. And what you see on the right is one line that's got two sharp peaks. That's what happens if you take Xyrem and you wake up in the middle of the night and you take the second dose. And that other sort of nice-looking line is what they were showing happened when people took their sustained-release tablets, and it's that other, sort of, more gentle curve.

And Mr. Allphin, we discovered over the course of discovery in this the case, talked about this. This is one of those e-mails. This one is from 2014. He's talking about that U.S. application for film-coated tablets, and he

says, "The figures may be fairly easy for someone to digest. If one didn't know better, figure 12 and 13 showing fasted state look pretty sweet." So if you didn't know better, this would look pretty sweet. And you know what? It does. We actually thought it did. It looks like you've got a nice -- they achieved a pretty nice-looking sustained release.

We didn't know better; we then learned better, because we went through discovery in this case and -- in an e-mail in 2014, in talking about Flamel, Mr. Allphin said, "If they did their initial studies without a food-effect component, they could be in for a rude surprise." We were in for a surprise. It turned out not necessarily to be rude, but we were in for a surprise, because it turned out that they did not share all the results of that study with the Patent Office. They gave the Patent Office some of the data, but not all of the data. And Mr. Allphin admitted that. There was other data from the study that was not given to the Patent Office. And that other data was for people who had eaten before they took the drug.

This is, again, an internal Jazz document. They're talking about that PLE-2 program, and they're talking about that study. "A well-powered PK" -- you heard Dr. Mégret explain that, pharmacokinetic study -- "revealed substantial variability even in the fasted state. Certain

subjects in the fed state experienced delayed and sometimes biphasic profiles." What does that mean?

This is Exhibit 251. I encourage you to look at it. It's reporting on the study. This line here that we've highlighted in green, this is what happened when you took the two doses of Xyrem. This line here is what it looked like for people who had fasted. Not bad. This is what it looked like for people who had eaten. Almost nothing and then a peak dose of drug at the 8-hour mark. This is a drug you take at bedtime. You take the drug at bedtime, you get almost no drug until eight hours after you take it, which is to say in the morning, and then all of a sudden you get hit with a massive dose of a drug that's supposed to put you to sleep. That's just not remotely feasible.

And this is one of the individual examples. We've highlighted what it looks like. Under that curve, you can see if you took this drug at 10:00 p.m., you'd get almost no drug, almost no drug, and then starting around 6:00 in the morning or 8:00 in the morning, you'd start to get a dose of drug, and then at 8:00 in the morning, you would have a massive dose of drug and you would be asleep. No surprise that Jazz found these results completely unacceptable and chose not to share them with the Patent Office. And Mr. Allphin admitted, I mean, the interpretation of the data, there's no question about it,

you get a peak load of drug really late, and that's really undesirable.

What did Jazz internally say about this? Our formulations don't work, because they have this result and they didn't understand why this was happening. Cause of food effect is unknown and a risk for any future formulation. They did not understand why this was happening, and that's why they abandoned that tablet project, because of these results that they did not tell the Patent Office about.

And what did Mr. Allphin say about this? What's been tried before unsuccessfully? "ER film-coated tablets" -- that's the '488 project -- "got very good human PK results in fasted state" -- that's what they told the Patent Office, that's what we saw -- "bizarre and completely unacceptable results in fed state," not publicly disclosed.

They made a selective disclosure of the data. We thought it was good data until we saw the whole story and we realized that it's not. And it's interesting, Jazz never tried to get claims to blood concentrations off of this patent. You look at the patent claims, there's not any there, and you know why, because they know the data is bad. We did actually do the PK studies and get the data.

Dr. Mégret talked to you about that, she talked about the studies that we ran, she talked about the PK

profiles that we got. We had people eat because we knew that people were going to eat before dinner, and we got good results anyway. And you heard her talk about that, and we published our data and the results of that in our patent with the ranges that Jazz, then, copied like they copied everything else into the '782 claims.

I'm almost done. I do want to talk really briefly about damages. Now, to be clear, you're going to be asked to go back and fill out this jury -- this verdict form. I'm not going to go through it with you because from my point of view, it's pretty simple. Everywhere that you go, it tells you whether your vote is for Jazz or for Avadel. You'll be shocked to learn that we think the vote should be for Avadel. You don't need me to tell you that, right? The question at the end is a question about damages. You don't answer that question unless you find that we infringe a valid claim of the patent. The Judge is going to give you an instruction that is specific to that point. So if you agree with me on the merits, you don't get to damages and you shouldn't consider damages in your deliberation.

I very, very much hope that I don't need to say anything about this. But Jazz's damages demand is so outrageous that I have to say something, partly to make sure you understand why and partly because I do agree that a lot of this is about credibility and I think this is useful in

thinking about the credibility of the parties' positions. So what is Jazz's damages demand? How are they going to protect their oxybate franchise? They are going to ask for royalty rates of up to 27 percent. Over a quarter of the money that we make, they want to take.

What's their theory for this, which adds up to a almost $800 million that they want from this case?

Well, the Court is going to instruct you on what the standard for patent damages is. It's called a reasonable royalty, and the Court is going to say, what you're supposed to be considering is the incremental value that the patented invention adds to the end product. The product is Lumryz, what did they contribute to Lumryz?

I would suggest the answer to that question is nothing. We made it absolutely 100 percent ourselves. Their technology doesn't work, ours does. What did they contribute to Lumryz? And that's it. That's what they're supposed to get compensation for, if anything, the value attributable to the infringing features of the product as a function of the incremental value that they brought to the table.

That's not what their damages expert did. Their damages expert said, we want 27 percent because we have patents on Xyrem and Xywav that are protecting those products. And then those Xyrem patents are going to go

away, now we only want 13 percent and then the Xywav's patents are going to go away and now we only want three and a half percent. The value that they brought to the table for us has nothing to do with whether they have patents on Xyrem or Xywav. That is a complete distraction.

This is about the patents at issue in this lawsuit. And if you look at this, in that third period of time, patents at issue in this lawsuit are enforced, they are saying three and a half percent is a reasonable royalty for our use of those patents. If that's true then, it's true at any time if what you're measuring is the value of what we got from them.

Now, again, I want to be really clear. The value of what we got from them was nothing, but this, this has nothing to do with the instructions that the Court is going to give you on damages.

And Dr. Rainey admitted, he said, A reasonable royalty must be based on the incremental value that the patented invention adds to the end product.

So how did he justify it? He didn't try to figure out the actual value of putting a drug in a sachet or anything that relates to the actual claims of the invention. An idea, by the way, that we obviously had back in 2010. Instead, what he said is: The patents allow for a once-nightly formulation, which is the key to the success of

Lumryz.

I mean, come on, they don't have a once-nightly formulation, it cannot be that the value that we got from Jazz was a once-nightly formulation that they have been trying to make for 20 years and have been unable to come up with. That makes absolutely no sense.

Mr. Allphin was right back in 2019. We didn't follow them into once-nightly; they followed us. And the idea that we got the value of a once-nightly formulation from them is not consistent with any of the evidence that you've seen in this case.

So, again, the one only correct answer for the amount of damages is zero.

If you are going to consider the damages question, that number, three and a half percent from Dr. Rainey, which he said is a reasonable royalty for the patents involved in this case, would be the only number that could possibly comport with the Court's instructions.

But, again, I want to be really clear. I am only talking about this because I think I have to and because I think their demand is so crazy, but you should not get to this question because the right answer is nothing.

So I told you at the very beginning that this, at its heart, is a case about inventorship. And it is. And I want you to ask yourself -- I don't get to talk to you

again. You're going to go in the jury room, you're going to talk to each other, you're going to look at the evidence. But I want you to ask these questions to yourselves as you look at that evidence.

If Jazz actually made these inventions back in 2011 and 2016, why did they wait until after they saw our patent application and our patent to claim to have made those inventions? Why didn't they say so back in the day? Why did they wait?

And if Jazz made those inventions, if they already had those inventions back in 2011 and 2016, why did they try to buy our product from us in 2018? And why didn't they say so? Why didn't they say, in 2018, You're using our intellectual property if they'd already made those inventions?

And, finally, if they made those inventions in 2011 and 2016, why did they copy our claims? Why didn't they tell the Patent Office, easy enough to tell, why didn't they just say, Hey, we copied these claims? And why did they keep their claims a secret if this was all on the up-and-up?

So the question for you is: Who are the real inventors? Is it Mr. Bura, who didn't even come to court to subject himself to cross-examination about his contributions? Is it Mr. Allphin? Or is it Dr. Mégret and

Dr. Guillard, who came here all the way from France? They're former employees, they didn't have to be here, but who came and testified and sat through trial because this is their invention and they care about it and they care about getting credit for the work that they did.

I know this has been a lot. We are incredibly appreciative. This case is existentially important to Avadel. You heard, this is our one and only product.

We thank you very much for your attention and we really, really appreciate your service, thank you.

THE COURT: All right.

MR. CERRITO: I told you she'd say something. That was quite a "something." It was mostly her. Attorney argument is not evidence. She put up documents that nobody in this case has ever talked about, no witness ever saw, nobody was able to explain it to you. She told you about them, that's not evidence. You can't use that back in the room. That's argument.

And there's a reason she didn't put those documents in front of actual witnesses, because when she did with Mr. Allphin, remember, the Holy Grail, oh, we got the Holy Grail, this once-nightly, Mr. Allphin tried to explain that document, what did she do? She cut him off.

Mr. Calvosa had to put him back on redirect and said, Did you want to explain that? Yeah, he explained it.

He said it had nothing to do with once-nightly. Stayed away from him after that, didn't she?

All those documents you saw up there, a vast majority of them were shown to other witnesses. I have been doing this a long time. 31 years. That was the shortest cross-examination of an inventor I have ever seen in my life. Why? Because she didn't want to hear him tell the truth. She didn't want to hear him explain what those documents meant. She wanted to tell you. That's not evidence. It's not evidence.

Can't rely on what she said, that is not evidence. You heard what the witness said. Great. Her -- her discussion of documents, that's not evidence.

That's why he was up there for such a short time, she didn't want to hear the truth from him, she didn't want to hear the explanation.

I just have to touch on Dr. Guillard. Dr. Guillard is sitting in this courtroom right now because he's being paid, as he was when he was on the witness stand. Paid for his testimony. A fact witness. You don't pay for their testimony. They did. That's why he's sitting here all the way from France.

Early on -- again, I'll try to point out as much as I can but this story was thick, there was a lot drama in it, there was conspiracy theory, all kinds of things going

on here.

Remember, important detail are the dates. Who did it first, who got there first, that's what matters. They had this great invention, where were they? We got to the Patent Office first. They said they looked up -- they looked at the two claims together and she said, Well, they're -- they're about the same, we have the same invention in the claims, but she said -- she said she had a little bit more in the Avadel claims.

Do you remember that cheeseburger I showed you? That cheese is a little bit more, I'll give her that, but she still has the parts we patented.

I'm going to jump around a little bit, hopefully not confusingly, just that I have a lot to do in a short period of time. There's a lot of unpack there. She said a lot of things. Maybe another great example of her testifying was, you heard all about the SEC document and how that doesn't really say this and it doesn't really mean this, ironically -- can I borrow this for one second?

Ironically, her witness never said that. Dr. Klibanov didn't touch that document because he knew Dr. Little was right. So she had to come in here and tell you, Oh, that didn't mean that. That's not evidence.

She likes to show you the baseball. I like this baseball, too, see if I can buy it off her afterwards, that

drug-layered core that he was talking about, this is a great example of evidence, hoping she brought this. That ring, that's the drug layer over the core. That's what Dr. Little was talking about, in which they stayed away from, Dr. Klibanov wouldn't talk about that. She had to testify on his behalf. That's not evidence.

Another good example of what was going on there is the story she told about Dr. Allphin, Mr. Allphin, saying he didn't know if he invented something. Remember, he said, "I don't know," asked if he was the inventor of this, and he said, "I don't know." So did Dr. Guillard. Then he said, well, isn't -- aren't you -- you know, the reason Clark was talking about that is because he's not a patent attorney, he's not an agent, he doesn't know the legal definition of an inventor. So we asked Dr. Guillard, said, Are you inventor of that, of your product? He said, "I don't know."

Mr. Calvosa said, "Well, aren't you a patent engineer? He said, "No." We showed him that he was a patent engineer, then he admitted it.

Want to talk about credibility? This guy is a patent lawyer. He didn't know if he invented it and then he sat and told us he wasn't a patent lawyer, we had to prove him wrong on the stand.

Just want to hit this quick, on -- this Claim 19 thing, I hope you're not as confused as I am because I'm

pretty lost. We saw almost nothing on this. They admitted that the blood levels in these patent -- that claims were disclosed. Avadel had an expert about these PK tables up until a few weeks ago and they pulled him because he admitted it.

Again, they don't want you to hear the actual evidence, she wants to testify for you. The expert said it was there, and we've met the limitation of our claim.

No one has said that pH data that she pointed to was unreliable, not a single witness. She did. She's not evidence.

Want to hit another random -- I apologize for bouncing around a little bit.

Damages, the only damage evidence you heard here was from Dr. Rainey, that's all you heard, and that's unrebutted.

Attorney argument, again, Ms. Durie's argument, it's not evidence, not something you can consider back there when you're debating this case, it's not evidence. It's her argument.

Again, why put things in front of people when they can explain what's actually going on? Well, you can just tell a story, doesn't have to be true, doesn't have to be accurate, tell a story. We tried to use facts in evidence that you heard in this case with real witnesses,

saw very little of that from Ms. Durie, very little of that.

Made some big deals about this copying claims. Again, I don't know how many times you have to say it before we get this through to myself and others here, there has never been an accusation that Claim 24 was copied, just never was. Because it wasn't. Believe me, you'd see all kinds of slides and boards and arguments about that if it was. It wasn't.

At the end of the day, you have to remember what we talked about at the beginning of this case, and it rings true at the last minutes of this case, and that is, these dates are critical, they're important: March 2011, February 2016.

What's important about those is, you don't have to take my word for it, you don't even have to take Mr. Allphin's word for it. United States Patent Office, two different examiners, not one, not one that was out to lunch.

And by the way, let me stop on that a second. 600,000 applications, 9,000 examiners, oh, that sounded like a lot. It's five; five applications a month for each examiner, five. And by the way, most of the time, they get rejected, get thrown out before they ever get to the -- down the road in prosecution, before they get to allowance, it's five a month, that doesn't seem like a heavy load for people who are educated, severely educated people who do this for a

living.

So, at the end of the day, you have two independent examiners looking at two different patents, patent applications. At two different times, they both see our invention in the patent applications. They both see them independently, two separate times. They'll have you believe they made a mistake twice, two different people on two different patents made two different mistakes, nonsense. It's convenient.

They have to say it, right. They infringed the '782, they have to -- they have to say something. That's what I told you when we started this case, they have to say something. So they're going to tell you, oh, patent is invalid. Oh, yeah, based on the same arguments we're making here before you, the examiner just blew it. Don't believe it, it's not true.

What are the odds? Think about that, in the real world, how many times have you made two different mistakes on two different applications by two different examiners? And they just happen to be in court in front of you today. What are the odds of that? Didn't happen.

By the way, they made this big deal of Mr. McGarrigle, I think she used the word "pretzel." He's tall and thin, I don't know if he contorted into a pretzel. He gave answers honestly and truthfully. Before the

examiner.

And by the way, he also testified that he provided the examiner with direction towards the Avadel patent. He knew what it was. It was the first one disclosed. He specifically told him, go look at that patent, there's claims like it -- in it, because they are not copies, they're not identical.

And even if they did copy, there's absolutely no requirement that they disclose it. The examiner does his job independently.

And by the way, what did Mr. Matal say that he would do different if there was a disclosure, what did he tell us? Nothing. He said there would be no difference. Mr. Stoll told you the same thing.

Mr. Stoll actually prosecutes patents, actually worked as an examiner, actually knows how this works. Not a lawyer for the Patent Office.

We had a big discussion about tablets versus capsules. I think it's quite clear what was stated on this issue. This is from -- sorry, Dr. Moreton's testimony from yesterday concerning this issue made it clear, there's no question here.

The snippet that they showed you, that Ms. Durie showed you about some of the prosecution history -- which, again, nobody testified on, she didn't testify on it. The

piece that they showed you concerned tablet claims, those were different claims, not the microparticulate claims. Misdirection, misguidance.

Dr. Moreton said, "In my experience, working both in formulation and as a practicing pharmacist formally, sustained-release capsules have, in my experience, the ones I have encountered, all contained microparticulates, coated microparticulates."

You know, that, again, goes back to the one thing that I told you the first time we met, the first time I got a chance to speak with you. You're going to be instructed by the Court that there is no requirement that Jazz make, use, or sell its patented invention for damages to occur, we don't have to, we don't have to make a product.

What if you were inventing in your garage and you come up with something that they use in a motorcycle or a car? I don't think you have a car shop in your house. I don't think you built -- you're not an auto company. Would you not want Ford Motor Company to pay you if they used your invention or if they copied your patent, even if they didn't know it? Yeah, you'd want your accountability for your contribution.

I'm going to stop talking now. It's been a long trial, it's been a long week. Thank you so much for your time, so much for your efforts. Go back and consider the

evidence, not the argument. I appreciate it, thank you. I'd also like to thank the Court for its time.

THE COURT: Ladies and gentlemen of the jury, that completes the closing arguments. Before I give you the final jury instructions, I'm going to give you a break. I know you have been going, so let's take a 10-minute break, if that's all right.

(Break taken.)

THE COURT: All right. Ladies and gentlemen of the jury, this concludes the time where it's time for the Court to give you the final jury instructions.

Each of you have been provided a copy of these instructions. You may read along as I deliver them, if you prefer.

I will start by explaining your duties and the general rules that you must use in evaluating the testimony and evidence. Then I will explain the positions of the parties and the law that you will apply in this case.

And last, I will explain the rules that you must follow during your deliberations in the jury room, and the possible verdicts that you may return.

Please listen very carefully to everything I say.

You will have a written copy of these instructions with you in the jury room for your reference

during your deliberations. You will also have a verdict form, which will list the questions that you must answer to decide this case.

You have two main duties as jurors: The first is to decide what the facts are from the evidence that you saw and heard in court.

Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way. You are the sole judges of the facts.

Your second duty is to take the law that I give you, apply it to the facts, and decide under the appropriate burden of proof which party should prevail on any given issue.

It is my job to instruct you about the law, and you are bound by the oath you took at the beginning of the trial to follow the instructions that I give you even if you personally disagree with them. This includes the instructions that I gave you before and during the trial and these instructions. All of the instructions are important, and you should consider them together as a whole.

Perform these duties fairly, do not guess or speculate, and do not let any bias, sympathy or prejudice you may feel toward one side or the other influence your decision in any way.

Now, let's talk about evidence.

You must make your decision based only on the evidence that you saw and heard here in court. Do not let rumors, suspicions, or anything else that you may have seen or heard outside of court influence your decision in any way.

The evidence in this case includes only what the witnesses said while they were testifying under oath, including deposition transcript testimony that has been played by video or read to you, the exhibits that I allowed into evidence, matters I have instructed you to take judicial notice of and the stipulations to which the lawyers agreed.

Certain charts, summaries, and graphics have been used to illustrate certain evidence and testimony from witnesses. Unless I have specifically admitted them into evidence, these charts, summaries and graphics are not themselves evidence, even if they refer to, identify or summarize evidence and you will not have these demonstratives in the jury room.

Nothing else is evidence. The lawyers' statements and arguments are not evidence. The arguments of the lawyers are offered solely as an aid to help you in your determination of the facts. Their questions and objections are not evidence. My legal rulings are not evidence. You

should not be influenced by a lawyer's objection or by my ruling on that objection. Any of my comments and questions are not evidence.

During the trial, I may have not let you hear the answers to some of the questions that the lawyers asked. I also may have ruled that you could not see some of the exhibits that the lawyers wanted you to see. And sometimes I may have ordered you to disregard things that you saw or heard or that I struck from the record. Those things are not evidence. You must base your decision only based on the evidence as I have defined it and nothing else.

Now, let's talk about direct and circumstantial evidence.

During the preliminary instructions, I told you about direct evidence and circumstantial evidence. I will now remind you what each means.

Direct evidence is simply evidence like the testimony of an eyewitness which, if you believe it directly proves a fact. If a witness testified that he saw it raining outside and you believe him, that would be direct evidence that it was raining.

Circumstantial evidence is simply a chain of circumstances that indirectly proves a fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be

circumstantial evidence from which you could conclude that it was raining. It is your job to decide how much weight to give the direct and circumstantial evidence. The law makes no distinction between the weight that you should give to either one, nor does it say that one is any better evidence than the other.

You should consider all the evidence, both direct and circumstantial and give it whatever weight you believe it deserves.

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events, and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

Now, let's talk about agencies.

Jazz and Avadel are corporations and can only act through their officers and employees. Any action or omission of an officer or employee within the scope of his or her employment is the act or omission of the corporation that employs him or her.

A further word about statements of counsel and arguments of counsel.

The attorneys' statements and arguments are not evidence. Instead, their statements and arguments are

intended to help you review the evidence presented. If you remember the evidence differently from the way it was described by the attorneys, you should rely on your own recollection.

Now, let's talk about facts admitted.

Certain facts that the parties have admitted during the course of this case have been read to you during this trial. You must treat these facts as having been proved for purposes of this case.

Now, you are the sole judges of each witness's credibility. You may believe everything a witness says or part of it or none of it. You should consider each witness's means of knowledge; strength of memory; opportunity to observe; how reasonable or unreasonable the testimony is; whether its is consistent or inconsistent; whether it has been contradicted; the witness's biases, prejudices, or interests; the witness's manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.

In determining the weight to give to the testimony of a witness, you should ask yourself whether there was evidence tending to prove that the witness testified falsely about some important fact or whether there was evidence that at some other time the witness said or did

something, or failed to say or do something, that was different from the testimony he or she gave at the trial by deposition testimony played by video. You have the right to distrust such a witness's testimony, and you may reject all or some of the testimony of that witness or give it such credibility as you may think it deserves.

You should remember that a simple mistake by a witness does not necessarily mean that the witness was not telling the truth. People may tend to forget some things or remember other things inaccurately. If a witness has made a misstatement, you must consider whether it was simply an innocent lapse of memory that they have remembered better on reconsideration or an intentional falsehood, and that may depend on whether it concerns an important fact or an unimportant detail.

Now, let's talk about expert witnesses.

Expert testimony is testimony from a person who has a special skill or knowledge in some science, profession, or business. This skill or knowledge is not common to the average person but has been acquired by the expert through special study or experience.

In weighing expert testimony, you may consider the expert's qualifications, the reasons for the expert's opinions, and the reliability of the information supporting the expert's opinions, as well as the factors I have

previously mentioned for weighing testimony of any other witness. Expert testimony should receive whatever weight and credit you think appropriate, given all the other evidence in the case. You are free to accept or reject the testimony of experts, just as with any other witness.

Now, during the trial, certain testimony was presented to you by playing the video of -- by playing of video excerpts from a deposition. The deposition testimony may have been edited or cut to exclude irrelevant testimony, as the parties have only a limited amount of time to present you with evidence. You should not attribute any significance to the fact that the deposition videos may appear to have been edited.

Deposition testimony is out-of-court testimony given under oath and is entitled to the same consideration you would give it had the witness personally appeared here in court.

Now, one more point about the witnesses. Sometimes jurors wonder if the number of witnesses who testified makes any difference.

Do not make any decisions based only on the number of witnesses who testified. What is more important is how believable the witnesses were and how much weight you think their testimony deserves. Concentrate on that, not the numbers.

Now, during the course of the trial, you have seen many exhibits. Many of these exhibits were admitted as evidence. You will have these admitted exhibits in the jury room to consider as evidence for your deliberations.

The remainder of the exhibits --including charts, graphics, PowerPoint presentations, and animations -- were offered to help illustrate the testimony of the various witnesses. These illustrative exhibits, called "demonstrative exhibits," will not be in the jury room and have not been admitted, are not evidence, and should not be considered as evidence. Rather, it is the underlying testimony of the witness that you heard when you saw those demonstrative exhibits that is the evidence in this case.

Now, you may have taken notes during trial to assist your memory. As I instructed you at the beginning of the case, you should use caution in consulting your notes. There is generally a tendency to attach undue importance to matters which one has written down. Some testimony which is considered unimportant at the time presented, and thus not written down, takes on greater importance later in the trial in light of all the evidence presented. Therefore, your notes are only a tool to aid your own individual memory, and you should not compare notes with other jurors in determining the content of any testimony or in evaluating the importance of any evidence. Your notes are not evidence

and are by no means a complete outline of the proceedings or a list of the highlights of the trial.

Above all, your memory should be the greatest asset when it comes time to deliberate and render a decision in this case.

Now, let's talk about burdens of proof.

In any legal action, facts must be proven by a required standard of evidence, known as the "burden of proof." In a case involving patents, two different burdens of proof are used. The first is a lower burden called "preponderance of the evidence." The second is a higher burden called "clear and convincing evidence." I told you about these standards of proof during my preliminary instructions to you, and I will now remind you what they mean.

Jazz has accused Avadel of infringing certain claims of two patents. Avadel denies infringement for the '488 patent but admits infringement for the '782 patent. Avadel also contends that the asserted claims are invalid.

Jazz bears the burden of proving infringement and the amount of monetary damages by a preponderance of the evidence. Preponderance of the evidence is evidence that is more likely true than not. To put it another way, if you were to put Jazz's and Avadel's evidence on opposite sides of the same scale and the evidence supporting Jazz's claims

would make the scale tip to Jazz's side, then you should find for Jazz. If the scale should remain equal or tip somewhat to Avadel's side, then Jazz has not met its burden of proof.

Avadel bears the burden of proving that each of the asserted claims is invalid and must do so by clear and convincing evidence. Clear and convincing evidence means evidence that it is highly probable that a fact is true. Proof by clear and convincing evidence is a higher standard of proof than proof by a preponderance of the evidence.

You may have heard of the term "proof beyond a reasonable doubt" from criminal cases. That requirement is the highest burden of proof in our judicial system. It applies only in criminal cases and has nothing to do with a civil case like this one. You should therefore not consider that burden of proof in this case.

I will now review for you the parties in this action and the positions of the parties that you will have to consider in reaching your verdict.

As I have previously told you, the plaintiffs in this case are Jazz Pharmaceuticals, Incorporated, and Jazz Pharmaceuticals Ireland Limited. We have referred to the plaintiffs together as Jazz. The defendant in this case is Avadel CNS Pharmaceuticals. We have referred to the defendant as Avadel.

Plaintiff Jazz is the owner of two patents at issue in this case: U.S. Patent No. 10,758,488 and 11,147,782. You have heard the lawyers and the witnesses in the case refer to these patents by their last three numbers: The '488 patent and the '782 patent. Sometimes we referred to them collectively as the asserted patents or patents-in-suit.

Jazz contends that Avadel has infringed the asserted claims and that it is entitled to the damages for Avadel's past infringement of those asserted claims.

Avadel denies that it infringes two limitations of the '488 patent, which the parties have referred to as the "core" and the "deionized water" limitations. Avadel admits infringement of the '782 patent. Avadel also contends that each asserted claim is invalid for one or more of the following reasons, which will be explained further below: Lack of written description, lack of enablement, derivation, and/or improper inventorship. Avadel also denies that Jazz is entitled to recover past damages related to the patents.

I will now summarize the patent issues that you must decide and for which I will provide instructions to guide your deliberations.

The specific questions you must answer are listed on the verdict sheet you will be given. Here are the

issues you must decide.

First, whether Jazz has proven by a preponderance of the evidence that Avadel has infringed Claim 7 of '488 patent.

Second, whether Jazz has proven by a preponderance of the evidence that Avadel has infringed Claim 11 of the '488 patent.

Third, whether Avadel has proven by clear and convincing evidence that Claim 7 of the '488 patent is invalid.

Fourth, whether Avadel has proven by clear and convincing evidence that Claim 11 of the '488 patent is invalid.

Fifth, whether Avadel has proven by clear and convincing evidence that Claim 24 of the '782 patent is invalid.

If you decide that Avadel has infringed any asserted claim of a patent-in-suit that is not invalid, you will also need to decide any money damages to be awarded to Jazz to compensate Jazz for that past infringement. That decision will include both whether Jazz has proven by a preponderance of the evidence that it is entitled to damages as well as the amount of damages for past infringement.

I will provide more detailed instruction on each of these issues you must decide elsewhere in these jury

instructions.

Now, at the beginning of the trial, I gave you some general information about patents and the patent system and a brief overview of the patent laws relevant to this case. I will now give you more detailed instruction about the patent laws that specifically relate to this case. If you would like to review my instructions at any time during your deliberations, you will have a copy available to you in the jury room.

Now, let's talk about patent claims generally.

Before you can decide many of the issues in this case, you will need to understand the role of the patent "claims." The patent claims are the numbered paragraphs at the end of each patent. Everything before the claims in the numbered paragraphs is referred to as the "specification." The claims are important because it is the words of the claims that define what a patent covers. Only the claims of a patent can be infringed.

The claims are intended to define, in words, the bounds of an invention. The text in the rest of the patent provides a description of the invention and provides context for the claims, but it is the claims that define what the patent covers. Each of the asserted claims must be considered individually.

In patent law, the requirements of a claim are

often referred to as "claim elements" or "claim limitations." For example, a claim that covers the invention of a table may recite the tabletop, four legs, and the glue that secures the legs to the tabletop. The tabletop, legs, and glue are each separate limitations of the claim. When a thing, such as a product, meets each and every requirement of a claim, the claim is said to "cover" that thing, and that thing is said to "fall" within the scope of that claim.

One claim may cover more or less than another claim. Therefore, what a patent covers depends, in turn, on what each of its claims cover.

You will first need to understand what each claim covers in order to decide whether there is infringement of the claim and to decide whether the claim is invalid. You must use the same claim meaning for both your decision on infringement and your decision on invalidity.

Now, let's talk about claim construction or construction of the claims.

It is the Court's duty under the law to define what the words in the patent claims mean. As I instructed you at the beginning of the case, I have made my determinations, and I will now instruct you on the meaning, or "construction," of the claim terms. You must apply the meaning that I give in each patent claim to decide if the

claim is infringed or invalid. You must accept my definitions of these words in the claims as being correct. You must ignore any different definitions used by the witnesses or the attorneys.

You are advised that the following definitions for the following terms must be applied:

First claim term that the Court has construed is "sustained-release portion." It's found in the '488 patent. The Court has construed that term to have its plain and ordinary meaning, which is "the portion of the formulation that is not immediate release and that releases over a period of time."

The next claim term the Court has construed is "by about 4 to about 6 hours." That's also found in the '488 patent. The Court has construed that claim to have its plain and ordinary meaning, which is "at any point prior to approximately 4 hours or at any point prior to approximately 6 hours."

The next claim term the Court has construed is "gamma-hydroxybutyrate." That claim term is also found in the '488 patent. The Court has construed that claim term to have its plain and ordinary meaning, which is "(1) gamma-hydroxybutyric acid, or (2) the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid."

The next claim the Court has construed is

"modified-release particles." That claim term is found in the '782 patent. The Court has construed that claim term to have its plain and ordinary meaning, which is "particles containing an active pharmaceutical ingredient with a release profile that is different from that of an immediate-release particle."

The last claim term the Court has construed that is relevant for the purposes here is "gamma-hydroxybutyric/oxybate." That is found in the '782 patent. The term -- that claim term is construed as "the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid."

For any words in a claim for which I have not provided you with a definition, you should apply the plain and ordinary meaning to a person of ordinary skill in the art.

Now, let's talk about independent and dependent claims. Patents have two types of claims: Independent claims and dependent claims.

An independent claim does not refer to any other claim of the patent and sets forth all of the requirements that must be met in order to be covered by that claim. Thus, it is not necessary to look at any other claim to determine what an independent claim covers. For example, in this case, Claim 1 of each patent is an independent claim.

As their name implies, an independent claim must be read independently from the other claims to determine the scope of the claim.

On the other hand, a dependent claim does not itself recite all of the requirements of the claim but refers to another claim or claims for some of its requirements. In this way, the claim "depends" on another claim or claims. A dependent claim incorporates all of the requirements of the claims to which it refers. The dependent claim then adds its own additional requirements. A dependent claim is therefore narrower than an independent claim. Each of the asserted claims are dependent claims.

Using the table analogy again, an independent claim would be Claim 1, a table comprised of a tabletop, four legs, and the glue that secures the legs to the tabletop. A dependent claim would be Claim 2, the table of Claim 1, wherein the table is the color red. While a blue table would be covered by Claim 1, a blue table would not be covered by Claim 2. Claim 2 is more narrow.

To determine what a dependent claim covers, it is necessary to look at both the dependent claim and any other claim or claims to which it refers. So a dependent claim requires all the elements of the claim or claims to which it refers, plus the additional requirement that is specifically set forth in the dependent claim.

Now, let's talk about comprising claims.

The word "comprising" in a patent claim means "including the following but not excluding others." A claim that uses the word "comprising" or "comprises" or "including" is not limited to products having only the elements that are recited in the claim, but also covers products that have additional elements.

If you find, for example, that the accused product includes all of the elements of a particular asserted claim, the fact that the accused product also includes additional elements would not avoid infringement of the claim. To use the table example again, a claim covering a table comprising "legs," "glue," and "the tabletop" that also has an umbrella would still infringe the claim to a table.

Now, let's talk about patent infringement and infringement generally.

I will now instruct you on the rules you must follow when deciding whether Jazz has proven by a preponderance of the evidence that Avadel has infringed the asserted claims.

Infringement is assessed on a claim-by-claim basis. You must compare each asserted claim separately against Avadel's Lumryz product to determine whether the accused product contains all elements of that individual

patent claim. You must apply these principles -- and those which I will describe further now -- to determine whether Jazz has proven infringement of the asserted claims by a preponderance of the evidence.

Let's talk about direct infringement.

Jazz contends that Avadel infringes the asserted claims. In order to prove infringement, Jazz must prove by a preponderance of the evidence that Avadel made a product, used a product, offered to sell a product, or sold a product that meets all of the elements of any one claim. Infringement requires comparing products to the claims, not the specification.

Deciding whether a claim has been infringed is a two-step process. The first step is to decide the meaning of the patent claim. I have already made this decision and I have already instructed you as to the meaning of some terms of the asserted claims. The second step is to decide whether the party accused of infringement has made, used, sold, offered for sale, or imported within the United States an accused product covered by an asserted claim of the patents-in-suit.

To decide whether Avadel's Lumryz product infringes an asserted claim, you must compare that product with the patent claim and determine whether every element (or as they so called, limitation) of the claim is included.

If so, then Avadel's Lumryz product infringes or did infringe that claim. If not, then the accused product does not infringe that claim.

You must determine, separately, for each asserted claim, whether or not there is any infringement. The presence of other features in the accused product beyond the claimed elements does not avoid infringement, as long as every claimed element is present.

For direct infringement, Jazz is not required to prove that Avadel intended to infringe or knew of the '488 patent. Whether or not Avadel knew the accused product infringed or even knew of the '488 patent does not matter in determining direct infringement. Instead, all that matters is whether Avadel's Lumryz product is covered by the asserted claims of the '488 patent.

The fact that an accused infringer has its own patent on the accused product does not, on its own, constitute a defense to infringement of someone else's patent. A patent grants only the right to exclude others. A patent confers no right on its holder to make, use, or sell a product that infringes someone else's patent. The existence of Avadel's patents is relevant to Avadel's defenses and its theories of written description, enablement, improper inventorship, and derivation.

Now, let's talk about invalidity.

I will now instruct you on the rules that you must follow in deciding whether or not Avadel has proven that asserted claims of the patents-in-suit are invalid.

As I previously told you, to prove that a claim of a patent is invalid, the parties challenging the validity must persuade you by clear and convincing evidence. The law presumes that the patent claims are valid. The law presumes that the Patent Office acted correctly in issuing the patent. Each of the asserted claims is presumed valid independently of the validity of each other claim. Nevertheless, when the validity of a patent has been put at issue as part of patent litigation, it is the responsibility of the jury to review what the Patent Office has done consistent with the Court's instructions on the law. However, the fact that a patent application is rejected or amended before the patent is issued has no bearing on its ultimate validity.

You should consider whether any evidence relating to invalidity is materially new compared to the evidence considered by the United States Patent and Trademark Office, which is referred to as the "USPTO." Where the USPTO did not previously have all the material facts before it, Avadel's burden to prove invalidity by clear and convincing evidence may be easier to sustain.

Like infringement, you must determine whether

each asserted claim is invalid on a claim-by-claim basis, with the exception of Avadel's contentions that the patents are invalid for improper inventorship and/or derivation, which are determined on a patent-by-patent basis.

As I instructed you earlier, there are independent claims and dependent claims in a patent. Finding the broader independent claim to be invalid does not mean the narrower dependent claims are also invalid. However, if you find a narrower claim to be invalid, you must find the broader independent claim from which it depends is also invalid.

Claims are construed in the same way for determining infringement as for determining invalidity. You must apply the claim language consistently and in the same manner for issues of infringement and for issues of invalidity.

Now, let's talk about this person of ordinary skill in the art, or "POSA," sometimes people referred to it as.

The question of invalidity of a patent claim is determined from the perspective a person of ordinary skill in the field of the invention at the time the invention was made. You may have heard the phrase "person of ordinary skill in the art" abbreviated as "P-O-S-A" or "POSA" throughout the trial.

In this case, the parties agree that a person of ordinary skill in the art would have had a doctorate degree, either a PhD or a PharmD, in pharmaceutical sciences or a related field and around 1 year of relevant experience, a master's degree with 3-5 years of experience in the pharmaceutical or related industries, or a bachelor's degree with 6-10 years of experience in the pharmaceutical or related industries. A POSA would typically have been a member of an interdisciplinary team of ordinarily skilled scientists involved in drug research and development and would have had direct access to other scientists with ordinary skills in, among other things, pharmacokinetics, pharmacodynamics, drug delivery, and other pharmaceutical characteristics. The team would also have included or had access to an ordinarily skilled individual with a medical degree with experience in treating sleep disorders, particularly of narcolepsy.

Now, let's talk about written description.

The patent law contains certain requirements for the part of the patent called the specification. The written description requirement is designed to ensure that the inventor invented the claimed subject matter and was in possession of the full scope of claimed invention as of the patent's effective filing date. Avadel contends that the three asserted claims are invalid because the respective

patent specifications do not contain an adequate written description of the invention.

To succeed with respect to Claims 7 and 11 of the '488 patent, Avadel must show by clear and convincing evidence that a person having ordinary skill in the field reading the '488 patent specification as of the filing priority date of the '488 patent would not have recognized that it describes the full scope of the inventions as they are finally claimed in asserted Claims 7 and 11 of the '488 patent.

To succeed with respect to Claim 24 of the '782 patent, Avadel must show by clear and convincing evidence that a person having ordinary skill in the field reading the '782 patent specification as of the filing priority date of the '782 patent would not have recognized that it describes the full scope of the invention as it is finally claimed in asserted Claim 24 of the '782 patent. If a patent claim lacks adequate written description, it is invalid.

In deciding whether the patent satisfies this written description requirement, you must consider the description from the viewpoint of a person having ordinary skill in the field of technology of the patent as of the effective filing date. The specification must describe the full scope of the claimed invention, including each element thereof, either expressly or inherently. A claimed element

is disclosed inherently if a person having ordinary skill in the field as of the effective filing date would have understood that the element is necessarily present in what the specification discloses. It is not sufficient that the specification discloses only enough to make the claimed invention obvious to the person having ordinary skill.

The written description does not have to be in the exact words of the claim. The requirement may be satisfied by any combination of the words, structures, figures, diagrams, formulas, etc., contained in the patent specification. Adequate written description does not require either examples or an actual reduction to practice of the claimed invention or inventions. It is not necessary to describe every compound used in the claimed composition by name or structure in order to satisfy the written description requirement as applied to a group of compounds as long as the patent includes a sufficient number of representative compounds or a common structural feature, such that a person of ordinary skill in the art would understand, from reading the patent, that the inventor invented the full scope of the claimed invention.

However, a mere wish or plan for obtaining the claimed invention or inventions is not adequate written description. Rather, the level of disclosure required depends on a variety of factors, such as the existing

knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and other considerations appropriate to subject matter.

During the patent application process, the applicant may keep the originally filed claims, or change the claims between the time the patent application is first filed and the time a patent is issued.

An application may amend the claims or add new claims provided there is sufficient support in the specification or any added claims. The written description requirement ensures that the issued claims correspond to the scope of the written description that was provided in the original application.

The hallmark of written description is disclosure, which is an objective inquiry into the four corners of the specifications from the perspective of a person of ordinary skill in the art. It is unnecessary to spell out every detail of the invention in the specification, and specific examples are not required; only enough must be included in the specification to convince persons of ordinary skill in the art that the inventor possessed the full scope of the invention.

However, written description support for the essential elements of the invention must be disclosed in the specification itself, and not merely present in the prior

art. Claims may be no broader than the supporting disclosure, and a narrow disclosure will limit claim breadth.

Now, let's talk about enablement. A patent must disclose sufficient information to enable or teach persons of ordinary skill in the field of the invention to make and use the full scope of the claimed invention without undue experimentation. This requirement is known as the enablement requirement. If a patent is not enabled, it is invalid. Avadel contends that each of the asserted claims is invalid for lack of enablement.

To succeed with respect to the asserted claims of the '488 patent, Avadel must show by clear and convincing evidence that the '488 patent specification does not contain a sufficiently full and clear description to have allowed a person of ordinary skill in the art to make and use the full scope of the claimed inventions without undue experimentation.

To succeed with respect to Claim 24 of the '782 patent, Avadel must show by clear and convincing evidence that the '782 patent specification does not contain a sufficiently full and clear description to have allowed a person of ordinary skill in the art to make and use the full scope of the claimed invention without undue experimentation.

The question of undue experimentation is a matter of degree and what is required is that the amount of experimentation not be unduly extensive. Some amount of experimentation to make and use the invention is allowable.

In deciding whether a person having ordinary skill would have to experiment unduly in order to make and use the invention, you may consider several factors including:

One, the time and cost of any necessary experimentation.

Two, how routine any necessary experimentation is in the field.

Three, the presence or absence of working examples in the patent.

Four, the amount and sufficiency of guidance presented in the patent.

Five, the nature and predictability of the field.

Six, the level of record ordinary skill in the field.

And, seven, the breadth of the claims.

The above list of factors are neither mandatory nor exclusive, and no one or more of the above factors is alone conclusive. Rather, you must make your decision about whether or not the degree of any required experimentation is

undue based upon all of the evidence presented to you.

You should weigh these factors, and any other evidence related to this issue, and determine whether or not, in the context of this invention, and the state of the art at the time of the applicable effective filing date, a person of ordinary skill in the art would need to experiment unduly to make and use the full scope of the claimed invention claimed in the asserted patents.

In considering whether a patent complies with the enablement requirement, you must keep in mind that patents are written for persons of ordinary skill in the field of the invention. Thus, a patent need not expressly state information that person of ordinary skill would be likely to know or could obtain, such as what was well known in the art and what would have already been available to the public. In addition, the patent disclosure need not enable persons of ordinary skill to make a commercially viable product or to otherwise meet the standards for success in the commercial marketplace.

Now, let's talk about inventorship. Avadel contends that the '488 and '782 patents are invalid because of improper inventorship.

Patents must name all of the true inventors, and only the true inventors, of the patent. This is known as the inventorship requirement. To prove invalidity of a

patent because of improper inventorship, Avadel must demonstrate by clear and convincing evidence that the patent does not name all of the true inventors, or named inventors -- or names inventor or inventors, who are not true inventor or inventors. In determining whether the inventorship requirement has been satisfied here, you should be guided by the following principles:

To be an inventor, one must make a significant contribution to the conception of at least one of the claims of the patent. Conception is the mental formulation and disclosure by the inventor of a complete idea of the inventive solution.

An inventive solution is considered to be a complete idea when disclosure of the idea would enable anyone with ordinary skill in the art to make, use, or practice the invention. Whether the contribution is significant is measured against the scope of the full invention.

All inventors, even those who contribute to only one claim or aspect of one claim of a patent, must be listed on that patent. Failure to name a true inventor of any claim invalidates the entire patent. For example, if Avadel proves that the actual inventor of any claim of the '488 patent is not named as an inventor, then all of the claims of the '488 patent are invalid for improper inventorship.

In making the determination whether the patents-in-suit are invalid for lack of proper inventorship, you must consider each patent in its entirety and any related evidence and testimony.

However, testimony alone is insufficient to support a claim for improper inventorship. A claim for improper inventorship must be supported by corroborating evidence. This corroborating evidence can include physical, documentary or circumstantial evidence, or reliable testimony from individuals other than the interested party.

Now let's talk about derivation. Avadel contends that the asserted claims of the '488 patent are invalid because the inventors named on those patents derived the subject matter at issue in those patents from another person. Avadel does not assert this defense against the '782 patent.

The patent laws require that the inventors named on the patent be the true inventors of the invention covered by patent claims. Inventors named on a patent are not the true inventors if they derived the invention from someone else. Avadel must prove this defense by clear and convincing evidence.

In determining whether the inventors derived the invention from someone else, you should be guided by the following principles:

An invention is said to be derived from another person if that other person or other people, one, conceived of the patented invention; and, two, communicated that conception to one of the inventors named in the patent.

Conception of an invention occurs when a person has formed the idea of how to make and use every aspect of the patented invention, and all that is required is that it can be made, without the need of further inventive effort.

Communication of the conception occurs when it enables one of ordinary skill in the art to make, use, and practice the patented invention. The communication may be made via public disclosure. If the named inventors derived the patented invention from someone else, then the patent is invalid.

Now, all of the instructions that I have given you up to this point have been about determining liability, meaning the determination as to whether Avadel has infringed the asserted claims of Jazz's patents and whether those asserted claims are valid.

If you find that Avadel infringed any valid claim of the asserted patents, you must then consider what amount of damages to award to Jazz for Avadel's past infringement. If you find that each of the asserted claims is either invalid or not infringed, then you should not consider damages in your deliberations.

I will instruct you now on how to determine the amount of damages, if any. By instructing you on damages, I am not suggesting which party should win this case, on any issue.

There is no requirement that Jazz make, use, or sell its patented invention for damages to occur. If you find Avadel infringed, the damages you award must be adequate to compensate Jazz for the infringement, and Jazz is in any event entitled to no less than a reasonable royalty. Damages are not meant to punish an infringer.

Jazz has the burden to establish the amount of its damages by a preponderance of the evidence. In other words, you should award those damages that Jazz establishes that it more likely than not has suffered. Jazz must prove the amount of damages with reasonable approximation under the circumstances, but need not prove the amount of damages with mathematical precision.

Even if the evidence at trial does not support one or both parties' specific royalty calculation, you are still required to determine what reasonable royalty, if any, is supported by the evidence.

Jazz seeks damages for Avadel's past patent infringement as measured by a reasonable royalty. A reasonable royalty is defined as the amount -- a reasonable royalty is defined as the money amount the parties would

have agreed upon as a fee for use of the invention at the time prior to when infringement began.

I will now give you more detailed instructions regarding damages.

If parties agree that Avadel imported Lumryz into the United States no earlier than May 17, 2023, and began selling Lumryz by June 2, 2023. Thus, if you find that the asserted patents are valid and infringed, you should calculate damages beginning as of the May-June 2023 timeframe.

Now let's talk about reasonable royalty generally. Jazz is seeking damages in the form of a reasonable royalty in this case. A royalty is a payment made to a patent owner by someone else in exchange for the rights to make, use, sell, or import a patented product. A reasonable royalty is the royalty that would have resulted from a hypothetical negotiation between the patent owner and the alleged infringer just before the alleged infringement began. It is a hypothetical royalty for the use of the patented technology by the alleged infringer, calculated as if the parties negotiated at arm's length as a willing licensor and a willing licensee on the date when the infringement began.

A reasonable royalty award should reflect the incremental value that the patented invention adds to the

end product as a whole. When the infringing products have both patented and unpatented features, measuring this value requires a determination of the value-added by the patented features. The total royalty rate must reflect the value attributable to the infringing features of the product, and no more.

In considering this hypothetical negotiation, you should focus on what the expectations of the patent owner and the infringer would have been if they had entered into an agreement at that time, and had they both acted reasonably in their negotiations. You must assume that both parties to the hypothetical negotiation believed the patent to be valid and infringed and that both parties are willing to enter into a license agreement just before the infringement began.

Having that in mind, you should consider all the facts known and available to the parties at the time the infringement began. The reasonable royalty must be a royalty that would have resulted from the hypothetical negotiation, and not simply a royalty either party would have preferred.

Now, in determining a reasonable royalty, you should consider evidence on any of the following factors, in addition to any other evidence presented by the parties on the economic value of the patents-in-suit. You'll see them

on page 43, and there's a list of 16 factors, all right, those are commonly known as the Georgia-Pacific factors. I'm not going to read those 16 factors. Read them to yourself in the jury room, you can read them to yourself and apply them.

No one of these factors is dispositive, and you can add and should consider the evidence that has been presented to you on each of these factors. You may also consider any other factors that would have increased or deceased the royalty that Avadel would have been willing to pay and that Jazz would have been willing to accept.

In determining a reasonable royalty, you may also consider evidence concerning the absence of acceptable noninfringing alternatives to using the patented invention. A noninfringing alternative must have been available at the time of the infringement, must provide the same advantages as the patented invention, must have been acceptable to the specific purchasers of the infringing products, not the public in general, and must not infringe the patent.

The relevant date for the hypothetical negotiation is at the time the infringement began. However, you may also consider in your determination of reasonable royalty any information the parties would have foreseen or estimated during the hypothetical negotiation, which may under certain circumstances include evidence of usage after

infringement started, license agreements entered into the parties shortly after the date of the hypothetical negotiation, profits earned by the infringer, and noninfringing alternatives.

Neither party's calculations include interest. Therefore, in arriving at your damages calculation, you should not consider interest in any way because it is the function of the court to award interest.

I have concluded the part of my instructions explaining the rules for considering some of the testimony and evidence. Now let me finish up by explaining some things about your deliberations in the jury room, and your possible verdicts.

Once you start deliberating, do not talk to the jury officer, or to me, or to anyone except each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and then give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take some time to get back to you. Any questions or messages normally should be sent to me through your foreperson, who by custom of this Court is Juror No. 1.

One more thing about messages. Do not ever write down or tell anyone how you stand on your votes. For

example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. That should stay secret until you are finished.

Now, let's talk about your unanimous verdict.

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, it is necessary that each juror agree to that verdict. Your verdict must be unanimous.

It is your duty as jurors to consult with one another and to deliberate with a view towards reaching an agreement, if you can do so without violence to your individual judgment. Each of you must decide the case for yourself, but do so only after the impartial consideration of the evidence with your fellow jurors.

In the course of your deliberations, do not hesitate to re-examine your own views and change your opinion, if convinced it is erroneous. But do not surrender your honest convince as to the weight or effect of evidence solely because of the opinion of your fellow jurors, or for the purpose of returning a verdict. Remember at all times that you are not partisans. You are judges -- judges of the facts. Your sole interest is to seek the truth from the evidence in the case.

A form of verdict has been prepared for you. I will review it with you in a moment. You will take this

form to the jury room and when you have reached unanimous agreement as to your verdict, you will have your foreperson fill in, date, and sign the form. You will then return to the courtroom and my deputy will read aloud your verdict.

Place the completed verdict sheet in the envelope that we will give you.

Do not show the completed verdict form to anyone or share it with anyone until you are in the courtroom. By the way, all of you will have to sign the verdict, not just the foreperson.

It is proper to add the caution that nothing said in these instructions, and nothing in the verdict form, is meant to suggest or convey in any way or manner any intimation as to what verdict I think you should find.

What the verdict shall be is your sole and exclusive duty and responsibility.

Now, before I go over these last couple of instructions, let's turn to the verdict form. You can give a copy of the verdict form to the jury foreperson. There's only one copy, there's only one verdict form that's given to the jury and given to the foreperson, but each of you will be able to read it and pass around in the jury room.

All right. So going to page 2 of the verdict form, the instructions. When entering the following questions and completing this verdict form, please follow

the instructions provided and follow the jury instructions that you've been given. Your answer to each question must be unanimous. Some of the questions contain legal terms that are defined and explained in the jury instructions. Please refer to the jury instructions if you are unsure about the meaning or usage of any legal term that appears in the questions below.

As used herein, Jazz collectively refers to the Plaintiffs, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland Limited. Avadel refers to Defendant Avadel CNS Pharmaceuticals, LLC. The '488 patent refers to U.S. Patent Number 10,758,488. The '782 patent refers to U.S. Patent Number 11,147,782. The asserted patents or the patents-in-suit refers collectively to the '488 patent and the '782 patent.

Question 1 asks: Did Jazz prove by a preponderance of the evidence that Avadel's Lumryz product infringes any of the following claims of the '488 patent?

If you find Jazz proved by a preponderance of the evidence that Lumryz infringes a claim, please place a check mark next to "yes" for that claim. So for the '488 patent, it lists the two claims at issue, Claim Number 7 and Claim Number 11. If you find that there's been infringement for either of those claims, you would check "yes" for Jazz, if you find that there has not been infringement, you would

check "no" for Avadel. All right.

Question 2 asks: For each claim of the '488 patent listed below, did Avadel prove by clear and convincing evidence that the claim is invalid for lack of sufficient written description?

If you find a claim invalid for lack of written description, answer "yes," otherwise answer "no."

So, again, for the '488 patent, each claim is listed on this question. If you find that the patent is invalid for lack of sufficient written description, you would answer "yes" for Avadel with respect to that claim. If you find that there is sufficient written description, you answer "no" for Jazz. All right.

Question No. 3 asks: For each claim of the '488 patent listed below, did Avadel prove by clear and convincing evidence that the claim is invalid for lack of enablement?

If you find a claim invalid for lack of enablement answer "yes," otherwise answer "no," same procedure.

Question 4: For each claim of the '488 patent listed below, did Avadel prove by clear and convincing evidence that the patent is invalid for failure to name the correct inventors?

If you find the patent invalid for failure to

name to name the correct inventors, answer "yes," otherwise, answer "no."

Same procedure.

Question No. 5 asks: Did Avadel prove by clear and convincing evidence that the '488 patent is invalid because it is derived from someone other than the presently named inventors?

If you find the patent invalid because it is derived from someone other than the presently named inventors, answer "yes," otherwise, answer "no."

Question 6 asks: For each claim of the '782 patent listed below, did Avadel prove by clear and convincing evidence that the claim is invalid for lack of sufficient written description?

If you find a claim invalid for lack of written description, answer "yes," otherwise, answer "no."

Question 7: For each claim of the '782 patent listed below, did Avadel prove by clear and convincing evidence that the claim is invalid for lack of enablement?

If you find a claim invalid for lack of enablement, answer "yes," otherwise, answer "no."

Question 8 asks: For each claim of the '782 patent listed below, did Avadel prove by clear and convincing evidence that the patent is invalid for failure to name the correct inventors?

If your answer to that question is yes, you check yes for Avadel. If your answer to that question is no, you check no for Jazz.

All right. The jury is not being asked to decide if Claim 24 of the '782 patent is infringed. Infringement of Claim 24 of the '782 patent has been stipulated to by the parties.

Answer Question 9 only if there is a claim of an asserted patent that is both infringed and not invalid.

Question 9 asks: What is the reasonable royalty to which Jazz is entitled for Avadel's past infringement?

It asks you to set forth the royalty rate -- the reasonable royalty rate that you find, what the amount of past sales to apply to that royalty rate, and then you would multiply the total amount, the royalty rate times the amount of past sales to get to that third figure for total amount of past infringement based on royalty rate, if you get to this question, all right.

Again, the Court is not implying who should or who shouldn't win this case, nothing I have said or did throughout this trial is meant to apply. It's totally up to you as the jury.

All right. Once you've reached unanimous verdict, the jury foreperson should sign first and then each juror, other jurors should sign.

All right. Date the form and then let the juror officer know that you've reached your verdict.

All right. Now going back to the instructions.

Now that all the evidence is in and the arguments are completed, you are free to talk about the case in the jury room. In fact, it is your duty to talk with each other about the evidence, and to make every reasonable effort you can to reach unanimous agreement.

Talk with each other, listen carefully and respectfully to each other's views, and keep an open mind as you listen to what your fellow jurors have to say. Try your best to work out your differences. Do not hesitate to change your mind if you are convinced that other jurors are right and that your original position was wrong. But do not ever change your mind just because other jurors see things differently, or just to get the case over with.

In the end, your vote must be exactly that, your own vote. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience. No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. So you should all feel free to speak your minds.

Listen carefully to what the other jurors have to say, and then decide for yourself.

Another reminder, social media. During your

deliberations, you must not communicate with or provide any information to anyone by any means about this case. You may not use an electronic device or media, such as the telephone, a cell phone, smart phone, iPhone, Blackberry, tablet or computer, the Internet, any Internet service, any text or instant messages service, any Internet chat room, blog or website, such as Facebook, LinkedIn, YouTube, Instagram, Snapchat, or X to communicate to anyone any information about this case or to conduct any research about this case until I accept your verdict.

In other words, you cannot talk to anyone on the phone, correspond with anyone, or electronically communicate with anyone about this case. You can only discuss the case in the jury room with your fellow jurors during deliberations.

Let me finish by repeating something I said to you earlier. Nothing I have said or done during this trial was meant to influence your decision in any way. You must decide the case yourselves based on the evidence presented.

Ladies and gentlemen of the jury, that completes the final jury instructions. At this time, we're going to have the deputy swear in the jury officer who will take you to the jury room so that you can begin your deliberations.

(Whereupon, the jury officer was sworn in.)

THE COURT: All right. Mr. Officer, you may

take the jury to the jury room to begin their deliberations.

Members of the jury, God speed.

(Whereupon, the jury left the room at 1:33 p.m. to deliberate.)

THE COURT: All right. You may be seated.

All right. Let me start by saying thank you and congratulations to both sides on your presentations. Jazz and Avadel, any corporate representatives that are here, irrespective how this jury comes back, you should be proud that you've been well represented. Both sides have made excellent presentations.

Mr. Teagan, Mr. Silver, Mr. Cerrito, Ms. Durie, Mr. Porter, Mr. Schuler, Mr. Calvosa, Mr. Brausa, Ms. Thompson, Mr. Zubick, Mr. LoCastro, Ms. Davies, Mr. Brier, Mr. Yue, Mr. Nimrod, Ms. Joyce, Ms. Murphy, Mr. Jorgensen, Ms. Bergman, Ms. Mattes, and if I -- in that, if I didn't include all of the young lawyers that stood up yesterday and argued on the final jury instructions, if I missed any of your names, I apologize, but all of you, please stand, I want to congratulate you all.

I also want to recognize all members of both sides' support team. The Court doesn't take lightly that trial is a gruelling exercise. And here you had a timed trial and you're working around the clock. The Court understands that. The Court is also working around the

clock. But I remember those days, and it's not just the lead attorneys, I know that you have teams of lawyers that are working, associates, staff, etc.

So to all, the Court appreciates all of your time and effort. You all did a great job. You may be seated.

Now, in terms of next. The jury will deliberate as long as they like. We will let them go as long as they like today. If they are still going when it comes sort of after normal business hours, we will go in and ask whether they want dinner. And if they say they want dinner, we will let Delaware counsel know, and you guys will coordinate it.

And we will also ask whether they would prefer to stay and continue to deliberate or come back on Monday. Sometimes jurors say that they would like to stay and at least try to reach a verdict, sometimes they say they will -- they would rather stop and come back on Monday, it's totally up to them. If they decide they want to stay, the Court will stay, all right.

What we ask is that counsel for both sides be within 15-20 minutes, when we get notice that there is a verdict, so that everybody can be back in the courtroom.

In the event the jurors have questions, you heard the procedures. They will write their question on paper, sign it, give it to the jury officer, the jury

officer will give it to me.

If it's a question that I can answer directly from jury instructions or something that's straightforward, I will do so, but I will -- in any event, circulate it to both sides. If it's something that I think that I need to consult with counsel about, we will circulate it to you and ask both sides for your input.

Understand it's not an opportunity to now start legal arguments, it's to answer the jury's question in a manner that both sides can agree to. If I'm asking for your input, then that means that I want you guys to agree on the response, all right.

And we'll give you a time limit to get back to us. If you don't get back to us by the time limit, then the Court will just go ahead and answer.

In terms of -- in the event we go past normal business hours, it's important to be back in the courthouse by 5:00. We can stay as late as we want, but you just have to be cleared from security in the building before they leave. All right.

We'll talk about -- we'll talk about, sort of, next steps once the jury comes back.

All right. Anything else?

Before I -- let me also thank my staff. The court reporter; deputy, Mr. Looby; my law clerk, who is

actually in another chambers now, but started on this case when she was in my chambers, and has come back to assist; as well as the other clerks that have worked on this case, I can't do what I do without them. So, I want to thank every member of my team. I appreciate all of your hard work.

All right. Anything else?

MR. CERRITO: Your Honor, I think I speak on behalf of all counsel and both parties in this matter, we want to thank you and the Court for your time and efforts. I know this has been going on for a while and we haven't always been the easiest, but Your Honor has always been patient with us and we appreciate that.

THE COURT: Our pleasure. Our pleasure. All right. We're adjourned.

(Whereupon, the following proceeding concluded at 1:41 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