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
Monday, February 26, 2024
Trial Day 1

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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
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The Plaintiff

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-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 8:33 a.m.)

THE COURT: Good morning. All right. So I reviewed the letter briefing on the recurring evidentiary objections and disputes that were outlined in Jazz's opening brief and Avadel's response, and my understanding is that you guys have reached agreement with respect to the witnesses testifying in English, right?

MR. CERRITO: We have, Your Honor.

THE COURT: All right. So that takes care of that issue.

So the direct and cross will be in English?

MS. DURIE: That is correct, Your Honor.

THE COURT: All right. So moving to the issues concerning the inventorship defense. So the Court re-reviewed its motion in limine rulings, particularly -- well, 1, 2, and 3 of Jazz's motions in limine, so the Court excluded -- well, precluded certain evidence that related solely to --

I'm sorry, I left my book.

(Short recess taken.)

THE COURT: So I precluded evidence if it was solely relevant to Jazz's request for injunctive relief, the '963 patent, which is no longer in the case, inequitable conduct, or other litigation between the parties. If the evidence also has relevance to the claims and the defenses in this action, it's not precluded. So when I look at these sort of broad categories, it appears as though many, if not all, of the documents also have some relevance to the inventorship defense. So I'm not prepared to exclude any of these exhibits at this time.

If there are exhibits that come up during the trial that Jazz believes that relate solely to something that has been precluded, we'll deal with those on a case-by-case basis other than what I'm going to deal with with respect to the specific objections that we got this morning.

So that deals with what was set forth in A, section A of your letter, and C.

With respect to B, Avadel has conceded that it's not arguing that its former employees invented the claimed inventions in 2004, rather -- and it also concedes that it will use the patent itself for the Micropump II platform, which was produced in discovery in the case and otherwise referenced in many other documents, and as set forth the

relevance of that evidence, which in part is relevant to rebut something in Jazz's opening demonstratives. So, you know, the Court, again, is not going to preclude anything at this time. All of that seems relevant.

MR. CALVOSA: Excuse me, Your Honor. May I just be heard on that for a second, because we didn't have a chance to respond after they said they weren't going to use --

THE COURT: You can be heard when I finish going through everything.

MR. CALVOSA: Yes, Your Honor.

THE COURT: All right. So now I'm going to move to these demonstratives. So Avadel -- the objections to Avadel's opening demonstratives Nos. 8 and 9 and 33, those are overruled consistent with my rulings on the supplemental briefing.

With respect to Avadel's opening slide No. 25, I want to hear from the parties on this issue. And specifically from Avadel, because I'm -- the Court's initial impression is that I'm going to grant it and sustain this objection because these are unasserted claims and inventorship is determined on a claim-by-claim basis. So -- and you can't -- and I didn't see any case law where you pointed me to where I should do anything else.

MS. DURIE: May I ask, Your Honor, did you Your

Honor want argument on that now or --

THE COURT: Yes.

MS. DURIE: Oh, I apologize. I apologize. I'm sorry, Your Honor.

So it is correct, Your Honor, that inventorship is evaluated claim-by-claim in the sense that you look to determine who the inventors of that claim are. However, if there is incorrect inventorship as to any claim, that invalidates all of the claims of the patent at issue. And that, Your Honor, is the *Plastipak Packaging* case from the Federal Circuit last year. So we agree that we are not trying to invalidate other claims for their own sake, but if by way of example we establish that Claim 16 is invalid because of improper inventorship, that means under that Federal Circuit precedent, the asserted claim, Claim 24, is invalid as well. And so our inventorship defense as to claim -- as to the claim that is asserted against us permits us to rely on improper inventorship as to any of the claims.

THE COURT: But did you disclose that anywhere in your invalidity contentions?

MS. DURIE: So our invalidity contentions were always addressed to all of the claims. Jazz, shortly before trial, appropriately narrowed the claims at issue to assert only some of them. But, yes, the answer to Your Honor's question is yes, we have always argued for invalidity of all

of the claims up until the point when Jazz made that election and we have been very clear as to the legal consequence of the inventorship theory that we are pursuing the -- we are pursuing an incorrect inventorship defense with respect to Claim 24 and that allows us to show that any claim is invalid and, therefore, Claim 24 cannot be asserted against us.

And this actually was an issue that came up, Your Honor, in the context of the briefing that we did on summary judgment because it came up in the context of our explaining in that briefing the difference between inventorship and more conventional invalidity theories, so Jazz has been on notice of this even before they elected to narrow their claims.

THE COURT: All right. Let me hear from Jazz on this issue.

(Discussion held between counsel off the record.)

MR. LOCASTRO: Your Honor, my name is Nicholas LoCastro for the record.

I'll address the disclosure issue first, Your Honor, and there simply was no disclosure of the theory that Claim 24 can be invalid for improper inventorship by reference or by looking back to an inventorship issue for Claim 19. That's the claim that Avadel specifically pointed

to in its portion of the submission last night. And I think with respect to the disclosure issue, what's paramount here is that there is no expert in this case whose expert reports have actually talked about the elements of Claim 19. So you're not going to hear from the experts that Claim 24 is somehow invalid because the inventors didn't arrive at the subject matter of Claim 19. So in addition to the contentions, it's not in the expert reports either.

And with respect to the law on this, Your Honor, I don't believe Ms. Durie addressed the *Fox* Group case, which we cited last night, and that's squarely on point. What happened there was very similar to here. There were 19 claims asserted, and then before summary judgment, 17 of those claims were withdrawn. Jazz withdraw a similar number of claims from the '782 patent, and what happened at trial there was the trial court determined that asserted claims -- and it looked at unasserted claims. And it came to a conclusion that there was no inventorship for both asserted and unasserted.

And when that went up on appeal, the Federal Circuit said the District Court didn't have subject matter jurisdiction over the unasserted claims. The District Court couldn't look at the unasserted claims, and that's essentially what Avadel is asking this Court to do here. And the *Plastipak Packaging* case that they cite, that didn't

address the unasserted claims issue that we're actually dealing with in this case, Your Honor.

THE COURT: All right.

MS. DURIE: May I respond on that point?

THE COURT: Yes.

And Jazz claims that disclosure did not take place, so can Avadel specifically point the Court to some -- to a document where that disclosure took place?

MS. DURIE: So we argued for the invalidity of all of the claims. So that, I think -- and I don't hear any argument --

THE COURT: So again, I need you to cite me to a document that I can look at that will -- that I can read that'll show me that the disclosure took place.

MS. DURIE: So I want to be clear about what I'm talking about. To the extent that the question is: Did we disclose our theories for the invalidity of all of the claims? Yes, I can point you to our expert reports that asserted that all of those claims were invalid.

To the extent the Court is talking about a legal question: What is the effect of the validity of some of those claims on other claims in the event that Jazz narrows the case? I think the first time that legal issue came up was in connection with the briefing on summary judgment. And that is a pure legal question, I think, for the Court.

Now -- and let me just pause there. And that came up, as I said, before Jazz made the election to narrow its claims, we were on record with respect to that legal question. The experts opined with respect to the validity or invalidity of each of the claims, and we can certainly point Your Honor to that.

THE COURT: Okay. So in response to Jazz's counsels' argument that no expert opined upon Claim 19, are you saying that's --

MS. DURIE: That's -- that's incorrect. There is an opinion that all the claims are invalid.

THE COURT: Okay. And there's specific evidence talking about Claim 19?

MS. DURIE: I don't know that there is expert testimony treating them differently. But there is certainly an opinion that they are invalid, and I think we -- we will not elicit expert testimony beyond the scope of what is in our expert reports. With respect to inventorship, of course, the inventors will testify and some of the testimony that will be relevant to that inventorship determination is testimony from the inventors, not merely the experts. So we -- and -- so we intend to present that inventor testimony on these other claims.

I will say with respect to ***Fox***, the issue in ***Fox*** was that the District Court invalidated all of the claims.

And the Court said, having invalidated the asserted claims, it didn't have jurisdiction then to go out and additionally invalidate unasserted claims. We agree with that. The issue here is the validity of Claim 24 and whether it can be asserted against us.

But our point is, in order to make that determination here, the Court can consider and the jury can consider our defense of inventorship and if Claim 19 -- or Claim 16, for example, is invalid, that's a defense.

THE COURT: But why would the Court have jurisdiction over Claim 19 or Claim 16?

MS. DURIE: Because the Court has jurisdiction over Claim 24. And --

THE COURT: Wouldn't that have been the same thing in *Fox*?

MS. DURIE: No, it didn't come up in *Fox*. Because once -- if Claim 24 were invalidated for improper inventorship on its face, there would be no need to look at any other claim. It would be moot at that point, because the only claim asserted against us would be invalid.

THE COURT: All right. So on this issue, the Court is going to have to do some additional research analysis on the law. So for purposes of the opening slides, we're not going to allow it.

MS. DURIE: Okay.

THE COURT: And we're not going to allow it until the Court has an opportunity to look at this issue further and decide which side's representation of the law is --

MS. DURIE: I appreciate that, Your Honor. I do want to flag for the Court that I think the issue will come up in Mr. Allphin's testimony. And I think he will be testifying later today. Because he is one of the inventors who we would question with respect to those claims.

THE COURT: Okay. So it would come up during his cross-examination?

MS. DURIE: That's correct, Your Honor.

THE COURT: All right. So, if --

MR. LOCASTRO: Your Honor, if I may just respond --

THE COURT: I'm going to hear you. I'm going to hear you.

MR. LOCASTRO: -- to one point.

THE COURT: If both sides could submit a three-page-or-less letter brief on this issue before the cross-examination of Mr. Allphin, then the Court can consider this further, read the case law, and come back and rule on this.

MS. DURIE: Understood, Your Honor, thank you.

THE COURT: All right. I'll hear you.

MR. LOCASTRO: I just want to note one thing for the record, Your Honor, and that's that Claim 19 was one of the claims that Jazz elected not to assert prior to opening expert reports. So it can't possibly be addressed in any of the expert reports in this case because Claim 19 was dropped before opening reports went in.

So I know the Court asked Avadel for a citation; they are not going to be able to find it based upon the fact that the claim was dropped.

MS. DURIE: We will provide the citation, Your Honor.

THE COURT: All right. So if both sides could plan to -- is Mr. Allphin going to be Jazz's first witness?

MR. CERRITO: He will be the second witness, Your Honor.

THE COURT: Second witness, okay.

So if both sides could plan to get that, let's shoot for -- I'm assuming -- if you can shoot to get me, get the Court that in between 11:30 and noon, that should -- I assume that that would give us enough time to review it and...

All right. Did you have something else that you wanted to say?

MR. CALVOSA: Yes, Your Honor, on the section B issue.

THE COURT: Sure.

MR. CALVOSA: Frank Calvosa for Plaintiffs. And I apologize for interrupting you before, Your Honor, I certainly didn't intend to do so.

THE COURT: No, no...

MR. CALVOSA: On the section B issue, they've now withdrawn that earlier 2004 reference, which was admittedly the focus of our letter. But now it becomes a relevance issue, and that's because there's two different patents in this case; one the '488 patent with a 2011 filing date, and one, the '782 patent, with a 2016 filing date.

If they can't get before the 2011 filing date, then prior conception and the work that Avadel did is irrelevant. And that's because the later filing date, 2016, is a post-AIA patent. And by law, prior conception is irrelevant for post-AIA patents, all that matters is who filed first.

And by introducing evidence that there was a sachet, which is in the '782 claims and in Jazz's internal documents, or anything else that goes to the '782 patent's claims, that Avadel supposedly got there first, is irrelevant to the '782 patent. And it's irrelevant if it's after -- if it's after 2011 to the '488 patent.

And, therefore, it's going to suggest to the jury an improper basis to decide -- to decide the

inventorship issue, so it's also prejudicial.

THE COURT: Well, what about the relevance of it to rebut Jazz's accusation that Dr. Guillard adopted it from Jazz?

MR. CALVOSA: Well, that's part of infringement, Your Honor. That's what we didn't get a chance to say in response. We're saying he did the dissolution testing, he saw it in our patent. It goes to both infringement and it goes to their argument that our patents lack -- are invalid for lack of enablement.

If Dr. Guillard could do it, certainly a person of ordinary skill could practice the invention. We're not saying he copied it and he did something wrong. We're saying he copied it and he infringed. And it's also evidence that someone could take the disclosure and practice the invention.

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

MS. DURIE: Yes, Your Honor. This issue is addressed in part in footnote 1 of our three-page letter brief.

THE COURT: I see that you said pre-AIA patents are still subject to the inventorship requirement.

MS. DURIE: Right. So I think there are two important points here. First, with respect to the '488 patent, we have defenses of both duration and inventorship.

And prior conception is relevant to duration. It's also relevant, as we said in that footnote, even to the '782 post-AIA patent.

In addition, our inventors' reliance on their platform technology explains their invention. They're going to -- this is an inventorship case. The jury needs to assess the credibility of the inventors and their respective explanations for where their invention came from.

THE COURT: I understand.

MS. DURIE: Thank you.

THE COURT: All right. So, nothing changes on my ruling with that. So let's keep moving.

Avadel slide number 32 and DTX675, so the objections are overruled. The slides in DTX675 are not excluded on the Court's granting of Jazz's motion in limine No. 1 and are independently relevant as Avadel articulated in its response.

All right. So now moving to Jazz's objections to Avadel's witness exhibits. DTX638, that's covered by my rulings in section B.

DTX750, same thing.

JTX213 and PTX643, same thing.

All right. Moving to Avadel's objections to Jazz's witness exhibits.

JTX0031, that's sustained.

So PTX164 and PTX109, let me hear from the parties on these exhibits.

MR. SCHULER: Your Honor, Kenneth Schuler for Avadel.

On PTX1675, the objection, Your Honor, is that the declaration goes to statements made distinguishing the prior art. We've -- we're not --

THE COURT: PTX164?

MR. SCHULER: No, I'm talking about 1675. Did you want to address that one first?

THE COURT: I don't have --

MR. SCHULER: I'm sorry, 164. That's the declaration.

THE COURT: Okay. Go ahead.

MR. SCHULER: And the subject matter of the declaration is all devoted to distinctions between what was then claimed in the application and various prior art references, and we're not advancing nonobviousness as a defense. There's not going to be any suggestion that -- by anyone that Dr. Vaughn was not familiar with the contents then of the application that they asked him questions about for purposes of infringement.

So they are only trying to get the declaration in, we believe, for improper purpose. There's no reason that he needs to -- that the document needs to come in for

the truth of the matter asserted because all of the matters are asserted -- other than him saying, I'm familiar with the application -- go to obviousness.

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

MR. LOCASTRO: Your Honor, there's no objection to Dr. Vaughn testifying about the subject matter of the '616 patent application, which I think the parties agree goes to the issue of infringement. We're not offering PTX164 in order to go to any obviousness issue. We know that obviousness is out of the case.

The reason why we're offering the document and the associated testimony is because, therein, Dr. Vaughn says that he's deeply familiar with the subject matter of the '616 application. So this testimony is admissible, pursuant to Rule 701(b), because it's helpful for the jury to understand Dr. Vaughn's testimony and to assess his credibility, that he's familiar with the patent application that everyone agrees he can talk about relevant to the infringement issue.

MR. SCHULER: Your Honor, we have no problem stipulating that Dr. Vaughn was aware -- well aware and familiar with the contents of the application, that's not the issue. The issue is the document. And they wanted it for the truth of the matter asserted.

MR. LOCASTRO: If the issue were the document,

then I don't understand the corresponding objection to the testimony, which is later in the table where Dr. Vaughn testifies he's deeply familiar. That's the limited purpose by which we're offering the document. And if it needs to go in with a limiting instruction that it's only be offered for that purpose, I think that's something maybe the parties can live with.

MR. SCHULER: Well, I have no problem, Your Honor, playing that clip where he says I am familiar with the contents of the application. We are not claiming that Dr. Vaughn lacked knowledge of the application. That should resolve counsel's concerns.

MR. LOCASTRO: Well, the jury should also be entitled to actually see the evidence, though. Excuse me, to see the actual declaration where Dr. Vaughn made that representation to the Patent Office, so...

THE COURT: All right. I'm going to overrule the objection, we'll admit it with a limiting instruction.

MR. LOCASTRO: Thank you, Your Honor.

MR. SCHULER: Your Honor, can we redact the part that they are not relying on then, of the declaration?

THE COURT: Yes. Yes. We'll admit it for the limited purpose and the other --

MR. SCHULER: Thank you, Your Honor.

THE COURT: It can be admitted in redacted form.

MR. LOCASTRO: We will confer on that, Your Honor, and put together an agreeable redaction.

THE COURT: Okay. All right.

MR. CERRITO: Your Honor...

THE COURT: Hold on.

MR. SCHULER: I apologize, Your Honor, did you also want to hear on PTX109?

THE COURT: That seems to be tied to PTX164, right?

MR. SCHULER: Defer to counsel.

MR. LOCASTRO: Your Honor, that's -- yes, that's another example of a document being used for a limited purpose to provide context for Dr. Vaughn's testimony so the jury can see what exactly he's testifying about when the deposition video was played.

Since Jazz is only utilizing one slide of what is a larger exhibit, again, maybe this is something that goes in with just the cover slide for context and then the actual slide that we're relying on.

MR. SCHULER: That makes sense, Your Honor, we'll work with counsel to produce that.

THE COURT: All right.

MR. CERRITO: Your Honor, I don't know if you're moving on to a different section now?

THE COURT: Yes, now I'm going to Avadel's

objections to Jazz's deposition designations.

MR. CERRITO: May I raise one issue on the ruling, Your Honor? And I apologize, I know Your Honor's ruled on JTX0031. I think, in view of the Court's other rulings this morning, obviously we didn't know what those rulings were, but it seems to me like Avadel gets the opportunity to take a shot at our inventors in saying they are not the true inventors, but we are being denied the opportunity to say the same about theirs. And this is coming from their witness, Dr. Thorsteinsson, who said they didn't do anything new.

So in view of the other rulings, I think JTX0031 --

THE COURT: But you're -- the objection here is about hearsay, right? And whether this guy is --

MR. CERRITO: It's a --

THE COURT: He's a third party, he was an independent --

MR. CERRITO: He's a consultant, he's an agent of the company.

THE COURT: Well, that's -- that's -- that's the issue, whether or not he -- what he says is something that's binding on Avadel or not, right. So you say he's an agent, they say he's not.

MR. CERRITO: I understand. I didn't understand

you to make the ruling based on that, I apologize.

THE COURT: Yeah, so this deposition designation of Dr. Vaughn is along the same lines as PTX164 and 109.

MR. SCHULER: Yeah, given Counsel's representation, that addresses our concern, Your Honor.

THE COURT: Okay.

All right. So those objections are overruled.

The objections about the background questions on Dr. Thorsteinsson --

MR. PORTER: Judge Williams, may I be heard for one moment, please, sir?

THE COURT: Yeah.

MR. PORTER: Chris Porter for the plaintiff, Your Honor, on the issue of the e-mail --

THE COURT: The e-mail?

MR. PORTER: The issue with Dr. Thorsteinsson, the hearsay point that we just discussed. I think one important note, this was an e-mail that this person, this agent -- which I think in and of itself, he's speaking on behalf of the company -- it would be not hearsay, but nevertheless he sent this e-mail to the CEO to Mr. Divis.

So this got into Avadel. This came to -- Avadel received this. And so I think that now it becomes a business record of Avadel. And as such, I don't think that the -- the hearsay would not be applicable because they are

the business records exception. So what we're trying to show is that the CEO of Avadel knew and received this information about what we're discussing. And, again, Your Honor, so I don't think that the hearsay -- I don't think that this is hearsay in that sense.

THE COURT: You're saying it's an exception to the hearsay because it's a business record.

MR. PORTER: Yes, Your Honor. Exactly.

THE COURT: That's a different argument.

MR. PORTER: Yes, Your Honor.

MR. SCHULER: That's an argument that wasn't made, Your Honor.

THE COURT: Okay. He's making it now.

MR. SCHULER: It cannot be that I received an e-mail from Best Buy that becomes a business record of Latham & Watkins. It's not a business record, he just got an e-mail. The statement -- and by the way, the statement they want is not in the e-mail. It has to be created in the ordinary course. This is a special third-party consultant, it's not the ordinary course of Avadel's business.

THE COURT: All right, so...

MR. PORTER: He --

THE COURT: This e-mail, does somebody have a copy of it?

MR. PORTER: May I approach, Your Honor? I

apologize, it's crossed through, but this is the e-mail where he says "Hello, Greg." It's much different than receiving something from Best Buy. Avadel hired him to do this, and it was an effect on the listener as well because they took action upon it. So this is much different than just an unsolicited e-mail coming from a big-box store. This is their consultant giving his opinion.

MR. SCHULER: To be a business record of a corporation, the corporation has to have created it.

MR. PORTER: No, Your Honor. If a corporation receives a business -- receives a document in the ordinary course of business, and particularly when it acts upon it, that becomes a business record of the company.

THE COURT: What witness is this going to be relevant to?

MR. PORTER: Here's the --

THE COURT: What witness is --

MR. PORTER: Thorsteinsson and Divis, Your Honor. Divis being the CEO.

THE COURT: And they are what order? The first person that we're going to hear from?

MR. CALVOSA: No, Your Honor. Thorsteinsson will be by video later this afternoon and Divis --

THE COURT: Okay. So I have some time to look at this, continue to look at this.

MR. PORTER: And if I may. I apologize.

THE COURT: You may have that back.

MR. PORTER: And for the Court, thank you.

THE COURT: All right. So I'll take this under further advisement and see if anything changes.

All right. So -- so that I'm clear, Thorsteinsson is a consultant for Avadel, and -- what was he consulting on?

MR. SCHULER: Your Honor, he was an independent consultant that was retained to oversee the retrieval and storage of documents to an off-site storage facility. When he was asked about the document, he said the document was written solely by him and that no one from Avadel had any input into it.

THE COURT: All right. Let me hear you.

MR. LOCASTRO: Your Honor, Dr. Thorsteinsson was engaged by Avadel to travel to their facilities in France and ascertain whether or not the technology could be transferred to the United States. It's a big deal to move a pharmaceutical operation from one country overseas back to the U.S.

So if you look at the report that's appended to JTX0031, it starts on page 3, you look at what he actually did. He went to the French facility; he spoke to witnesses, at least a dozen of them; he reviewed records. He was

specifically engaged by Avadel to do this job; prepared this report; sent it to Greg Divis, the CEO, who then forwarded it to others in the company. So it's not as if this is some unsolicited thing, this is something that Dr. Thorsteinsson was hired to do, gave it to Avadel, and then Avadel gave it internally. The other thing --

THE COURT: He was specifically hired to do this in this case?

MR. LOCASTRO: That's right, Your Honor. And then Dr. Thorsteinsson's testimony that isn't objected to is actually going to show that he wrote portions of Avadel's NDA. He was then retained by company to further do that. If you look at this gentleman's LinkedIn on the Internet, it actually says Avadel.

In addition to that, during his deposition, Avadel's counsel took the position that sharing privileged documents with Dr. Thorsteinsson wasn't a waiver because this is our guy. So I think for all of those reasons, Your Honor, the hearsay objection should be overruled.

THE COURT: Okay. I will take this under further advisement.

MR. SCHULER: Your Honor, just for the record, question -- page 38, line 17: You told me earlier that Strivecta was engaged by Avadel to work on technology transfer from France to the United States, did I hear that

right earlier today?

Answer: No. I said I was helping overseeing the retrieving and sending the documents to an off-site storage.

MR. PORTER: And Your Honor, one thing, I think the final point on this, not to belabor it, is that we were planning to use this in opening, so is the ruling we cannot use this particular slide in opening at this time?

THE COURT: Let me --

MR. PORTER: Well, they didn't object to that slide.

THE COURT: Okay. So you have no objection.

MR. SILVER: Your Honor, to be clear, we indicated that we didn't object to the slide, but we are pursuing our objection to the introduction of the document into evidence.

THE COURT: Okay. With the slide, there's no objection, both sides agree to that. I told you I'm reserving my ruling on this document --

MR. PORTER: Thank you, Your Honor.

THE COURT: -- whether or not this document comes in.

I take it that -- is Mr. Thorsteinsson subject to subpoena power?

MR. LOCASTRO: I believe he's -- last we

checked, he's located in Florida, so I don't believe so, unless Avadel's counsel knows differently.

THE COURT: And Avadel is not presenting him live?

MR. SCHULER: No, Your Honor.

THE COURT: All right. I'll give this further thought. Let's get the jury.

MR. CERRITO: One other issue, Your Honor. We raised with defense counsel the possibility during our first witness, Mr. Honerkamp, that certain confidential business records, financial records, third-party contracts that are confidential may be -- we don't know, they may cross him on some of those, and they didn't -- not tell me obviously, they don't have to tell me what their cross is, but they may come out, we may request a sealing of the courtroom.

THE COURT: Let me know.

MR. CERRITO: Yes, Your Honor. Thank you.

MS. DURIE: And, Your Honor, I wanted to let you know that we learned recently that our damages expert had emergency surgery over the weekend. We have raised this issue with opposing counsel. We don't yet have any request for the Court because we're not entirely sure what her status is. We are hopeful that she will be able to testify later in the week, but we might be making a request for an accommodation that she testify by video or potentially out

of order because we don't think she's going to be able to come live and testify in person.

THE COURT: Okay.

MS. DURIE: Thank you. I just wanted to alert the Court to that.

MR. CERRITO: Again, no objection to the remoteness. We may have an objection as to the timing of when she's placed into the mix, if you will.

THE COURT: All right. If she's going to testify remotely, then she could still testify in --

MS. DURIE: Well, I'm not -- she might actually still be in the hospital. I mean, I don't -- the remote is one issue, but she also --

THE COURT: We'll deal with it when it comes in.

MS. DURIE: Yes.

THE COURT: Let's get the jury.

(Whereupon, the jury entered the room at 9:34 a.m.)

THE COURT: All right. Good morning, ladies and gentlemen of the jury. I hope everyone had a great weekend. We're going to get started this morning with the opening statements.

All right. Plaintiff, you may begin.

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

Ladies and gentlemen of the jury, my name is Nick Cerrito, and I represent the plaintiff in this case, Jazz Pharmaceuticals, or sometimes we'll call them Jazz. This case is about protecting patented ideas. And at the core of the evidence in this case, we'll show three simple things: One, that Avadel infringes Jazz's patents. Two, that Avadel cannot prove that Jazz's patents are invalid. And, three, Jazz should be awarded damages.

I'm very pleased to be here today, along with my colleagues at the table here in the back of the courtroom, along with Jazz representatives also in the gallery. You'll hear from witnesses this week, you'll see documents, we'll go through a lot of information together, evidence that we'll talk about. That evidence will show that Avadel infringes valid patents from Jazz and what the damages are that Avadel owes for that infringement.

Before we get too far down the road here, let me talk about Jazz and who we are. Jazz was founded in 2003. It saw an opportunity to expand its reach into an a area where a lot of attention wasn't being given. So in 2015 -- I'm sorry, 2005, Jazz acquired a company called Orphan Medical. Since then, Jazz has been an innovator and leader in the treatment of rare sleep disorders, including one called narcolepsy. I'll talk about that this week.

And because of Jazz's success in sleep

medicines, Jazz has had -- has had -- been able to expand into other treatment areas such as treating seizures in children and various types of cancers.

Jazz is getting to help more patients.

So that's who we are. Let me move on to what we do.

As many of you know, developing pharmaceutical drugs, there's a lot of research that doesn't ultimately end up in a pharmaceutical product for patients.

But Jazz has provided seven FDA-approved drugs for patients, and they also continue to innovate. They have other things in the pipeline. What you see on the screen is their seven approved FDA products.

For the condition that we're here to talk about, this -- narcolepsy, Jazz has two FDA-approved products. Both are what we call "immediate release." This means it will work right away when it hits the patient, release the drug immediately into the patients. And both are what we call "oxybate products." Oxybate is the active ingredient in these drugs, and you're going to hear this week oxybate used a couple of different ways, a couple of different names. You may hear it as "oxybate" -- you'll hear that for sure -- or "gamma-hydroxybutyrate" -- that one will be another one -- or even "GHB." Don't worry about remembering those. Those are all the same thing.

So my point is that the drugs you're going to hear about this week, both Jazz's and Avadel's infringing drug, all use oxybate as the active ingredient in those drugs.

So let's talk about why we're here. We're here because of Jazz's work with oxybate and Avadel's infringement on that work. Avadel markets an extended-release product version of oxybate called Lumryz, but the evidence will show that before Avadel bought -- brought Lumryz to the market, Jazz did the work and got its patents that cover Avadel's product. Because of this, Avadel's oxybate product infringes Jazz's patents, and by selling that infringing product, Avadel is profiting off of the work that Jazz did first.

I just want to stop for a moment and show you, as you saw in the video, the two patents that are going to be issued in this case, the '488 patent and the '782 patent. These are as you get from the Patent Office with the official cover on it and the seal. I have to make sure I don't lose these because there's only one original. That's why we're here because you, as jurors, will be asked to listen to the evidence and determine the right outcome here.

So now I'm going to tell you about the evidence you'll hear this week, and I'm going to break this down into three chapters. First chapter is Jazz becomes an industry

leader in sleep medicine. The second chapter will be about Avadel infringing; I like that one. And the third chapter will be Avadel's defenses fail and Jazz should be fairly compensated.

So let's start with chapter 1. As I mentioned, Jazz is a leader in the safe and effective treatment of a sleep disorder called narcolepsy. You're going to hear about this from a gentleman named PJ Honerkamp. Mr. Honerkamp is Jazz's senior vice president in the sleep business unit. He started back at the company in 2004 in a much different role, and he worked his way up. You'll hear about that. During his time at Jazz, Mr. Honerkamp's gotten to opportunity to work directly with doctors and patients that Jazz serves, very impactful.

He's going to explain how debilitating narcolepsy is. Let's talk about narcolepsy for a second. Narcolepsy patients have something called excessive daytime sleepiness. They have issues with falling asleep involuntarily multiple times a day. They have issues at work, at school, caring for the family, and in relationships. These patients can also have a related condition that unexpectedly makes them lose muscle control or tone. They can simply -- they can go limp, they can even fall down when they experience an emotion, like laughter. You can all imagine how debilitating that can be. That's

called cataplexy.

But thankfully, there are medicines that can help, and specifically oxybate is one of them. In 2002, the FDA approved the oxybate product I mentioned earlier, Xyrem, and when we talk about the United States Food and Drug Administration, or FDA, that's the agency that approves drugs in this country.

Now, the evidence will show that Jazz's Xyrem product is dosed twice nightly, and that's because oxybate is a fast-acting drug. It gets in your body and moves through you very quickly. And the first dose, once it wears off, you're going to need a second dose, and this must seem strange. You got to wake up to take a second dose so you can go back to sleep? Well, this is how it -- this is how the drug works. But the evidence will show that narcolepsy patients have disrupted sleep during the night anyway. That's why they have excessive daytime sleepiness. They can get up to 80 times a night waking, 80. That's a lot. It's a lot.

These drugs help reduce the number of awakenings so patients can get more sleep during the night. And the more sleep during the night means better functioning during the day.

Another fact about oxybate is that it was originally formulated -- the way it was originally put

together, it contained an excessive amount of sodium. The amount of sodium at its highest dose of Xyrem is about the equivalent of eating four large orders of french fries every night before bed. Now, that sounds delicious, but that is a lot of sodium. Realizing this was an issue, Jazz didn't stop with Xyrem. It gets safe, effective drugs to patients as quickly as possible who need them and then figures out a way to make them better.

The evidence will show that Jazz focused on two paths to make oxybate better for narcolepsy patients. One was improved safety, and the other way was improved convenience. And you'll hear this week both are worthy paths. Jazz pursued both, but Jazz's top priority for improvement for narcolepsy patients is and always will be safety, number one, always. In this instance, it was reducing the sodium content of that Xyrem I told you, getting those french fries down. This was critically important for narcolepsy patients because those patients are at greater risk for high blood pressure, for stroke and other cardiovascular diseases, so any excessive amount of sodium is bad.

So after years of hard work, research, and development, Jazz began marking a 92 percent reduced version of the oxybate product it had, and that was called Xywav, and that's in 2020. And you'll hear it took about ten years

to get FDA approval for the low-sodium oxybate. That's a lot of work. That's a lot of investment, a lot of time, a lot of people involved in that.

The second priority, second improvement we're looking at for Jazz, one we're here to talk about this week and one Avadel infringes, was about convenience, extending the amount of time that oxybate could last. And you'll see the United States Patent Office awarded Jazz patents for extended release of oxybate, and I showed you those. One is the '488 and one is the '782. I'll walk more -- I'll walk through those patents in just a bit, but the evidence will show that Jazz's invention allowed for the release of oxybate to last for a longer period of time than the immediate-release version of oxybate that previously existed. Sometimes it will be referred to as sustained release or modified release. It's not immediate.

You'll get to hear from the lead inventor of those patents, Mr. Clark Allphin. Mr. Allphin had been in the -- has been in the pharmaceutical industry -- or I guess he has been in the industry for 27 years before he retired from Jazz just last year. During his time in the pharmaceutical industry, Mr. Allphin developed four different FDA-approved drugs. Most scientists never get their work delivered in a medicine to patients. He did it four times. That's a lot. That is a lot.

And he also invented and received patents for the longer-lasting version of oxybate that we're here talking about this week. In total, Mr. Allphin has been awarded about 30 United States patents for his work in the pharmaceutical industry.

As I said, one of those patents is the '488 that we're here to talk about this week. The '488 covers a combination of immediate-release and sustained-release portion of oxybates in a single dose. What that means is there's a portion of the drug that releases immediately and a portion of the dose that releases over a period of time.

And the thing that sustains the release or makes that extended is called -- is the part of the formulation that's called a functional coating, and it's partially made up of an ingredient called -- and stay with me for a second -- methacrylic acid-methyl methacrylate. There won't be a test on that. We're going to call it "MAMM" from now on, because I can barely say it and I've practiced it a hundred times. We're going to call it "MAMM."

You'll hear from Mr. Allphin that he and his co-inventors -- Jamie Pfeiffer, who unfortunately has passed away -- conducted the work leading into the '488 patent in September 2009. That's an important date. It will come up again. You'll get to see his laboratory notebooks and see how he made the sustained-release formulation by using this

functional coating with MAMM. And, again, that coating, you take the immediate release and you throw that coating over it. That functional coating covers the immediate release oxybate and it makes it release over time. Remember, I said the functional coating is partially made up of MAMM.

Mr. Allphin discovered that he could achieve the sustained release by using MAMM as what we call a "pore former" -- it forms a pore, pore former -- in that functional coating. Mr. Allphin will explain, just like you're seeing here on this slide here, that the MAMM pore former works by creating holes or channels. That part of it comes out. That part of the functional coating comes out and -- of the drug formulation. Specifically, the MAMM dissolves, as you're seeing here, and creates these holes, just like you see on the slide, and the oxybate comes out -- that's the drug that we're talking about -- releasing out over time.

Mr. Allphin made his MAMM formulation and conducted laboratory testing called DI water dissolution testing. "DI water" stands for deionized water, so that's highly purified. It doesn't have any ions on it, no minerals in it, very clean water. And you'll hear from Mr. Allphin and Mr. Pfeiffer determined that a successful outcome in this DI water test would show their sustained release worked. That's exactly what Mr. Allphin's testing

of the MAMM formulation that DI water showed, that the formulation achieved the claimed sustained-release profile, and you'll see that in an Excel spreadsheet that shows Mr. Allphin's September 2009 dissolution testing. And, again, that September 2009 date that Allphin -- Mr. Allphin did his work is an important date in this case. It will be referred to multiple times.

Another important date in this case is March 24, 2011. The evidence will show that Mr. Allphin filed his application for what became the '488 patent on that date, March 24, 2011. This is what's known as a priority date, all right. So once you apply for a patent and that application is granted, even if it's years later, you get the benefit of that date, that filing date. And, again, the priority date here, March 24, 2011 -- the priority date is a date that Jazz secures its place in line. That's the date.

Now, Mr. Allphin will explain what he did in his early sustained-release oxybate work as part of a project to get oxybate to more patients, and it was for a different condition. But that particular work got put aside, so Mr. Allphin's work shifted for the narcolepsy patient population. Again, Jazz decided the most important was safety. He got pushed over in that direction, and that's where his work was in coming up with the Xywav product I mentioned earlier.

But once that project was well underway in 2015, Mr. Allphin returned to his work to modified-release oxybate, and the evidence will show that Mr. Allphin worked on modified-release oxybate, again, from 2015 to early 2016. We'll hear Mr. Allphin explain that his work at that time is reflected in the second patent, the other one that we have, the '782 patent. And the priority date for that patent is February 18, 2016, again, another important date here. When he did his work, when the patents were filed, important dates.

You'll see some other dates on this slide. Those are what you've heard about in the patent video last week. Inventors are allowed to amend their claims during the patent prosecution process, and Jazz did that here. Jazz invented its claims for the '488 patent in July of 2018 and again for the '782 patent in March of 2021. It's important to remember that when Jazz made those amendments to the claims, it didn't change anything in the specification, anything in that long part that was shown on the -- on the video. Didn't change any of that. The Patent Office saw Jazz's amended claims, agreed there was support in the -- in Jazz's original application, and granted those patents. We'll talk more about this later, but what you will hear is Jazz amending the claims is 100 percent appropriate, no big deal.

The evidence will also show that the '782 builds upon the work that was done in the '488. Claim 24 in particular is one of the dependent claims that you heard about in the patent video. It includes all the elements -- it depends on Claim 14, so it includes all of the elements of Claim 14 plus the additional elements in Claim 24.

Claim 24, therefore, covers a combined immediate-release and modified-release particles of oxybate, with two other ingredients here, one called a viscosity-enhancing agent, and an acid. And those are separate from the oxybate particles, so not part of the particles themselves but separate components. And all that's put together in what we call a unit-dosage form, something that in this case is a sachet. Sachet, think of it as a sugar package. Put all of that in a package, that's how it's packaged up together.

And we'll get to see Dr. Allphin's documents related to that work as well. And Mr. Allphin will explain that -- why a packing oxybate in the sachet, with those two other ingredients, separate from the GHB particles, was the key from making the drug administrable to patients.

Let's move on to chapter 2. Let's remember the video we watched last week on the patent claims, they are like property deeds. Do you remember that part of it? They allow Jazz to receive compensation if another one steps on

them or uses their land, or in this case, in legal words, infringes.

The evidence Jazz will present this week will show that Avadel infringes on two claims of the '488 patent, they are also dependent claims, and they are Claim 7 and 11 of the '488 patent. When it comes to the '782 patent, Avadel admits it infringes. Won't have to hear about that, because they've already admitted.

Not something you're going to have to decide here because, again, they admitted it.

For Claim 7 and 11 of the '488 patent, there are a number of requirements in those claims, it's fairly long. We called individual requirements elements, that's how we refer to them in legal sense.

Avadel admits it meets all of those except for two particular items. The disputed ones are the DI water dissolution profile I referred to earlier. And the second one is the sustained-release core.

You're going to be asked to decide whether Avadel's product meets those claimed elements. To help you answer those questions, you're going to hear from the man who was responsible for working on Avadel's oxybate formulation, Dr. Herve' Guillard, it's an Avadel employee.

Let's start with the first disputed element, Jazz's claimed DI water dissolution profile. When

Dr. Guillard was working on Avadel's oxybate formulation it was called FT-218, that's what it was called at the time. FT-218 was the name that they assigned to it.

And he was doing that work while at a company called Flamel. Flamel later became Avadel through a merger, so if you see Flamel, it eventually became Avadel.

Most importantly, Jazz's '488 patent application published in March 2012. And only after that did Avadel and Dr. Guillard start their work on FT-218, so after our application published.

Then on July 22, 2016, after Jazz filed both the '488 and the '782 patent, Avadel filed its own patent on FT-218.

And you'll hear from the Jazz inventor, Clark Allphin, about his reaction when he saw Avadel's patent filing and it became public in 2018. At that time, Mr. Allphin saw what Avadel was doing was what he had already done. Avadel made a MAMM oxybate formulation and did dissolution testing in DI water just like Mr. Allphin.

You don't need to take my word for it because you'll hear from Dr. Guillard. Guillard admits to this. Dr. Guillard will testify that part of his job at Flamel was monitoring Jazz's patent portfolio, watching what your competitors are doing. And the published application for the '488 patent is one of the Jazz patents he was

specifically watching, specifically monitoring.

And Dr. Guillard will also admit that he only tested FT-218, their product, in DI water because he saw that Jazz did it first. In fact, Dr. Guillard had never done DI water testing before he saw it in the Jazz patent.

And you're going to see Dr. Guillard's laboratory notebook from October 2015 showing what he did, and it says, "Dissolution in deionized water, according to the Jazz patent," can't be -- right there in black and white.

You're also going to see the results of that testing, and they show that Avadel's Lumryz product infringes the '488 patent, the claimed DI water dissolution profile. Numbers don't lie. They did the test, it shows infringement.

Before I move on, you might be wondering how did Avadel get its own patent -- okay -- if it infringes the Jazz patent. Well, the law allows Avadel to get a patent on a technology even if it infringes on an earlier patent, that's just the way it works.

And maybe you can think about it this way: Jazz patented -- we got a lot of food going on in this presentation, sorry -- Jazz patented a burger with a bun. Avadel then came, used that same burger and bun, and threw some cheese on it, okay.

The problem is, to do that, what Avadel is doing, they still had to infringe, they still had to use the burger and bun that Jazz came up with first.

So let's move next to the second claimed element that Avadel disputes, that's the sustained-release core, core element.

The evidence will show that the same sustained-release oxybate core that's in Jazz's '488 patent claims is in Avadel product. And you'll hear Dr. Guillard again. He'll admit that the Avadel told the United States Patent Office, under oath in Avadel's own patent, that sodium oxybate is contained in the Lumryz's immediately released particles. And that those particles, those immediate-release particles are the core of the sustained-release particles. The coating goes on those, that's the core.

Again, you don't have to take my word for it, that's in their patent, that's what they say.

Now, Avadel is going to show you a picture over and over again in their opening suggesting to you that only the very inner portion of its particle is the core.

Let's look at the words they actually used. When you look at the words they actually used -- and this is from their patent -- again, right-hand side, composition of the IR particles, that's the immediate release. When you

come down to here, table 1.b, here's the components of the other half of the equation, the sustained release, or the modified-release particles. And right there it says core, microparticles, same as Jazz.

For that claim element, Avadel didn't do anything new. And Dr. Guillard will not be the only Avadel witness that you'll hear from on this issue.

After the merger I mentioned to you earlier, where Flamel became Avadel, Avadel hired a consultant, a man named Dr. Thorsteinn Thorsteinsson, to look at the work that Flamel did.

The evidence will show that based on his review of that work, Dr. Thorsteinsson came to the conclusion that there was no "secret ingredient" in the Flamel work, nothing special.

In fact, Dr. Thorsteinsson recommended that all of the Flamel employees could be fired because they were -- nothing new in what they were doing. And Avadel's CEO, Mr. Greg Divis, who you are going to hear from this week, fired all of those employees. I guess it was nothing new. One of those that they fired was Dr. Guillard also.

Now, while this was happening at Avadel, Jazz was monitoring the narcolepsy market to see what potential competitors may be out there. As I said, they look at each other. Jazz saw Avadel's work.

And as I already mentioned, Jazz amended its patent claims such that Avadel would not get away with using Jazz's technology. And an expert named Dr. Steven Little will explain to you how the patent claims that issued -- as Claim 7 and Claim 11 of the '488 patent are infringed by Avadel's product.

Dr. Little is a professor, chemical engineering, at the University of Pittsburgh. He's the director of the controlled-release laboratory there. He works on these types of sustained-release coatings that are involved in this case.

He analyzed information about Avadel's Lumryz product and confirmed that it checks all of the boxes of this case. He analyzed the information, Avadel's Lumryz, and confirms that it checks the boxes for claimed elements in Claim 7 and 11 of the '488 patent. And we'll take you through that this week and show you how Avadel infringes.

Let's move on to chapter 3. How do we fix this? Well, the patent law recognizes that when a party has infringed or uses another's patented ideas, they need to pay for that use. And here, Avadel should be held accountable for its action. This means Avadel should have to pay damages for infringement. It's only fair.

A patent owner can be compensated for it's unauthorized use through what's called a reasonable royalty.

And here, based on the evidence, Jazz is asking for a 27 percent royalty rate for use of any of the claims asserted against Avadel.

You're going to hear from a gentleman named Shawn Mindus who has been in the finance department at Jazz since 2004. Mr. Mindus will show how Jazz's forecast predicts itself expects some things, most companies do from the products it produces in this area.

Here he will show you that the forecast from Jazz's currently marketed oxybate products and how Jazz predicted Avadel's sales would affect Jazz's sales. Then you're going to hear from several Avadel witnesses, employees, including Avadel's CEO, again, Mr. Greg Divis.

The evidence will show that Avadel planned on targeting the patients that take Jazz's oxybate product, among others, to switch them over to Lumryz. I didn't make that word up, that's their word.

The evidence will show that Avadel even included instructions in its FDA-approved labeling for Lumryz, telling doctors how to make that switch from Jazz's product.

Then you're going to hear from an expert in damages in the pharmaceutical industry called -- his name is Dr. Mark Rainey. Dr. Rainey has a PhD in economics from MIT and has provided economic analysis and consulting in over 20 health and pharmaceutical matters, in addition to many

others during his 20-plus years of experience in the industry.

Dr. Rainey will show you how he took account of all the innovations from Jazz and Avadel and put that all together, also independent third-party resources, and calculated that 27 percent royalty rate that Jazz is asking for this week.

He'll explain how the royalty rate is more reasonable given the predictions out there, especially those from Avadel. As you'll see in this week, Avadel predictions of harm on Jazz were even higher than what Jazz thought was going to happen. They thought the impact was going to be much worse than even we thought. You'll see that, their words.

Now, we expect Avadel is going to tell you they should have to pay about 2 percent or maybe 3.5 percent royalty here.

It's interesting, because Avadel will also tell you that its Lumryz product that you're going to hear about, Avadel's CEO thought they were going to make a billion dollars, billion with a B. And they're willing to give us just a very small portion of that, even though they can't make their product without our patents.

Avadel will also try to make excuses, argue that the Patent Office made a mistake, that the patents are

invalid.

Remember from the video, Avadel has to prove that the Patent Office got it wrong by clear and convincing evidence. The evidence will show that Avadel cannot come close to meeting its burden.

Let me point out something very important first; Avadel doesn't dispute that both of Jazz's patented inventions are new and nonobvious. So Avadel is not here saying that Jazz -- what Jazz did was done before, that's not what they are saying.

Instead, they're going to distract you from the merits, the actual who should win, who should lose. But Avadel's attorneys will focus on Avadel's patents, okay. I already told you about those. And Avadel's attorneys will tell you that Jazz copied Avadel's patented claims, that Jazz is suing Avadel on here from Avadel's patents.

Since Jazz filed its patents first and secured its place in line, it's absolutely referred to in those claims. Jazz's attorney who is responsible for drafting patents will testify he did just that, of course he did. And that's because the evidence will also show that Jazz's attorney did was perfectly appropriate and acceptable practice.

On that issue, you're going to hear from the former commissioner of patents, big boss, from the U.S.

Patent Office, a gentleman appointed by United States Secretary of Commerce, named Robert Stoll. Mr. Stoll has 29 years of experience at the Patent Office, including 12 years as an actual examiner, a primary examiner. And even more years developing the rules and regulations for that office.

Mr. Stoll will tell you that a patent applicant has an earlier priority date -- and we talked about those dates earlier -- and secured that applicant's place in line, as Jazz did here, then referring to competitor's patent claims, who is doing what you've already done, is accepted practice. In fact, he does it all the time for his clients.

And the evidence will show that the Patent Office not only specifically evaluated Jazz patents for what we'll call "written description and enablement," you'll hear about that this week, but not only did they find support for both of those, they found it was there and the Patent Office also specifically considered Avadel's patent, the one I told you about earlier, when it was doing -- going through this prosecution. And it determined Jazz's patents were patentable.

So Avadel is not making any argument here that the Patent Office missed something, didn't consider something, that's not what you're going to hear.

And the evidence will show that, as I said, Jazz

did the work first, filed its patents first. And because of that, Jazz has a right to protect those inventions. That's what Jazz did. Jazz made sure Avadel couldn't take Jazz's innovations.

So Avadel will argue that Jazz's inventors aren't the true inventors and that Avadel employees supposedly are. Okay. You'll need to look at something different for each of the patents to decide this issue, and that's because the evidence will show that the patent law changed between the '488 patent and the '782 patent filing.

For the '488 patent, all that matters is who did the work first. You'll see that Mr. Allphin's laboratory notebook and Excel file, Jazz did the work in 2009, that's why I said it was an important date, and also filed its patent first, 2011. Avadel didn't even start its work until 2012. That's after Jazz's work and Jazz's patent filing.

And Avadel's laboratory notebooks will show they didn't do that DI water testing thing I was talking about earlier until 2015. And you'll hear Dr. Guillard testify that he only did the DI water testing because he saw it in the Jazz patent first.

And for the '782 patent, the question is slightly different. All that matters is who filed first, who got to the Patent Office first. And you'll see on this slide that Jazz filed its patent first. February 18, 2016,

is earlier than July 22, 2016. Avadel cannot change those dates. The evidence will show that Avadel cannot even come close to proving its inventorship defenses, and don't be mislead to Avadel's attempt to discredit Mr. Allphin and the work that he did.

And finally, Avadel will resort to super technical defenses called, I mentioned a little earlier, written description and enablement. Despite the Patent Office doing its own written description and enablement analysis on Jazz's patent, Avadel wants you to believe that Jazz supposedly didn't describe its inventions in its patent and that a person of ordinary skill in the art wouldn't understand how to make those inventions without what we call undue experimentation.

Well, Dr. Guillard certainly -- he understood it. He had no problem, did he? And the United States Patent Office understood it when they issued Jazz's patents.

You're also going to hear on this issue from experts in this case. You'll hear from Dr. Christian Moreton for Jazz's '488 patent and Dr. Steven Little for Jazz's '782 patent. I told you about a little bit about Dr. Little. For a second about Dr. Moreton. Dr. Moreton has a PhD in pharmaceutics and is also experienced in modified-release technologies. He has worked in the pharmaceutical field for about 45 years and has served on

expert committee for the United States Pharmacopeia, which you will hear about later in this case.

Both Dr. Little and Dr. Moreton will take you through the Jazz patent and show you how the information in them matches right up with the Jazz inventions. And both will explain to you why Avadel is wrong and that a person of ordinary skill in the art would be able to practice inventions without undue experimentation.

Avadel's expert is just going to say I don't see it there. Well, Jazz will take you through it and show you in black and white where it is. So don't be mislead by Avadel. They simply cannot meet their burden to show invalidity, as you saw in the video, again, by clear and convincing evidence.

Before I sit down, let me mention one more thing briefly. Avadel's attorney is likely to get up and try and make a big deal about the fact that Jazz doesn't have a product that uses its invention here of the '488 or the '782. She'll point out that no once-nightly product and that Jazz only sells a twice-nightly product. Don't get mislead. Whether or not Jazz has a product is completely irrelevant to whether or not Avadel infringes our patents. Completely irrelevant.

There's nothing in the patent law that requires you to have a product to get a patent, not required. It's

not a defense the patent infringement. Avadel won't dispute that. Remember, the evidence will show that Jazz decided to focus on safety, getting its safer low-sodium product first, get that approved, that was its focus and the product, again, Xywav.

Look, at the end, you have one party, not hired by Jazz, not hired by Avadel, no horse in this race, before this case ever began, took a look at these patents and said it was patentable. Who was that? United States Patent Office. No horse in the race, they found it all there. Avadel would prefer you to believe two examiners on two different patents got it wrong twice. What are the odds of that? Did not happen, did not happen, don't be mislead. And for all that, Jazz will ask you to award its damages compensating for Avadel's infringement and fix the wrong that was done. Thank you for being here, thank you for your time devoted to this very important process. Thank you again.

MS. DURIE: Thank you. Ladies and gentlemen, good morning. My name is Daralyn Durie and I represent Avadel. This is the CEO of Avadel, Greg Divis. Avadel has one product. This is our product. It is Lumryz. Lumryz is a treatment for narcolepsy. You can take Lumryz once at bedtime and sleep through the entire night.

Now, narcolepsy is a devastating disease. If

you have narcolepsy, it's like you have pulled two or three all-nighters in a row. You're exhausted, you can't think straight, it can cause you to fall asleep at the wheel, it can cause you to fall asleep in class. Sodium oxybate and Lumryz is an effective treatment for narcolepsy, and it's better than either of Jazz's two products. That is what the United States Food and Drug Administration decided when it approved Lumryz. That Lumryz is clinically superior.

And the reason that Lumryz is clinically superior is because it lets you sleep through the night. That's not just the judgment of the FDA. Jazz's inventor, Mr. Allphin, called once-nightly sodium oxybate the holy grail in his line of work. And Jazz spent years and years and years chasing that holy grail. They were not able to do it. We did.

And when Jazz saw that we had been successful, what did they do? They tried to buy it. Jazz offered Avadel $150 million and royalties for the rights to Lumryz. Why did they do that? Because it's better. And because it is something they had not been able to do.

But Lumryz was worth more and Jazz did not want to pay the price. So instead of buying it, they decided to take it. Avadel has patents on Lumryz. Jazz copied those claims and then turned around and said that it was their invention. You know why you turn around and copy something

from someone else? If a kid looks over and copies down the test results it is because you did not do your homework. And they had not done their homework. They have not been able to develop this formulation.

Now, having Jazz walk away from the bargaining table did wind up being really hard on Avadel. I told you Lumryz is our only product. That's because when we were not able to make a deal with Jazz, Mr. Divis had to lay off a lot of people, including the inventors in France, and focus the company's entire efforts on bringing this product to market. And that's what we did.

You just heard the story about chapters one, two and three. Most of the books we read probably have more than three chapters. You're going to hear that's not the whole story. There was a lot of stuff that happened that was left out. And we're going to try to show you a little bit this morning, and then more over the course of the trial, what some of that other information is. But I want to start by telling you a little bit about Jazz's product.

Now, Jazz has a twice-nightly product called Xyrem. And we said this is a formulation of sodium oxybate. Sodium oxybate itself is old. Jazz did not invent it. It's been around since the 1960s. It's what we call public domain. Anyone is allowed to make a drug out of sodium oxybate. Not Jazz's property. Jazz made a liquid

formulation of that, and you take that liquid formulation twice a night. So you take it once when you go to bed, you leave it by your bedside table and you set an alarm. Your alarm goes off, you wake up in the middle of the night, you take your second dose and then you get an additional amount of sleep.

Now, we just heard a suggestion that narcolepsy patients have disrupted sleep anyway, so this isn't such a big deal. You're going to hear evidence about this. This is a really big deal. Often these patients have to set multiple alarms. They've taken a drug that causes them to sleep. And if they sleep through that alarm, if they miss that alarm, it's a big problem, because Xyrem has to be taken at a very precise point in time. You take it too late, you're going to sleep too late. You're going to miss work, you're going to miss school, whatever it is. You miss that middle dose, you're not going to get enough sleep, and you're going to be subject to those symptoms of narcolepsy. Being at risk of falling asleep while you're driving to work, for example, during the day.

Imagine, too, what this is like for other family members. You've got a spouse with narcolepsy, they are setting their alarm multiple times trying to wake up in the night. You have a kid with narcolepsy, you've got to set your alarm so that you can give them the drug. And there

are a lot of patients who can't take this. Sodium oxybate is a scheduled drug. It's sometimes called the "date rape drug" because, basically, it knocks people unconscious. If you're a college student, you can't have a bottle of Xyrem sitting next to your desk. If you have little kids in the house, you can't have a bottle of Xyrem next to your bedside. It's dangerous. So there are a lot of patients for whom this is just not a realistic option.

I said that the FDA approved our product Lumryz and said that it's clinically superior. One of the other things the FDA said in making that decision is that waking up to take a second dose of Xyrem and Xywav is antithetical to the goal of improving sleep. Those are the words of the FDA. And the reality is that these problems are so severe that about half of the people who start Xyrem stop within the first dose because it doesn't work for them and because there are too many problems associated with that middle-of-the-night waking.

Now, Jazz told you that Xyrem and that our product Lumryz is bad because it has a lot of salt. Now, it's true, there is a pretty high salt load in this product. And there are some patients for whom that's not great. If you have high blood pressure, if you have certain heart conditions, taking a lot of extra salt is not good for you. There are other patients who make the decision that it is

more important for them to be able to sleep through the night and that they can tolerate that amount of salt.

Now, Jazz told you that they have a new, low-salt product. But to be clear, they're still selling Xyrem, that's their higher-salt product. Same amount of salt as this.

You know how much money Jazz is going to make this year from selling its high-salt products? $500 million. So when Jazz comes in here and they tell you salt is a huge problem, they don't actually think it's that huge a problem when they're selling that product and making that money.

Now, the truth of the matter, as I said, is that low salt is better for some patients, sleeping through the night is better for some patients. From our point of view, patients should be given that choice. And that is a decision that should be made by patients and their doctors. But when Jazz comes in and says, oh, this is just about convenience, we prioritized patient safety, I want you to look at the evidence of what they were saying at the time. Because what they were saying at the time was once-nightly is the holy grail. We need it, we want it, we can't figure out how to do it, we want to buy it, and if we can't buy it, we're going to take it and say that it was ours all along.

So how is it that Avadel was able to solve this

problem that Jazz couldn't solve? This was the work of a team of inventors led by two people.

And if I can ask you to stand up, Herve' and Claire. Hérve Guillard and Claire Mégret, these are the inventors -- thank you -- these are the inventors of Lumryz, and they used technology, platform technology that goes back to 2001.

Now, you're going to see references in this case to Flamel. Avadel changed it's name from Flamel to Avadel, so same thing. Flamel, Avadel, same thing. Avadel's Micropump technology goes back to, as I said, to 2001, and this is what we call a platform technology. You can use it and apply it to different drugs. And the way that it works, you have a core, and in this particular example, it's what we call an inert core. It could be sugar, something like that. You've got a little tiny bead, and you spray the drug onto the bead, and these are little tiny beads. It looks like sugar or salt. They're tiny, tiny. You spray the drug onto the bead, and then you put a coating on top of the drug. And that coating can control how that drug releases and when it releases and where in the human body it releases.

And Avadel used that technology, which it had used before to make other drugs, including a drug for GSK, to make Lumryz. Now, Avadel had the original idea to do

this back in 2010, and it actually talked to Jazz and said, We think it would be a good idea to use this Micropump technology to make once-nightly sodium oxybate. Jazz didn't think it was going to work, so Avadel decided to do it on its own. So from 2012 through 2016, Avadel did that development work using its technology and developed Lumryz.

And Lumryz is made up of two different kinds of these little particles. What you see, the orange particle, that's the immediate release. That is made up of that little core with drug on it. And what that means is when you take that, it acts immediately and it puts you to sleep. The other little pellets have that coating on it, and that coating is what allows this to be a once-a-night drug.

And the way this works requires you to understand the concept of pH. So pH is how acidic or basic is something. Lemons, acid. Milk, pretty neutral. Milk of magnesia, basic. So your stomach is very acidic. That's why people have acid reflux, because there's a lot of acid in your stomach. Your intestines are neutral.

So the way that coating works, it gets triggered by a change in pH. So you take Lumryz. The immediate part releases. You go to sleep. While you're asleep, it travels through your body. While it's in your stomach, no drug comes out from those blue-coated particles because those don't release in a high-acid environment. They go down into

your intestines. Now they're in a more neutral environment. That coating dissolves, and now the drug is released. You get a second burst of the drug, and you stay asleep for the night.

And the particular formulation for Lumryz using this Micropump technology is this little inert core. It's made out of something called MCC, but it's inert. It's -- you buy -- you can buy it. You can buy a bag of little cores out of MCC. It has the sodium oxybate along with some other things sprayed onto it. That's a drug layer on top of that core. And then on top of that, there's this coating. And one of the ingredients in that coating is methacrylic acid-methyl methacrylate, and as you heard, we're going to call that "MAMM." And it's that MAMM that is triggered by that change in pH and that allows those particles not to release their drug until they hit your intestine.

Now, I said Dr. Mégret and Dr. Guillard invented this. They applied that Micropump technology to make this formulation and figured out that it would work, why it would work and how it would work, and published those results in 2014, the first in-man clinical trial of Micropump sodium oxybate for once-nightly dosing. And they said they were using this microparticle technology, these little, little tiny particles that, as I said, look like sugar.

Now, you heard in Jazz's presentation that in

2015, Mr. Allphin returned to modified-release oxybate. What you didn't really hear is why. And what you're going to learn is the reason that Mr. Allphin went back to it is because he had done some early work on tablets. It had been unsuccessful. They had abandoned it. He saw Avadel's results, initially thought it wouldn't work, looked at it more and thought, huh, maybe it does. Went back to try to figure out how and why and then rushed to try to figure something out because Jazz realized it was behind.

So in 2018, our patent application publishes. You file a patent application at the Patent Office. It's confidential for a limited period of time, and then it publishes. And two things happened. First thing that happened is that Jazz read it. And I want to be very clear: That is perfectly fine. Part of the patent bargain that you heard about in that video on Friday is when you file for a patent, you make all of your work public. Anyone is allowed to read it, study it, learn from it, use it. You get patent protection in exchange for making that information public. So reading it, learning about it, studying, trying to figure out how it works, all totally fine. Jazz did that with respect to our patent; we did that with respect to their patents. And that is all completely okay.

Now, you heard Jazz in their opening say that Mr. Guillard studied the Jazz patent, looked at their

testing protocols. He did. That's perfectly fine. That's the way science works. You look at what other people have done, and you learn from it. What you're not supposed to do, however, is to take it and claim it as your own.

Now, the other thing that happened when we published our patent application is that Jazz realized we really did have a solution. And this is when they came to us and said, We want the rights to Lumryz. Now, I told you there were negotiations around that, offers went back and forth. Ultimately, we didn't agree on a price, and Jazz walked away.

But there's another thing about those negotiations that are really important: Not once did Jazz say, We already have the rights to this. We've already invented this. You're using our intellectual property. They never said that. You know what they said instead? We, Jazz, want a license to your patents, Avadel. They wanted a license to our patents. They never said anything to suggest that they have already invented this.

I said those negotiations broke down. Jazz still wanted the rights to the product. In our patent application, we had published the details of our formulation. Because that's what you do. And one of the ingredients in our formulation, methacrylic acid-methyl methacrylate. You know what happened next? For the first

time, Jazz filed a patent application and said, We invented methacrylic acid-methyl methacrylate as part of this coating, and we want a patent to it.

Now, you heard Jazz say that they filed this patent application -- this is the first patent, it's the '488 patent -- in 2011. That's not exactly right. You have copies of the patents in your binder. And if you look at them, you're going to see -- this is the '488 patent. It's about a third of the way down. If you look on the first page, it says, "Filed." It's about a third of the way down. "Filed."

Do you see what that date is? July 2nd, 2018. That's when they filed that application and those claims. 2018.

And then what they did is they said, Okay, we're filing this in 2018, but we really invented it back in 2011. So that's the question that you're going to be asked to decide: Was this something they copied and didn't invent until -- invent until 2018, or is this an invention they had all along, an invention they actually made back in 2011?

So let's talk about this patent application they had filed back in 2011. What was that patent application about? Well, let's look at what they said in their own internal documents.

One of the things that happens in lawsuits is

that parties have to exchange documents with each other. They got our internal documents; we got their internal documents. This is one of their internal documents. This is Mr. Allphin, their inventor. He's talking about that patent application from 2011. He says, "It's the U.S. application we filed for sustained-release film-coated tablets." And you're going to learn that's right. Jazz had had a program back in 2009, 2010, 2011 to try to develop tablets. It didn't work. They abandoned it. And this e-mail actually talks a little bit about why they abandoned it. It says, "It's got lots of details. The figures may be easy for someone to digest. If one didn't know better, figures 12 and 13 showing fasted state look pretty sweet."

So you're going to learn that Jazz did experiments with these tablets, they gave them to people. Some of those people had not eaten for ten hours. The results looked pretty good. The problem is this is a drug you take at bedtime. So it's not realistic to think that people aren't going to eat for ten hours before bedtime. So they also gave the drug to people who had eaten. Those results are what led Jazz to discontinue the program. Because you're going to see that what happened for the people who had eaten, they got a huge spike of the drug eight hours later, which is to say when you're supposed to waking up. It was all over the map. There was too much

variability. They dropped the program. And they concluded once-nightly tablets are not going to work.

But they did file a patent application. And that's that patent application from 2011. And those tablets used, to be clear, different ingredients. They weren't about methacrylic acid-methyl methacrylate. They used something different. It's called ethylcellulose and hydroxypropyl cellulose. And those differences were significant because -- remember I told you our invention triggers with pH, right? That's how it gets down into the intestine and then releases the drug. The ingredients they were using were not pH-triggered ingredients. In fact, Mr. Allphin thought having a pH trigger was a bad idea, and so he was using different ingredients. That's why Jazz's lawyers didn't come up to you and say, Here's our 2011 application. Here's where we made that invention. Right? You didn't hear them do that.

Instead, they said, Here's some lab notebook pages. Let's go even earlier to 2009, since it's not in the patent application. Here's some lab notebook pages. Mr. Allphin did a few experiments with MAMM. He did do a few experiments with MAMM, a few pages in a big lab notebook. And you know what he concluded when he did those experiments? That's not the way he wanted to go. This was pH sensitive. He thought that was a bad idea. It was

behaving in ways that he didn't understand.

Did a few experiments, dropped it. Went with those tablets, with ethylcellulose, tested them. Results in a fed state were terrible. Didn't put that data in the patent but knew that it was a problem and dropped the program, and then came back to it once he saw that Avadel had been successful.

Now, in Avadel's patent filing didn't just talk about the formulation characteristics. It had testing data to test. And this testing data included testing in what is called USP Apparatus 2. USP is different methodologies for testing how formulations behave, including how they release drug. There's one called USP 7. There's one called USP 2. Our patent, we said, tested with USP 2. And Jazz wrote that into their claim too. They copied that: Do this testing with USP 2.

Why does that matter? Because the Patent Office raised a question about this, and they said, Is that -- we're not seeing that. Is that something you actually did? And Mr. Allphin put in a declaration to the Patent Office. And I'm going to say, I think this declaration was very, very carefully written because what he said is, I'm giving you some data that shows the dissolution profile of a sustained-release portion of a formulation meeting the limitations of the claims, which sounded like, Here's some

data that shows that we did the thing that the claim says you should do. That's what it sounds like. That's not, I think, what he was actually trying to say because that would not be true. Because the claim, as we just saw, requires USP 2. The testing he was talking about was actually in USP 7. See a little further down, it says it was tested in a dissolution apparatus, but it doesn't say what kind of dissolution apparatus? That's because it was a different one.

And you may wonder, Is that a big deal? And the answer is it's actually a really big deal. That's why they didn't make that clear to the Patent Office. Because the results in USP 2 and USP 7 can be very different. And you're going to hear from the woman who wrote the book about that. And when I say she "wrote the book," I mean she actually wrote the book. This is the *Handbook of Dissolution Testing* by Vivian Gray. She wrote the book. She's going to come and testify, and she's going to explain these different ways that you test matter because you get different results. They were not straight with the Patent Office about that. But it makes a difference.

So that gets us to the substantive issues you're going to be asked to decide on this '488 patent. And the first question is: Do we infringe? And the evidence will show the answer to that question is "no." Because although

Jazz copied us for this one, they didn't copy us very well. And one of the requirements here basically carried over from their tablet work, and it doesn't apply to what we do. And that's this idea that you have a core and that there is a drug inside the core.

Now, in the case of a tablet, that's often how it works. But that's not the way that it works with our product. Remember I told you we have a core, we have a drug layer, and we have coating. Now, this baseball is obviously a lot bigger than a microparticle, but it helps to illustrate this point, because if you take a baseball and you cut it open, assuming it's a pretty good baseball, what you have is actually a core, it's made of cork in there. And then you've got stuff around the core. You can think of this as being like the drug. And then you've got a coating on top, it's like the leather that's holding it all together.

Inert core, active drug, coating. We're like that baseball, that's the way that we work. So there isn't drug inside the core, the core is just that MCC neutral thing in the middle there.

Now, you heard some documents and some references to our patent. Jazz tries to make this very confusing. But if you look at the figure in our patent, it's clear. On the left, that's our immediate-release

particle. And you see it's labeled, there's the core, there's the drug layer on top of it.

On the right, that's the figure from our patent for our modified-release particle. It's still got the core, that neutral core, still got the drug layer, see those labeled. And then around that is the modified-release coating.

So that's the question you're going to be asked to decide, is that true, do we actually have that neutral core in there? And the answer is: We do, just like it shows there. And that means we don't infringe.

Because our product has an inert core with no drug and a separate drug layer. Their patent is about a core that has the drug layer inside of it. And you can think of that as being a little bit like kind of cheapo version of a baseball.

This is a -- this is a good baseball with a core in here. But you can get a cheap baseball and the rubber and the core are all mixed together, and then there's a wrapper around it.

This is what their patent claim covers. It's all mixed together. The drug is in the core. It is actually possible to develop a formulation that way, Jazz tried doing that using some technology that's called extrusion and sterilization. You mix the drug together with

stuff and you squeeze it out, like out of a toothpaste, and you make it into little chunks. Didn't work very well, but that would be the idea. And that is not what we do. And that is why we don't infringe, because we have this, we have the neutral core.

Now, in addition to the fact that we don't infringe, as I said, the patent is invalid. We're going talk more about that. But it's also invalid because it's our idea. We were the ones who first came up with that idea of having methacrylic acid-methyl methacrylate, MAMM, as a coating for a modified-release particle for sodium oxybate, that was our idea and they copied it. You're going hear more about that.

I want to turn to the second patent.

So, I said our patent application published in 2018. Then in 2020, our patent issued from that patent application. And we -- in that patent, we had claims. We wrote the language of these claims to cover our product. An immediate-release portion, a modified-release portion, a viscosity agent, an acidifying agent, and they are separate and distinct from the other particles.

We wrote that claim to cover our product, and the Patent Office looked at it, agreed, and issued us our patent with that language.

So what did Jazz do? Jazz copied it. In 2021,

they filed a patent application with almost identical language.

Now, again, Jazz told you they filed that application in 2016, but if you pull out that patent, it's the other patent in your binder, you're going to see it has a filing date too. The filing date is March 23, 2021. After our patent issued.

And they copied our claims. I mean, if there's any question, look at it, it's almost word for word. We had some extra words. But viscosity agent, a viscosity enhancing agent, an acidifying agent, an acid wherein the suspending and viscosifying agent and the acidifying agent are separate and distinct from the immediate-release portion and the modified-release portion, that's our invention.

So Jazz came in and said we infringe this. And you probably thought that sounded pretty bad. And I get that would sound bad, but the reality of the situation is we wrote those words in the first place to describe our product. So, yes, those words describe our product because that's our invention, that's what they mean when they say we infringe.

So the question for you is not whether that's our invention; it is. The question for you is, who made that invention? Did they make that invention or did we make that invention?

And if we made that invention, they don't get a patent on it. And that means their patent trying to claim the same thing that we did is invalid.

And, again, to make that determination, Jazz is saying we didn't actually invent this in 2021, when for the first time we said that this was our invention, we had actually made that invention back in 2015.

And, again, it's going to be your job to go back and look at what they actually did back in 2015. And what you're going to see they did back in 2015 was work different and very specific kind of thing for a few weeks that didn't work very well, and they wrote about it in their patent.

Now, Jazz's '782 patent, this is the second of these patents that at issue, has some examples. And in those examples, they talked about these GHB resinate beads. This was a very specific kind of technology, not what we do, totally different than what we do, that they were experimenting with after they found out that we had been successful by reading our results from 2014.

Remember, in 2014, they saw our results, they knew that we were using microparticles. They didn't know what kind of microparticles. So they were trying to figure out what might work and they were experimenting with these resin beads.

You're going to hear what they actually did;

they did very few experiments. They didn't even get release. These wrote some examples in the patent, here's one of the examples. There's a batch of beads, they're prepared, all sorts of things happen. And then you see about four lines up from the bottom, they're administered to six beagle dogs, who have fasted and weigh a certain amount. And then blood is sampled.

None of that happened. That didn't happen. That's what they call a prophetic example. There were no beagle dogs. What they're saying is, we had the idea that we could give something to a beagle dog, and we could check their blood and we could see what happened. But they didn't actually do it, and that's why there's no results there.

It says blood is sampled, it doesn't say what the results of the sampling was. And the reason it doesn't say the results of the sampling were was because it never happened. They didn't actually come up with an invention.

So when Jazz says to you they had a hamburger and we had a cheeseburger, I would ask you to ask yourself, where is the burger? There's no product, there's no nothing.

We developed this product on our own from scratch. And it is ours.

You know what Mr. Allphin had to say about that in their own internal documents? "We got into

once-nightly" -- because, to be clear, they're still trying to do this. "We got into once-nightly only because Flamel went there first so we had to follow."

And that is true. We are the innovators.

And at the end of this case, after you've heard all of the evidence and all of the other chapters in the story, we will come back and ask you to render a verdict in our favor. Thank you very much.

THE COURT: All right. Jazz, you may call your first witness.

MR. PORTER: Your Honor, we call Mr. PJ Honerkamp.

THE COURT: Okay. Mr. Honerkamp, please take the witness stand.

MS. DURIE: Oh, Your Honor, may we invoke the rule with respect to excluding from the Court witnesses who will be witnesses in the proceeding?

THE COURT: Okay.

MR. CERRITO: We always assumed that was the rule, Your Honor.

THE COURT: All right. If there is any persons in the courtroom who will be witnesses in the proceeding, you should exit the courtroom.

MR. CERRITO: Obviously that doesn't apply to experts.

MS. DURIE: Correct.

MR. CERRITO: We agree on that at least.

THE COURT: Okay.

MR. PORTER: Your Honor, I have witness binders, may I...

THE COURT: You may approach.

MR. PORTER: Thank you, Your Honor. He was in the breakout room, Your Honor, so just...

THE COURT: We can wait for him.

PHILIP J. HONERKAMP, having been called on the part and behalf of the Plaintiff as a witness, having first affirmed to tell the truth, testified as follows:

MR. PORTER: Your Honor, we exchanged documents before, if I could ask if I could admit when necessary?

THE COURT: Yes, you may admit them.

MR. PORTER: Thank you, Your Honor.

THE COURT: Please introduce yourself to the jury, please.

MR. PORTER: Thank you, Your Honor.

Good morning, everyone. My name is Chris Porter, and I am one of the attorneys for Jazz, nice to meet you all.

May it please the Court?

THE COURT: Yes.

DIRECT EXAMINATION

BY MR. PORTER:

Q. Good morning, Mr. Honerkamp.

A. Good morning.

Q. How are you today, sir?

A. I'm fine, thank you.

Q. Would you please introduce yourself to the Court and to the jury?

A. My name is PJ Honerkamp.

Q. And Mr. Honerkamp, where do you work?

A. I work at Jazz Pharmaceuticals.

Q. And how long have you worked at Jazz Pharmaceuticals?

A. Almost 20 years.

Q. And is it okay with you if I just called it Jazz today for short?

A. Sure.

Q. Okay. Great.

What is your current title at Jazz?

A. I am the senior vice president and business unit head for the sleep business.

Q. Okay. And we'll come back and discuss Jazz in just a bit, but I'd first like to get just a little bit of background information on you, if that's okay?

A. Sure.

Q. Okay. Where do you currently live, sir?

A. I live in Menlo Park, California.

Q. **Okay. Weather is a little bit different there than it is here in Delaware?**

A. **A little bit but it's warming up today, so pretty similar.**

Q. **And do you have any kids, sir?**

A. **I do. I have three, two girls and a boy.**

Q. **Okay. And did you attend college?**

A. **I did.**

Q. **And where did you attend?**

A. **I went to Davidson College. Steph Curry made it famous. I don't think many people knew where it was before him.**

Q. **Okay. So you're the second most famous?**

A. **No. I'm a little lower than that.**

Q. **Did you earn a degree?**

A. **I did.**

Q. **Okay. And what was your degree in?**

A. **My degree was in philosophy.**

Q. **And what did you after completing your degree?**

A. **I moved to Japan and I taught English at two high schools.**

Q. **How long did you teach in Japan?**

A. **I taught there for a little over a year.**

Q. **And what did you do next?**

A. **I moved to New York and I worked as a paralegal in a**

law firm.

Q. And how long did you work at that law firm?

A. A little over a year as well.

Q. Okay. And what did you do after that?

A. So I'd always wanted to go to law school, and so I used two years to save up money and then I attended law school after that.

Q. And where did you attend law school?

A. I went to Harvard Law School.

Q. And did you graduate?

A. I did.

Q. Okay. And please tell the jury what you did next.

A. I worked for a law firm in the greater Boston area.

Q. And how long did you stay at that firm?

A. It's about four and a half years.

Q. And what did you do next?

A. And then we moved cross country with a 2-year-old to California to join Jazz.

Q. Now, before we talk about your time at Jazz, Mr. Honerkamp, can you tell the jury exactly what Jazz does as a company?

A. Sure. So Jazz is a biopharmaceutical company seeking to develop novel medicines for higher need and then bring those medicines to patients.

Q. Do you remember the year you first started working at

Jazz?

A. **Yes, 2004.**

Q. **Okay. And how many employees did Jazz have when you first started working there?**

A. **Yeah, I was the 26th employee.**

Q. **And approximately how many employees does Jazz have today?**

A. **It's over 3000 employees.**

Q. **Okay. Now, was it easy for Jazz to grow to over 3000 employees or did the company face some challenges along the way?**

A. **No. You know, I think with any business there's ups and downs. In particular during the financial crisis back in 2008, 2009, we almost had to shut down. I remember it vividly just because that's when we had our third child and we were living out in California. I used to talk with the CEO about, you know, who is going to have to shut the lights out maybe one day and shut down the business. So it was some pretty dire times at that point.**

Q. **Okay and you were all able to make it out of that?**

A. **We did, thankfully.**

Q. **Now, have you had different roles during your time at Jazz?**

A. **I have.**

Q. **Okay. And can you walk us through some of those**

roles, please?

A. So I joined the company as a lawyer. We were 26 employees, so you did a little bit of everything at that point. And I was a lawyer for -- until about 2010, 2011. And then I took over business development, helping the company identify new opportunities, and also work on the strategy. And I did that for a number of years, and then I took over my current role, which is the business unit head for the sleep business.

Q. And how long have you held this current position?

A. Almost eight years.

Q. And what is your responsibility in that role?

A. So I'm in charge of managing products that we have that serve the sleep disorders, as well as working with our research and development colleagues to identify potentially novel medicines that we could develop in the future.

Q. Let's move next and talk a little bit more about Jazz. Okay.

Now, Mr. Honerkamp, you told us generally what Jazz does as a company, so can you now tell us what type of products Jazz offers?

A. Yeah. So there's two primary areas we're focused on. The first is oncology, so drugs that treat various forms of cancer. And those are both for adults and for pediatric patients. And then we have a neuroscience business and it's

divided into two separate areas. The first focuses on seizures disorders, so epilepsies in both adults and pediatric patients, and then we have the sleep business, which I'm responsible for, and that focuses on some rare sleep disorders.

Q. Now, are you familiar with what are known as oxybates?

A. I am.

Q. Okay. And can you explain to the jurors what oxybates are, please, sir?

A. So oxybates are a class of drugs that are used to treat certain sleep disorders.

Q. Okay. And is narcolepsy one of those disorders?

A. Yes, it is.

Q. Okay. And can you explain some of the issues that patients with narcolepsy can face?

A. Absolutely. I think when most people think of narcolepsy they think about, maybe, somebody that dozes off at random times. And there certainly is an element which is that excessive daytime sleepiness, but it's not the type of sleepiness you can fix with an energy drink or a large cup of coffee.

It's a debilitating level of sleepiness and the reason for that is narcoleptics live at the border of sleep and wake. Whereas most healthy individuals have their sleep

at night and their wake during the day, narcoleptics experience sleep and wake throughout a 24-hour period. So they might sleep for 8 hours, but it's 8 hours over a 24-hour period. So it's highly, highly disrupted and they are constantly going between sleep and wake. Because of that, not only are they sleepy, but some of the things that happen to us at night happen to them during the day and vice versa.

One of the most common symptoms is something called cataplexy. And what cataplexy is, is it's the complete loss of muscle tone and it's normally brought on by, like, by a big stimuli. So if someone makes you laugh or someone makes you cry. It could be as simple as a drooping of the head or a weakness in the knees, but in its most extreme versions the person collapses to the ground and can't control any of the muscles. Your body does that when you're sleeping to prevent you from living your dreams, and this is an intrusion of that ability into the daytime. So it's highly, highly debilitating. It often occurs -- onset often occurs in adolescence and it's misdiagnosed for a long period of time. I had one patient I knew of that she said 10,000 days between when she thought she actually had symptom onset and when it was actually diagnosed.

BY MR. PORTER:

Q. Thank you, Mr. Honerkamp. Do you know on average or

in general how many times per night a person with narcolepsy can actually wake up?

A. **Yeah, so, again, their sleep is scattered over 24 hours, so in a course of a night untreated they'll be waking upwards of 80 times a night.**

Q. **And how do oxybates help patients with narcolepsy?**

A. **Yeah, so it's pretty amazing because until the oxybates came around, most of the focus was on treating that sleepiness during the day, so treating the daytime sleepiness. And it's crazy because it's a sleep disorder and so nothing was really done at night. And what the oxybates are able to do is help consolidate that sleep at night, bring together those scattered fragments over the night into a more consolidated sleep.**

Now, that doesn't get rid of this disrupted nighttime sleep. These patients are still going to wake up some in the night. It's not going from 80 to 0 with any oxybate, but it certainly consolidates and helps with that. And so by consolidating that sleep, it allows for your battery to charge more at night. And so by charging that battery more at night, that excessive daytime sleepiness that you have during the day is often reduced. And what's unique to the oxybates is they were the first treatment ever approved for the treatment of that cataplexy, that sudden muscle loss that I mentioned.

Q. **Now, Mr. Honerkamp, does Jazz sell any oxybate products in the United States?**

A. **It does.**

Q. **Can you tell the jurors what those products are?**

A. **There's two, one is called Xyrem, and the other one is called Xywav.**

Q. **Okay. And let's talk about those, starting first with Xyrem.**

MR. PORTER: And, Your Honor, I'd like to publish a demonstrative from Xyrem, no objection has been made.

THE COURT: Okay.

BY MR. PORTER:

Q. **And, Mr. Honerkamp, is this the label for Xyrem?**

A. **It is.**

Q. **And can you explain exactly what Xyrem is used for?**

A. **So Xyrem is used to treat both excessive daytime sleepiness in patients with narcolepsy, as well as cataplexy in patients with narcolepsy. There's no cure for narcolepsy currently, so these are chronic treatments. Once you start taking them, you need to take them for the rest of your life if you choose so.**

Q. **And can you explain how Xyrem actually works?**

A. **Yeah, so as I mentioned, Xyrem is a version of oxybate, so you take it once at bedtime, and then two to**

four hours later you take a second dose. As I mentioned, these are patients that have highly disrupted sleep, so I think to a healthy person the idea of waking up in the night sounds anathema, but I think for these patients the benefit they see from the drug is transformative.

Q. Why is it, Mr. Honerkamp, that a patient with narcolepsy has to take it twice per night?

A. So the active ingredient is very quickly metabolized, meaning it's in and out of your system very, very fast. So when you take it, within a very short period of time it has its effect, and then it's out of your system. So the two doses provide the coverage over the course of the entire night.

Q. How long has Xyrem been on the market?

A. So Xyrem was original approved in 2002 for the treatment of cataplexy in adult patients with narcolepsy. That was the original approval.

Q. And is government approval required for Xyrem to be on the market?

A. It is.

Q. And do you know which government agency approved Xyrem?

A. The FDA.

Q. What does that stand for?

A. The Food and Drug Administration.

Q. **You said this was back in 2002 when the FDA first approved it; is that correct?**

A. **Yes.**

Q. **Okay. Now, was Jazz the distributor of Xyrem when the FDA first approved it?**

A. **No, it was not.**

Q. **Who was the distributor then?**

A. **It was a company called Orphan Medical.**

Q. **And so how did Jazz end up becoming the distributor?**

A. **So Jazz acquired Orphan Medical in 2005.**

Q. **Okay. And when Jazz acquired Orphan in 2005, what category of patients was Xyrem approved for?**

A. **It was only approved at the time for adult patients with cataplexy.**

Q. **Okay. And did that ever expand the category of patients?**

A. **Yes. So after that, it was approved in adult patients with excessive daytime sleepiness associated with narcolepsy. And then later on, it became the first drug approved for pediatric patients in narcolepsy. There had never been a successful trial in pediatric narcolepsy, and it was eventually approved for patients as young as seven years old in both the treatment of their cataplexy, as well as their excessive daytime sleepiness.**

Q. **Okay. Now, I'd like to move next and talk for just a**

moment about Xywav.

MR. PORTER: Your Honor, if I may pull up the demonstrative of that.

THE COURT: Yes.

MR. PORTER: There's been no objection.

BY MR. PORTER:

Q. And is this the label for Xywav, Mr. Honerkamp?

A. Yes, it is.

Q. Okay. Can you explain to the jury the difference between Xyrem and Xywav, please?

A. Yes. So Xywav, one of the things about narcoleptics is they are at increased risk of cardiovascular comorbidity, so higher risks of heart disease, stroke. When you disrupt your sleep as much as a narcoleptic, it puts a strain on your cardiovascular system. When Xyrem was initially approved, it's called sodium oxybate, so it contains essentially salt. And the salt content is upwards of 1600 milligrams a night. I think of that as about four large fast food fries every night. And, you know, in talking with physicians about, you know, what they thought was a real unmet need is, you have a population that's at increased cardiovascular risk and it's an incredibly effective drug, but if you could get rid of it or reduce it, that would be great. And Xywav has 92 percent less sodium.

So in Xyrem there's a -- all high-sodium

oxybates other than Xywav carry a warning about the sodium burden. Only Xywav does not have that warning because of the reduced sodium. So we were able to conduct a clinical trial, it's a different product, and show that we can maintain the efficacy, the promise of what oxybate brought to these patients, while reducing the burden of sodium in that for those patients.

Q. Mr. Honerkamp, just I want to follow up on something. You said that it's like taking -- the equivalent of eating four french fries -- four large fries per night. Is that something that a person would do, maybe, for a few months or for a couple of years or for longer than that?

A. Yeah, it's -- it's a chronic medication. There's no cure. So if you're on oxybate -- and we have patients that were in those original Xyrem clinical trials that have been on the drug for 22, 23 years. And so it's a lifetime choice you're making when you choose this therapy.

Q. Okay. And how often do patients use Xywav per night?

A. It's the same. It's twice per night.

Q. Okay. Now, was it a quick process to develop the lower-sodium Xywav, or did it take time?

A. No, it took a number of years, because when you take something out, you have to put something back in. So when you take the sodium out, you have to put other things in, and what you don't want to do is you don't want to put

something in that's going to create a new problem for the patient. So if you took all the sodium out and made it all potassium, that would be a problem for some patients, or if you put all magnesium in and -- for the -- same thing. And so you had to do this mix.

And what we found also is as you took the sodium out, the way the product worked was a little different, so finding the right mix of -- of -- a right recipe for it that would maintain the efficacy and not create any new safety problems because you are taking away a safety problem, that took a lot of time.

Q. And did Xywav have to go through the FDA approval process as well?

A. It did.

Q. Okay. And do you know when Xywav was approved?

A. It was approved in 2020.

Q. Okay. And is Xywav approved for anything other than narcolepsy?

A. It is. It's actually the first and only drug approved for another rare sleep condition called idiopathic hypersomnia.

Q. And what is that?

A. So we talked about a narcoleptic having, like, this highly disrupted sleep. Idiopathic hypersomnia patients, they can sleep for 15 to 16 hours sometimes. And so

sleeping is not a problem; the problem is getting up. And also their sleep doesn't make them feel any better. So when a narcoleptic wakes up and is tired, they can take a nap and they feel a little bit better. Idiopathic hypersomnia patients dread their naps because they go to sleep and they don't feel any better after it. They have really hard times getting up.

I know one student at MIT, his last alarm was a water gun that would shoot him because that was the only way he got up. I've seen other patients that have 30 alarms on their phones. I know other patients whose friends have to call them if they don't wake up by a certain time. There was never a drug approved for it until Xywav.

Q. And upon FDA approval, did Jazz start marketing Xywav?

A. It did.

Q. Okay. Now, Mr. Honerkamp, does Jazz currently sell a once-nightly product for narcolepsy?

A. It does not.

Q. And why is that?

A. We prioritized the low-sodium benefit because all narcoleptics are at increased cardiovascular risk and felt that reducing the sodium was the -- was what we thought was most important. Xyrem had been on the market as a twice-nightly medication for a long period of time, and

people may have expressed concern with taking it twice a night before they took it, but once they took it, they felt very comfortable with it, as we have -- obviously as a company, we have narcoleptics who now work for us because they believe in the mission. And one patient who was in the original Xyrem clinical trial once told me that once-nightly is a concept dreamt of by non-narcoleptics, because they're still getting disrupted sleep in the night.

Q. Now, are you familiar with a product called Lumryz?

A. I am.

Q. Okay. Let's move next and talk about that. Mr. Honerkamp, what is Lumryz?

A. It is a once-at-bedtime version of sodium oxybate sold by Avadel Pharmaceuticals.

Q. Okay. And what is it used for?

A. It's approved for the treatment of cataplexy and excessive daytime sleepiness only in adult patients with narcolepsy.

Q. And how often do patients use it at bedtime?

A. They take it once at bedtime.

Q. Okay. And are you familiar with the sodium content of Lumryz?

A. Yes, it's a high-sodium oxybate, around the same sodium content as Xyrem.

Q. Okay. But Xywav has substantially less sodium than

both Xyrem and Lumryz; is that correct?

A. **It's why it's the only oxybate without the sodium warning in the label.**

Q. **Okay. So just to be clear, Lumryz also has a warning for its sodium content on the label; is that correct?**

A. **It's the exact same warning as Xyrem has.**

Q. **Okay. Now, is Lumryz approved, to your knowledge, for pediatric use?**

A. **It is not.**

Q. **Do you -- again, which drugs -- or which drugs are approved for pediatric use for pediatric narcolepsy patients?**

A. **Both Xyrem and Xywav are both approved for pediatric patients.**

Q. **Okay. Now, do you know how long that -- Lumryz has been on the market?**

A. **Since -- since last year, in 2023.**

Q. **Okay. And in your position, sir, do you monitor Avadel and the products that it puts on the market?**

A. **Absolutely.**

Q. **Okay. Can you explain to the jury why you do that?**

A. **Just as sports teams scout their competition, if you're in a therapeutic space, whether it's our oncology/cancer products or in our neuroscience products, you're always wanting to understand what's going on in your**

therapeutic area.

Q. And do you know if other pharmaceutical companies monitor each other and each other's products?

A. I think everyone does.

Q. Okay. Now, do you know, sir, whether Avadel received FDA approval for its Lumryz product?

A. It did.

Q. Okay.

MR. PORTER: And, Your Honor, I would like to move to admit PTX1966 into evidence.

THE COURT: Any objection?

MR. BRAUSA: No objection.

THE COURT: PTX1966 is admitted.

(Exhibit admitted.)

MR. PORTER: Thank you, Your Honor.

BY MR. PORTER:

Q. And, Mr. Honerkamp, you have it in your notebook, but you can also see it on the screen.

Are you familiar with this document?

A. I am.

Q. Can you please tell the jury what it is?

A. It was the public press release Avadel put out when they received FDA approval for Lumryz.

Q. Okay. And what is the date of this document?

A. May 1st, 2023.

Q. **Okay. And did Avadel ultimately introduce Lumryz into the market?**

A. **Yes.**

Q. **Okay.**

MR. PORTER: And, Your Honor, I would now like to admit PTX1977 into evidence.

MR. BRAUSA: No objection.

THE COURT: PTX1977 is admitted.

(Exhibit admitted.)

MR. PORTER: Thank you.

BY MR. PORTER:

Q. **And that's in your notebook, as well, Mr. Honerkamp, or you can look on the screen.**

Mr. Honerkamp, have you seen this document before?

A. **I have.**

Q. **Can you please tell the jury what it is?**

A. **It's the public announcement from Avadel of their commercial launch of Lumryz.**

Q. **Okay. And what is the date of this document?**

A. **June 5th, 2023.**

Q. **Okay. So about a month after the approval?**

A. **Yes.**

Q. **Okay. Now, Mr. Honerkamp, back when Lumryz was still in development, did Jazz and Avadel ever talk about**

potentially working together on Lumryz?
A. They did.
Q. Okay. And approximately when did this occur?
A. It was around 2018.
Q. Okay. And what is your understanding of why the parties considered working together on Lumryz?
A. You know, the sleep space is rather small. We had a lot of experience in oxybate. At that time Avadel was struggling in their clinical trials. It was going on much longer than they had ever anticipated, and it had put -- it had been a challenge. And so there was a potential of taking what they were doing and potentially partnering with us, given that we had a lot of experience in clinical trials and a lot of expertise in the area.
Q. Now, internally at Jazz, did the potential collaboration between Jazz and Avadel on Lumryz have a nickname?
A. It did.
Q. Okay. And what was it?
A. It was called Project Zeta. We're a public company and Avadel at the time was a public company as well, and so you always need to protect from stuff like insider trading, so you have to give a name to any potential business interaction between two public companies.
Q. Okay. And did Project Zeta ultimately result in Jazz

and Avadel working together on Lumryz?

A. **No, it did not.**

Q. **And why is that?**

A. **So the first step in potentially there being an -- a transaction or an agreement is coming to agreement on terms. It's called a term sheet. It's kind of like the first quarter of a football game. And it just never got past that point.**

Q. **Okay. Now, I'd like to go back to the FDA approval that Avadel sought for Lumryz for just a moment.**

In seeking that approval from the FDA, do you know if any of Jazz's information assisted Avadel?

A. **It did.**

Q. **Okay. Let's discuss that next.**

Now, Mr. Honerkamp, in your experience, are you familiar with a new drug application, or an NDA?

A. **I am.**

Q. **Okay. Can you explain to the jurors what that is, please?**

A. **So a new drug application, or an NDA, is the FDA's recipe that you need to follow if you want to get a drug approved. It lays out the specific conditions that are required, the information required to be provided so that they can make a determination whether the drug is both safe and effective.**

Q. **Do you know, sir, whether Avadel submitted an NDA for its drug Lumryz?**

A. **I do.**

MR. PORTER: Your Honor, I would now like to move to admit PTX2009 into evidence.

MR. BRAUSA: No objection.

THE COURT: All right. PTX2009 is admitted.

(Exhibit admitted.)

BY MR. PORTER:

Q. **Mr. Honerkamp, are you familiar with this document? Have you seen it before?**

A. **I have.**

Q. **Okay. Can you tell the jury what this is, please?**

A. **It's the public announcement by Avadel of the submission of their NDA.**

Q. **Okay. Now, we see FT-218. Do you see that?**

A. **I do.**

Q. **What is FT-218?**

A. **You know, often a product before -- a product candidate before it's approved has a -- a name that the company gives it. It only has the formal name once it's approved, and so FT-218 was the internal name that Avadel and Flamel before then used for the development project that was Lumryz.**

Q. **Okay. So when we see FT-218, or FT-218, that just**

means Lumryz?

A. Yes.

Q. And what is the date of this document?

A. December 16th, 2020.

Q. Okay. And, sir, do you know what kind of NDA Avadel submitted to the FDA for approval for Lumryz?

A. Yes, it was a 505(b)(2) application.

Q. Okay. And based on your experience, what is a 505(b)(2) NDA?

MR. BRAUSA: Objection, Your Honor. This calls for expert testimony on FDA regulatory procedures.

MR. PORTER: And, Your Honor, no, it does not. He has over 20 years of experience in the pharmaceutical industry. We just established that. This is in his personal knowledge, and a fact witness is allowed to give testimony based upon his or her experience, and so --

THE COURT: It's general knowledge, his background, so I'll allow it.

MR. PORTER: Thank you, Your Honor.

BY MR. PORTER:

Q. I'll ask again. Mr. Honerkamp, based on your experience in the pharmaceutical industry, what is a 505(b)(2) NDA?

A. So once a product is approved with a certain, like, active ingredient, in the future, other companies that want

to develop a similar drug using the same active ingredient can skip a few steps by relying on what the innovator company did in their application rather than having to do all of the same work, which accelerates both the time and the cost.

Q. And do you know what a reference listed drug is?

A. Yes. So in that 505(b)(2) application, you have to reference the drug that you're relying on and the data that you're relying on from that drug.

Q. Okay. And here, do you know what reference listed drug Avadel used in submitting its 505(b)(2) NDA for Lumryz?

A. Yes, it was Xyrem, sodium oxybate.

Q. Okay. So to be clear for the jury, Avadel replied on Xyrem in submitting its new drug application for FDA approval; is that correct?

A. It did.

Q. Okay. And in your experience, sir, is there any benefit that a company sees in being able to submit a 505(b)(2) application?

A. It reduces the time and cost to develop the drug.

Q. Okay. Now, while we're on the subject of the FDA, are you familiar with a concept called clinical superiority?

A. I am.

Q. And can you explain that concept to the jury, please?

A. So, again, going back to, like, when there's a drug

on the market and new versions of that drug, that active drug are being developed, the FDA, in approving the new drugs, can determine whether or not they have any benefit over the existing drugs. And that's clinical superiority.

And there's really two main criteria or buckets for that. The first is called clinical superiority based on efficacy. So you have a drug that actually works better on the disease than the drug before it. Then there's clinical superiority based on safety. Your drug has a safety benefit relative to the drug that came before it.

And then there's a third smaller bucket called major contribution to patient care. And that -- the drug is not more efficacious or more safe but it has some perceived benefit that the FDA wants to recognize.

Q. And do you know, sir, whether or not the FDA came out with guidance on clinical superiority as it relates to Xyrem, Xywav, and Lumryz?

A. I am.

Q. Okay. And do you know, sir, whether the FDA found that Lumryz is safer than Xyrem or Xywav?

A. It did not.

Q. And do you know whether the FDA found that Lumryz is more effective than Xyrem or Xywav?

A. It did not.

Q. Okay. Let's move next to talk about ways in which

companies can protect their products.

So, Mr. Honerkamp, based on your general business experience in the pharmaceutical industry, do you have a general understanding of what a patent is?

A. I do.

Q. Okay. Can you explain to the jurors your understanding of a patent?

A. So whether you work in tech or biotech, you're doing lots of research and development, things fail, things work. As part of those experiments, sometimes you discover something novel. And in certain cases, it's something that you think is meaningful enough that you can apply to the federal government in their Patent Office and seek a patent on.

And then the government has to, you know, determine whether that's true, whether it is novel, whether there was something that came before it that had already discovered that.

And at the end, if the government decides that what you have done is novel, they can give you a patent. And in our industry, that confers certain rights, it's kind of like having a -- you know, some property, right. And then knowing that you've been given that right from the government, it helps give the company confidence that it can make additional investments around that discovery and

protect that right.

Q. Now, Mr. Honerkamp, if we wanted to get into greater detail over patents, particularly for the patents at issue here, would it be best for us to speak with other individuals who may be more familiar with patents; is that fair?

A. Yeah, I don't think the philosophy major is the best person for that.

Q. Fair enough.

Okay. So we're not going to get into great detail here, but at a high level, in your experience, are patents important to Jazz?

A. Yes. They recognize the value of the discoveries we've made over time.

Q. Okay. And are you familiar, sir, with the concept of companies licensing their patents?

A. Sure.

Q. And can you explain that to the jury, please?

A. You know, different companies have different strengths, and often a company will only want to, you know, be devoted to certain areas of the development process. And so they might make discoveries, but they don't want to bring those discoveries to market, so they look for a partner that has that capability. And so they'll license their technology to the company they believe can take that product

to market.

That -- that's a common circumstance.

Q. And do you know, sir, if Jazz licenses its patents to others?

A. No. So we like to do the discovery -- I mean, I think it is part of Jazz's sort of founding vision is we didn't just want to discover drugs or just bring the drugs to market, we wanted to do all aspects of development. And so we really focus on -- on developing to the full potential our discoveries.

Q. Okay. And there may be some one-off situations where licenses occur. But as a general of thumb, you don't license; is that fair?

A. That's fair.

Q. Okay. And at a high level, sir, do you know the patents that are issued in this dispute?

A. I do.

Q. Okay. And was Jazz interested in licensing those patents to Avadel?

A. It was not.

Q. And why is that?

A. Because that's not our business. You know, we're constantly prioritizing, we make discoveries all the time. We have to decide, you know, how and when we want to -- to move forward with those. And just because we don't move

forward on one company's timeline doesn't mean that we don't think they're valuable in the long-term and that we might use them in the future.

Q. Okay. And at the end of the day, Mr. Honerkamp, what is it that Jazz is looking for here in this trial?

A. Yeah, we've been in the space a long time and we've spent a lot of time trying to seek to understand how oxybate works, and in that process have made some novel discoveries, and one of those discoveries relates to an extend -- you know, extended release versions of this drug that, you know, we think are valuable and that the government recognized, and we're just asking for a recognition and a fair share of a royalty based on that.

MR. PORTER: Thank you, Mr. Honerkamp.

Pass the witness.

THE COURT: All right. Before we have the cross, we're going to give the jury the morning break.

So take the jury out for the morning break.

(Whereupon, the jury left the courtroom.)

THE COURT: All right. Mr. Honerkamp, you may step down from the witness stand. You are still under examination, so you can't talk to counsel while you're under examination.

THE WITNESS: Yes, Your Honor.

THE COURT: All right. So let me see counsel at

sidebar. I want to talk about JTX0031.

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

THE COURT: All right. So with respect to JTX0031, I'm going to overrule the objection. Jazz can use it; it's going to come into evidence. I'm admitting it both, I think, it is admissible under 801(d)(2)(d), it's made within the scope of the relationship and while it existed.

I also find it's admissible under rule 807; it's a statement that's supported by sufficient guarantees of trustworthiness after considering the totality of the circumstances under which it's made.

All right.

ALL COUNSEL: Thank you, Your Honor.

(Whereupon, the discussion held at sidebar concluded.)

THE COURT: Come back at 11:50 a.m.

(Recess taken.)

MR. SILVER: Your Honor, before we bring the jury in, can I raise one issue?

THE COURT: Does it need to be --

MR. SILVER: Either without the jury here or if we go to sidebar.

THE COURT: Is it something that's going to be

relevant to the cross-examination?

MR. SILVER: To the cross-examination.

THE COURT: All right. Let's do it now.

MR. SILVER: Okay. So as Your Honor recalls from the motions in limine, one of the things that Jazz sought to exclude from presentation of trial is the fact that they are seeking a permanent injunction. They just opened the door, as Your Honor warned them in the opinion, by asking Mr. Honerkamp what Jazz is seeking in this case.

And he said, I quote, "We were just seeking recognition and a fair share of our royalty based on that." So they opened the door to allowing us to introduce the fact that they are pursuing an injunction in this case. They didn't have to ask that question. They did, the door is now open.

MR. PORTER: Your Honor, the issue is not coming in this trial regarding the injunction as we understood it because of the Court's motion in limine. So that answer was completely consistent. That's what we're talking about.

THE COURT: He didn't mention injunction in his answer.

MR. PORTER: He did not.

MR. SILVER: No, but that's the point, Your Honor. They presented to the jury that they are just here for their fair share and that's all they want. But in

reality, they are trying to take us off the market. It's misleading, it's incomplete, and they've opened the door.

MR. PORTER: Your Honor, we did not open the door. He answered the question honestly with what is at issue in this trial, which is what -- the juries is going to hear.

THE COURT: Right. I don't believe he's opened the door. To go beyond that, because that -- the damages is what's before this Court, and he testified as to damages. I assume that they've instructed their witnesses that, you know, injunctive relief is not something that's at issue, and that's why he answered that question, he stuck to what's at issue. So I don't think the question and his answer opened that door.

MR. SILVER: May I address that briefly, Your Honor?

THE COURT: Yes.

MR. SILVER: So it's an entirely gratuitous, unnecessary question, because they have a damages expert who is going to come to trial and present what their theory of damages is and their quantum of damages. And so there's no need to ask a Jazz witness on the stand, What are you seeking in this case?" And have him say, Oh, you know, we're good people. We just want our fair share of the royalty, because that's not true. And they opened the door

by asking the questioning unnecessarily.

THE COURT: I don't agree with you. I don't agree with you on that, so... I don't believe that opens the door. If something else later opens the door, you can re-raise it, but I don't think that interplay opened the door.

MR. SILVER: Thank you, Your Honor.

MR. PORTER: Thank you, Your Honor.

MS. DAVIS: Your Honor, permission to approach with the binders?

THE COURT: Yes.

(Whereupon, the jury entered the room.)

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

All right. Introduce yourself to the jury and you can begin.

MR. BRAUSA: My name is Adam Brausa, and I'm an attorney for Avadel.

CROSS-EXAMINATION

BY MR. BRAUSA:

Q. Welcome back, Mr. Honerkamp. I just have a few questions. Hopefully we can agree on them.

When we broke, you were talking about discoveries and Jazz discoveries, correct?

A. Yes.

Q. **Jazz didn't discover sodium oxybate, right?**

A. **It did not.**

Q. **Jazz didn't invent sodium oxybate?**

A. **No.**

Q. **It's an old drug, correct?**

A. **As a drug, it was only approved in 2002, but, yes, it's been around for a while.**

Q. **Right. The chemical compound sodium oxybate has been around since the '60s, right?**

A. **That sounds right.**

Q. **And Jazz didn't develop the formula that was approved in 2002, did it?**

A. **It did not.**

Q. **That was done by Orphan Medical?**

A. **Yes.**

Q. **And Jazz acquired Orphan Medical and the Xyrem product in 2005, correct?**

A. **It did.**

Q. **You were actually one of the lawyers that worked on that corporate acquisition, correct?**

A. **I was.**

Q. **How much did Jazz pay for Orphan Medical and Xyrem?**

A. **I want to say it was between 125 and $150 million.**

Q. **And that was in 2005, correct?**

A. **Yes.**

Q. **And from your testimony, it sounds like you're pretty familiar with the FDA, correct?**

A. **I am.**

Q. **And it's the government body that regulates new drugs and determines if they are safe and effective for human consumption, right?**

A. **Yes.**

Q. **You have to have FDA approval if you're going to sell a drug in the United States, correct?**

A. **That's correct.**

Q. **And in May 2023, as we saw, the FDA approved Avadel's product Lumryz, correct?**

A. **Yes.**

Q. **And in doing so, the FDA concluded that Lumryz is clinically superior to both Xyrem and Xywav, correct?**

A. **Yes, on the basis of major contribution to patient care.**

Q. **Right. It concluded that Lumryz provides a major contribution to patient care over Xyrem and Xywav, correct?**

A. **Yes.**

Q. **Can you turn to JTX112 in your binder.**

A. **It's this big binder, right?**

Q. **The tabs are on the right. They have the JTX and DTX numbers.**

A. **Sorry, can you just say it one more time?**

Q. **Sure. It's JTX112.**

A. **Oh. Got it.**

Q. **You've seen this document before, right, Mr. Honerkamp?**

A. **I'm just looking at it.**

Q. **Sure. This is a March 1, 2023, letter from the FDA, right, Mr. Honerkamp?**

A. **Yeah, it's from the FDA.**

Q. **And it's addressed to Jazz's representatives, on page 2 of the document, correct?**

A. **Yes.**

Q. **Okay. And this is a letter that FDA sent Jazz's representatives outlining its decision on Orphan drug exclusivity with respect to Lumryz, correct?**

A. **I'm not sure of the scope of the letter, it's just.**

Q. **You've seen this letter before though in your role as the head of the sleep business at Jazz, correct?**

A. **I'm trying to think if I've seen the whole letter.**

Q. **Why don't we just turn to page 28 -- or, rather, let's just start at page 3 of the letter, JTX112.3.**

Are you there, Mr. Honerkamp?

A. **Page 3 of the letter, right?**

Q. **Correct. The lower right hand corner, JTX.3.**

A. **Oh.**

Q. **And in the second paragraph down, the FDA states --**

MR. PORTER: Your Honor, I'm going to object. This isn't in evidence yet, so I don't know if he's asking to refresh his recollection, if he's seen it, that's fine, but if he is going to start reading from it, I think he needs to introduce it into evidence.

THE COURT: Well, this is cross-examination, so he doesn't have to admit it into evidence.

MR. PORTER: Right, but now he's reading from the letter.

THE COURT: Okay. So let me -- let's -- he's asking about the document, so I assume that he is going to follow what he was reading with a question.

MR. PORTER: Okay.

BY MR. BRAUSA:

Q. **And in this page of the letter, JTX112.3, the FDA lays out its position that Lumryz is clinically superior to every previously approved oxybate drug for the treatment of narcolepsy, i.e., both Xyrem and Xywav, correct?**

A. **I'm just reading. It says it's eligible for its own term.**

Q. **Okay.**

A. **Because it's clinically superior to both.**

Q. **Right. And the FDA goes on to say that it's clinically superior to every previously approved oxybate drug for the treatment of narcolepsy, including Xyrem and**

Xywav, right?

A. **It says -- I'm sorry, this is a dense paragraph of regulatory legalese. It's -- may be eligible for its own term, it's superior to every such -- I mean, there's a sentence about that. Again, I haven't read this whole document so I see the words you're talking about, yes.**

Q. **Okay. And this regulatory legalese is from the FDA that you're familiar with, correct?**

A. **Yes.**

Q. **Okay. Why don't we try PTX1966 instead that you talked about during your direct examination. It's in evidence.**

MR. BRAUSA: Mr. Jared, if you could pull up PTX1966. And if we could blow up the paragraph that says "With this approval, the FDA has found Lumryz to be clinically superior to currently marketed twice-nightly oxybate products and granted Lumryz seven years of working drug exclusivity."

BY MR. BRAUSA:

Q. **You are familiar with this document, right, Mr. Honerkamp?**

A. **I am.**

Q. **Okay. And then it goes on to say, "in particular, FDA found that Lumryz makes a major contribution to patient care over currently available, twice-nightly oxybate**

products..."; correct?

A. Major contribution because it avoids the nocturnal arousal. It doesn't say it's safer or more effective than the others.

Q. Right. It says, "It provides a major contribution to patient care by providing a once-nightly dosing regimen that avoids nocturnal arousal to take a second dose." I read that correctly; right?

A. I read that as saying that they think that there's a benefit to some patients that not having to take the second dose is important. So, yes, I agree with you.

Q. Understood. And I think you told the jury you have a degree in philosophy, right?

A. I do.

Q. You're not a medical doctor?

A. I am not.

MR. BRAUSA: Why don't we turn to 12, Mr. Jared, or rather 11, Mr. Jared.

BY MR. BRAUSA:

Q. Now, Jazz doesn't have its own FDA-approved products for once-nightly dosing for the treatment of narcolepsy, correct?

A. It does not.

Q. And Jazz doesn't use the patents that are at issue in this case for Xyrem or Xywav, correct?

A. **Not at this time.**

Q. **Okay. And, in fact, Jazz doesn't use the patents in this case for any of its FDA products that we heard about in opening, correct?**

A. **Again, not at this time, no.**

Q. **Okay. Jazz first learned that Avadel was developing a once-nightly product in about March 2014?**

A. **That sounds about right, yes.**

Q. **Could you turn to DTX317 in your binder, please, Mr. Honerkamp.**

A. **JTX did you say?**

Q. **DTX?**

A. **DTX.**

Q. **And this is an e-mail from you dated March 19, 2014, correct?**

A. **Yes.**

MR. BRAUSA: We move to admit this into evidence, Your Honor.

MR. PORTER: No objection, Your Honor.

THE COURT: DTX317 is admitted.

(Exhibit admitted.)

MR. BRAUSA: Permission to publish, Your Honor?

THE COURT: You may.

MR. BRAUSA: Mr. Jared, if you could pull up 12.

BY MR. BRAUSA:

Q. **In this e-mail you wrote on March 2014, you report that as part of Jazz's ongoing monitoring of treatments for narcolepsy it's become aware of Flamel Technologies and their development of a once-nightly version of sodium oxybate, correct?**

A. **Yes.**

Q. **And as we heard, Flamel is the same thing as Avadel, correct?**

A. **It is.**

Q. **And then you go on to say in the next paragraph that you've also conducted an IP search to look for any Flamel patents related to sodium oxybate, right?**

A. **Yes.**

Q. **And that Jazz was going to continue to work on monitoring to see what additional information it could gather, right?**

A. **Yes.**

Q. **And just to be clear, I think you testified, there's nothing wrong with looking at another company's publicly available information, correct?**

A. **Not at all.**

Q. **And Jazz continued its monitoring over the years, correct?**

A. **Yes.**

Q. **Legal would monitor the patents Avadel was**

publishing?

A. **Yes.**

Q. **And Jazz employees would go to medical meetings and obtain information about Avadel's development of a once-nightly formulation?**

A. **Just like Avadel took pictures of our booths at sleep conferences, yes.**

Q. **Okay, Jazz did the same thing?**

A. **Yes.**

Q. **Are you familiar with a woman named Dr. Diane Guinta?**

A. **Yes.**

Q. **Dr. Guinta was Jazz's vice president of clinical research and development at the time this e-mail was sent, right?**

A. **That's correct.**

Q. **Okay. And when she heard about Flamel's product candidate, she said "Well, if this is true, they have made what we would have wanted," right?**

A. **I don't know. At this point, it was -- like, again, it was very early on in what we knew, so I don't know what she was basing that on.**

Q. **So my question is: When she heard about that, Dr. Guinta said, well, if this is true, they have made what we would have wanted, right, in 2014?**

MR. PORTER: Your Honor, I'm going to object as hearsay.

THE COURT: Again, no, because it's a question from an employee of Jazz. So it's not hearsay. It wasn't by a party opponent.

THE WITNESS: I don't know if Dr. Guinta said it. Obviously, some people at Jazz, when they heard there was a once-nightly formulation, were interested in that. She may have said it, I just don't recollect her specifically saying that.

BY MR. BRAUSA:

Q. **Would looking at an e-mail from May 2014 refresh your recollection?**

A. **It would.**

Q. **Okay. Can you turn to tab A in your binder. And read that silently to yourself and let me know when you're finished.**

A. **I'm done reading it.**

Q. **Does that refresh your recollection as to Dr. Guinta's reaction?**

A. **Yeah, she was reacting to an external report sort of summarizing what it might be, and she made a comment that if it was what they said it was that would be very interesting. And then I said, I mean, and then I responded to her that you needed to see the data, I'm not -- it was just too**

speculative to believe, to know what it was.

Q. Right. The data is important to know what somebody has done, correct?

A. Yes, of course.

Q. And just to clarify, Dr. Guinta's actual comments were "Well, if this is true, they have made what we would have wanted," correct? That's what she said?

A. Yes.

Q. And by April 10, 2014, a few days later, you were aware that Flamel was pursuing microbeads and sachets, right?

A. I don't know if I knew the formulation at that time, I think it was still very general.

Q. Okay. Would looking at an e-mail from you on April 10, 2014, refresh your recollection?

A. Yes, it would.

Q. Could you turn to tab B in your binder, please, Mr. Honerkamp. And read that silently to yourself.

A. Okay.

Q. Does that refresh your recollection?

A. Yes.

Q. So in April 2014 you were aware that Flamel was pursuing sachet delivery of microbeads, right?

A. Based on reports I'm responding to, it looks like an analyst from an investment bank, yes.

Q. **After you learned about that, you asked Mr. Allphin and his colleague Mr. DesJardin if Jazz wanted to, it could produce a prototype based on what we know about the technology, correct?**

A. **Yes.**

Q. **We heard in opening about Jazz's Xywav product and you provided some testimony on Xywav. It has lower sodium than Xyrem, correct?**

A. **And Lumryz, yes.**

Q. **Correct. And it was approved by the FDA in 2020?**

A. **It was.**

Q. **What type of NDA was used as part of the Xywav submission?**

A. **I believe since it was our product, it was called the 505(b)(1).**

Q. **And so that application relied on the data that had been submitted for Xyrem?**

A. **It did.**

Q. **Okay. And Xyrem was developed by Orphan Medical, not Jazz, right?**

A. **Well, no, not completely, because, remember, when we acquired it, it was only approved for adults in patients with cataplexy associated with narcolepsy. And so since then, we had done the first and only Phase III trial in pediatrics. Our approval for Xywav includes pediatrics, so**

it didn't just reference the work done by Orphan, but the subsequent work that led to the adult approval in excessive daytime sleepiness of patients with narcolepsy and then as well as the pediatric work, so it referenced that as well.

Q. The original formulation of Xyrem was developed by Orphan Medical, correct?

A. It was.

Q. And the formulation of Xyrem hasn't changed any over time, has it?

A. Not in any meaningful way.

Q. Not in any meaningful way, correct?

A. Yeah, I can't think if there's, like, an excipient or something that's not active that we've changed, so I'm just trying to be as truthful as possible.

Q. Sure, I appreciate that.

Now, when Xywav was approved in 2020, Jazz didn't stop selling high-sodium Xyrem, did it?

A. No, it did not.

Q. Jazz doesn't think high-sodium Xyrem is unsafe, does it?

A. Jazz believes that all patients should be on a low-sodium oxybate, but Jazz also recognizes that there are some patients that have been on Xyrem for 20 years, and it's not the position of the company to force that decision. What we want to have happen is we want to educate physicians

and patients on the benefit and we want them to come to it, but we're not going to take away their medicine.

Q. Right. Jazz doesn't have any plans to stop selling Xyrem, correct?

A. Not at this time.

Q. Jazz has also authorized several generics of Xyrem?

A. It has.

Q. And these generic versions of Xyrem also have high sodium?

A. They do.

Q. Jazz makes money from the sale of these authorized Xyrem generics, correct?

A. It does.

Q. And Jazz hasn't told any of these generic companies that they should stop selling this high-sodium Xyrem?

A. We're not in the business of pulling drugs that are effective from the market. Like I said, Xyrem was the only drug approved for 20 years, and so there's patients that this changed their life. And I would like them all to be on low-sodium oxybate because I think they would all benefit from it, but I want them to make that decision with their physician, not -- not Jazz.

Q. Right. And you're not a physician, correct?

A. Absolutely not.

Q. Okay. Could you turn to PTX614 in your binder,

please. This is Jazz's 10-K submitted to the Securities and Exchange Commission at the end of 2022, correct?

A. Just looking for the date. I'm a little rusty on the legal stuff sometimes now.

Sorry. Just bear with me.

Q. I believe it's on the cover page, if you're looking for the date, Mr. Honerkamp.

A. Oh, thank you. Yes.

Q. And these are filings that Jazz is required to make in which it reports its financial performance to the government, right?

A. Yes.

Q. Okay. Could you turn to PTX.614.81? So, again, it's the number in the lower right-hand corner of the document.

A. I'm there.

Q. And there's a table in which Jazz reports the revenues it's earned from the sales of Xyrem for 2020, 2021, and 2022, right?

A. Yes.

Q. And in 2020, Jazz made $1.74 billion from the sales of high-sodium Xyrem, correct?

A. It did.

Q. And in 2021, Jazz made $1.265 billion from the sales of high-sodium Xyrem, correct?

A. Yes.

Q. **And in 2022, Jazz still made over $1 billion from the sales of sodium -- or high-sodium Xyrem, two and a half years after Xywav had been approved, correct?**

A. **Yes, because, again, going back to my point, it was important to note --**

Q. **I'm just asking you a question, Mr. Honerkamp.**

A. **Yeah.**

Q. **The revenue for Jazz in 2022 from the sales of high-sodium Xyrem was over $1 billion, correct?**

A. **It was.**

Q. **And you're the head of Jazz's business unit, correct?**

A. **Yes.**

Q. **Thank you.**

MR. BRAUSA: Pass the witness.

THE COURT: All right. Redirect?

MR. PORTER: Yes, briefly, Your Honor.

REDIRECT EXAMINATION

BY MR. PORTER:

Q. **Mr. Honerkamp, hello again.**

A. **Hi.**

Q. **Good afternoon now.**

Before you were cut off by the lawyer for Avadel, you were going to answer a question. I wanted to give you an opportunity to finish.

A. **Yeah, so I do believe every patient should be on**

Xywav, but Xyrem had been around for 20 years and it did change people's lives. And so it was important to us that when Xywav was approved, if a Xyrem patient came to get a refill the next day, they wouldn't notice any difference, that they wouldn't be paying any more or anything would be different in that experience because we wanted them to come to it. So, you know, there are companies that had -- would pull the old drug from the market and force them onto the new one, and that's not what we wanted to do.

We believe that it's the best oxybate, and so a significant amount of the business was still in Xyrem. And, you know, as long as people are taking Xyrem, we're trying to make that available to them so that they can make that decision.

Q. **Thank you.**

Mr. Honerkamp, you still have open the 10-K that Jazz's lawyer went over with you?

A. **I do.**

Q. **Okay. And do you see where he talked -- he started you at 2020 and said that Jazz made $1.7 billion from Xyrem, do you...**

A. **I do.**

Q. **Okay. He did not ask you about how much money Jazz made from Xywav over the three-year term, did he?**

A. **He did not.**

Q. **Okay. Let's look at that for just a second. So in 2020, as noted, it was $1.7 billion for Xyrem, correct?**

A. **It was.**

Q. **And then looks like $15 million for Xywav?**

A. **Yes.**

Q. **Okay. And Xywav was recently introduced to the market at that time?**

A. **At -- in November of 2020, it was made available.**

Q. **Great. Okay.**

So then 2021, the first full year that Xywav was on the market, it's $1.2 billion for Xyrem; is that right?

A. **Yes.**

Q. **And $535 million for Xywav; is that right?**

A. **Yes.**

Q. **Okay. So what we're seeing is we're making less money from Xyrem; is that -- from 2020 to 2021; is that right?**

A. **Yes.**

Q. **And an in- -- a substantial increase in Xywav; is that right?**

A. **Yes.**

Q. **Okay. And then for 2022, again, we're seeing even less from Xyrem, just -- just over a billion; is that right?**

A. **Yes.**

Q. **But for Xywav, $958 million; is that right?**

A. **That's correct.**

Q. **Okay. So for -- over the three-year span, we go from $15 million to $958 million for Xywav, correct?**

A. **Yes.**

Q. **Now, Mr. Honerkamp, is that consistent with your position that you want to educate to get patients to switch from the high-sodium to the low-sodium?**

A. **Yes.**

Q. **Okay. And, again, he didn't ask you about that trend, did he?**

A. **No, he did not.**

Q. **Okay. Now, does Jazz have a sleep sales force?**

A. **It does.**

Q. **And how many people, approximately, does it have?**

A. **Approximately 80 representatives.**

Q. **Okay. And do any of those people in the sales force market Xyrem?**

A. **No, they do not.**

Q. **Okay. And, again, that's consistent with the educating people that you -- Jazz wants folks to move to the lower sodium?**

A. **Yes.**

Q. **But that's a decision that we leave to the patients to make with their -- with their healthcare providers; is that right?**

A. **Yes.**

Q. **Okay.**

A. **We still support them at the pharmacy and a coupon program so that they can continue to get their drug as they got it previously.**

Q. **Okay. And last question: Jazz is -- are Xyrem and Xywav the only two drugs that Jazz puts out?**

A. **No.**

Q. **Okay. And I think that for Lumryz, is that -- to your knowledge, is that the only drug that Avadel has?**

A. **Yes.**

Q. **So are you -- so for -- at Jazz, are you using resources in -- on a number of -- in a number of different areas?**

A. **Yeah, I mean, a good example is we have seven marketed products. I mentioned that we have an oncology business, and we started that business in 2012. And the first product we have was used in pediatric leukemia, and it was used after patients would fail the first-line treatment. Not fail, sorry. They would have an allergic reaction to the first-line treatment, so they would need to use the second-line treatment that we had which was called Erwinase. And now, when we acquired Erwinase, we also acquired the company -- we had to work with the company that manufactured the product and they consistently were not able to deliver**

the amount that we needed. And so there was a consistent shortage of the product, but we couldn't move manufacturing from them.

So what we had to do over that period of time is we actually had to create a whole new product called Rylaze so that we could consistently supply the market. And so we're always prioritizing, and when you have pediatric patients that are saying, How can you help me get my treatment, and you have a shortage, we are -- you know, that's something that we're prioritizing as well. So -- and obviously we have seizure medications now, and so, again, thinking about how we prioritize what we should be doing in the seizure space as well.

MR. PORTER: Thank you, Mr. Honerkamp.

No further questions at this time, Your Honor.

THE COURT: All right. Mr. Honerkamp, you may step down. Thank you, sir.

THE WITNESS: Thank you, Your Honor.

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

MR. CALVOSA: Your Honor, Jazz calls Clark Allphin.

THE COURT: All right. Mr. Allphin, would you please --

MR. PORTER: Judge, just -- is Mr. Honerkamp

free to stay now because he's...

THE COURT: Yes.

MR. PORTER: Okay.

CLARK ALLPHIN, having been called on the part and behalf of the Plaintiff as a witness, having first affirmed to tell the truth, testified as follows:

MR. CALVOSA: Your Honor, may I approach?

THE COURT: Yes.

DIRECT EXAMINATION

BY MR. CALVOSA:

Q. Afternoon now. Good afternoon. Can you please introduce yourself to the jury?

A. Hi, I'm Clark Patrick Allphin.

Q. And are you currently employed, Mr. Allphin?

A. No, I'm retired.

Q. Where were you working when you retired?

A. I retired from Jazz Pharmaceuticals.

Q. When did you start working at Jazz?

A. 2006, I started.

Q. And when did you retire?

A. 2023.

Q. So about 17 years you worked at the company?

A. That's correct.

Q. And what was your position when you retired from Jazz?

A. **I was executive director of product and process science.**

Q. **Can you please tell the jury what product and process science is?**

A. **Sure. Product and process science brings together both very important aspects of drug development. The product is what you take, the formulation; and the process is how you make it. And my job in particular was about both.**

Understanding the product well enough that you can solve problems, but more importantly, select the right formulation for the job that you're asking it to do. And understanding the process by which it's made well enough to select the right process, one that is going to be durable, scaleable, and most importantly, reliable. And then also, furthermore, understanding it well enough and deeply enough that when it doesn't go right, you know how to fix it.

Q. **Did you have any other positions at Jazz?**

A. **Yes, I did.**

Q. **And what was that?**

A. **I started out in the early product development group.**

Q. **Can you explain to the jury what a early product development is?**

A. **Oh, yeah, I would love to explain this.**

Early product development is what I really

consider the fun part of the job. It's when you get a new idea or a new product concept, or perhaps a new molecule to work on, and you have the world of possibility. How do you make the best product for a patient?

And I got to explore lots of different approaches to make that product, whittle it down to the few approaches that made sense to me, and then ultimately select approaches that would go into a later stage, clinical development.

Q. And before your time at Jazz, did you work at any other companies in the pharmaceutical industry?

A. In the pharmaceutical industry, yes. I worked at Alza corporation.

Q. And what type of work did you do at Alza corporation?

A. At Alza corporation, I did mostly late-stage development. And Alza corporation was a leader in drug delivery so all of our products were controlled-release products.

Q. And when you use the term "controlled release," what do you mean?

A. Controlled release is delivering the right drug to the right place at the right time. And Alza corporation had technology in order to do that.

Q. As part of your work in the pharmaceutical industry, have you ever developed any FDA-approved products?

A. **Yes, I did.**

Q. **How many?**

A. **Four.**

Q. **And was that at Jazz or Alza?**

A. **Both.**

Q. **Any controlled- or modified-release products that you've developed?**

A. **Yes, two of them at Alza.**

Q. **And can you tell the jury what those are, please?**

A. **Sure. The first that I developed was a product called Ditropan XL, which is a once-a-day controlled-release form of oxybutynin chloride, and that's used to treat overactive bladder.**

And the second one is Concerta, which many of you may recognize, that's a once-a-day treatment of methylphenidate, and that's for ADHD and primarily used in children.

Q. **And what about the two other FDA-approved products, was that at Alza or Jazz?**

A. **Those were at Jazz.**

Q. **And what were those products?**

A. **The first one I worked on was -- became Sunosi. And that's an immediate-release tablet of solriamfetol. And that's used to treat excessive daytime sleepiness.**

Q. **And what about the second product?**

A. **The second one was -- is, I should say, Xywav, which is a reduced-sodium version of oxybate, and also an immediate-release liquid.**

Q. **In your experience, how long on average did it take you to get FDA approval of all of the drugs you developed?**

A. **I would say about seven years, on average.**

Q. **And what's the longest it took you?**

A. **That would be Xywav, that took ten years.**

Q. **Why did it take ten years for Xywav?**

A. **Well, Xywav, or oxybate in general, is kind of unique in that it's a really small patient population, and so it's harder to do clinical trials, especially efficacy trials. Because there's just fewer patients to recruit for those trials. They take a lot longer, and so that costs a certain amount of time, more than typical.**

Another issue with oxybate, or GHB, many of you may know, is that it's a highly controlled substance, it's DEA Schedule 1. And that means that you need to seek permission to do almost anything with it. So in the case of Xywav, that costs us at least a year of development because we had to apply for that permission.

And then the third thing is unexpected things happen. This happens in all drug development. And this one wasn't any different. And there was one in particular unexpected thing that probably took us a year or two to

figure out and move forward with.

Q. I want to pick up on the last thing you just said, unexpected things happen in development.

You have four FDA-approved drugs. Has it always been success for you or have you come up with ideas that haven't worked?

A. No, no. In our -- in our business, it's way more likely that you're going to fail than succeed. And fail is good because it means you've tried something that looked like it should work, but ultimately it has to work in the patient.

And so if you spend a lot of time doing early development, you just have to live with the fact that most of what you work on isn't going to go into late-stage clinical trials or to the market.

Q. Have you ever been awarded any United States patents for your work on drug development?

A. Yes, 30 that relate to drug development.

Q. Any of those relate to oxybate?

A. I would say most of them do, yes.

MR. CALVOSA: And hopefully this is okay with Your Honor, but I didn't introduce myself to the jury at the beginning and I'm sure you noticed that.

I'm Frank Calvosa. I work at Quinn Emanuel Urquhart & Sullivan, and I am an attorney for Jazz.

BY MR. CALVOSA:

Q. I gave a binder up there for you, can you please turn to JTX003.

MR. CALVOSA: And, Your Honor, at this time I'd like to admit JTX003 into evidence.

MS. DURIE: No objection.

THE COURT: Okay. JTX003 is admitted.

(Exhibit admitted.)

THE WITNESS: Okay. I'm there.

BY MR. CALVOSA:

Q. And Mr. Allphin, what is JTX003?

A. This is U.S. Patent Number 10,758,488.

Q. Okay. And is it okay with you if I call it the '488 patent?

A. Yes.

Q. Who are the named inventors on the '488 patent?

A. Myself, Clark Allphin, and my collaborator James Pfeiffer, whom I often call "Jamie."

Q. And can you generally explain to the jury the technology that's described in the '488 patent?

A. Sure. This patent talks about an approach that I selected called core-shell, where you have a core that is the oxybate component, which is solid, surrounded by a shell or a membrane. And that shell or membrane is used to control how quickly the oxybate dissolves and leaves the

dosage form.

Q. What time frame were you doing this work at Jazz?

A. I did this work in 2009.

Q. And why was Jazz interested in doing this type of controlled release work in 2009?

A. In 2009, we had in clinical development a -- the use of Xyrem, or something like Xyrem, sodium oxybate, in fibromyalgia, which we intended to seek approval for. This controlled-release once-nightly form would have been something that we would introduce to our patients as quickly as we could after approval with that immediate-release formula.

Q. And we keep saying "controlled release," is there another name you use for the work that's in the '488 patent?

A. Sustained release.

Q. And what was your specific contribution to the work that's in the '488 patent?

A. In this patent, I conceived all of the ideas, all of the formulation and approaches, as I described. And also performed most of the experiments.

Q. And is there anything that guided your work in what sort of formulations to make for this patent?

A. Yes, my collaborator, Jamie Pfeiffer, did PK modeling. And the outcome of his PK modeling was to suggest particular in vitro dissolution profiles; in other words,

the targets that I should try to meet.

Q. A lot of science in there so I want to break it down a little bit.

First, PK modeling, can you please explain to the jury what that is?

A. Sure. "PK modeling" is -- stands for pharmacokinetic modeling. And what that means is when you swallow a dosage form, suppose it's a tablet, when you swallow a tablet, you -- it enters your gut and it gets absorbed, okay.

So PK modeling tries to make that connection between how it's dissolved and how it's absorbed, because only if it's absorbed and into your blood is it going to do you any good. Most of our testing is done in a lab in vitro dissolution testing, and that's that connection that PK modeling makes between the testing in the lab in vitro and how it ends up in your blood.

Q. Was there a specific liquid that you chose for your dissolution testing?

A. Yes, I chose deionized water.

Q. And can you please explain to the jury what deionized water is?

A. Sure, it's purified water that's free of ions.

Q. At the time you were doing your work, was testing in deionized water commonly done?

A. No, I wouldn't say that that was common.

Q. **Then why did you choose to use deionized water?**

A. **It seemed like and was, I think, the right solution for the particular problem of how do you accurately and quickly measure sodium oxybate.**

Q. **And why did it allow you to quickly and accurately measure sodium oxybate in the dissolution test?**

A. **Right. One of the unusual things in sodium oxybate is that, first, it's a salt, but, secondly, it's a very large dose of salt. Conductivity is a really fast and accurate way to measure high concentrations of salt. And then the medium that you use, it can also contribute to conductivity and give you some noise, as it were.**

If you do use DI water as that medium, you have no background noise, you get a very clean signal and, therefore, very accurate and precise measurement.

Q. **And you mentioned that your co-inventor's work on the PK modeling informed the sustained-release profile that you were looking for, what was that profile?**

A. **The profile that he directed me to achieve was a lag time of about an hour. And lag time is just the time before which little or no drug releases. And then after that, a total release duration of about four to six hours.**

Q. **Okay. And why was that lag time at the front important?**

A. **That lag time was important for his modeling because**

when you consider the immediate-release portion of the dose, that lag time allows the -- according to his modeling, the achievement of what would be considered a flatter PK profile or a flatter blood levels.

And really slow and steady is the objective; we wanted to have something smooth that worked smoothly for the patients.

Q. And formulation-wise, how did you go about achieving that sustained-release profile with the lag time?

A. I used a core-shell approach, as I described earlier. And with that core-shell approach, I selected pore formers and screened a very large number of them in order to achieve a lag time.

Q. And what is a pore former?

A. A pore former -- okay, so you have a membrane which is enveloping the core, so think of it as maybe a baseball or something like that, the membrane is the skin of that. Now, that membrane may not be permeable enough to allow for the release rates or the -- the speed of release of the drug.

What the pore former does is it creates channels. So it's a material that will dissolve while the thing is being dissolution tested. And as it dissolves, it creates these channels through which the drug can move faster. Choosing the right pore former may allow, in fact

did allow us to achieve the right delivery pattern.

Q. **And what type of pore formers did you investigate?**

A. **Well, I would say broadly we tried two classes of pore formers. We tried regular water soluble, that could be polymers or sugars, things that dissolve in water regardless of pH. And then we tried enteric pore formers, things that require a certain pH before they will dissolve.**

Q. **Did you do any testing with water-soluble pore formers?**

A. **Yes, quite a bit.**

Q. **And are there any particular water-soluble pore formers that you use more than others?**

A. **Yes, I would say that the two that we use the most were Poloxamer 188 and hydroxypropyl cellulose, which I often refer to as "HPC."**

Q. **And did you do any testing with enteric pore formers?**

A. **Yes, I did.**

Q. **And any particular enteric pore formers you used more than most?**

A. **I screened, I believe, three of them and the one that I felt performed the best was methacrylic acid, methyl methacrylate. Yes.**

Q. **And is it okay if I call them "MAMM," which I'll pronounce "ma'am"?**

A. **Please do.**

Q. **Okay. Thank you.**

For those MAMM pore former experiments, did you record your formulation work anywhere?

A. **Yes, it would be in my lab notebook.**

Q. **Could you please turn to JTX246 in your binder?**

A. **Okay.**

MR. CALVOSA: Your Honor, at this time I move to admit JTX246 into evidence.

MS. DURIE: No objection.

THE COURT: Okay. JTX246 is admitted.

(Exhibit admitted.)

BY MR. CALVOSA:

Q. **And, Mr. Allphin, at the bottom, there's -- there's some Bates stamps, we call them, with a dot and then a number afterwards.**

Can I ask you to turn to page number 10, please?

A. **Sure.**

Q. **I just want to walk through some information on this page. I'll start at the top, there's a form that says, "SXB GRAN prep." Do you see that?**

A. **Yes, I do.**

Q. **And can you please describe for the jury what we're seeing there?**

A. **Yeah. So, first, that's our shorthand notation for sodium oxybate, SXB, granulation preparation.**

And what you're seeing there is the formula for the batch of granulation that we made. And for those of you who don't know, a granulation is what you would ultimately compress into a tablet that would become the core.

Q. **And the next section down there is coating solution.**

A. **Yes.**

Q. **You see that? Can you explain to the jury what we're seeing there?**

A. **Sure. These are the materials that would make up the shell. And in this particular experiment, coating solution A had a composition that is 17 percent poloxamer 188, 28 percent L100, which is shorthand notation for MAMM, this L100 for trade name, and 55 percent EC 10 or ethyl cellulose.**

Q. **So this particular formulation on this page had 28 percent MAMM in the functional coding?**

A. **That's correct.**

Q. **Did you do any dissolution testing on this formulation?**

A. **I did.**

Q. **What dissolution liquids did you use?**

A. **I used several, deionized water, in addition to artificial gastric fluid and a buffer that represents intestinal fluid.**

Q. **And is artificial gastric fluid representative of any**

specific area in the body?

A. That would be the stomach.

Q. And out of all of the testing that you did, nondeionized water, is there a particular one that's industry standard for trying to represent the conditions in the body?

A. Yeah, 2 hours in AGF or in the stomach is considered representative for the dissolution testing.

Q. And can you please point out to the jury where that 2 hours in the stomach, then in the intestine, is noted in your notebook?

A. Yeah. So you'll see the shorthand "bath one and bath two," that represents the two dissolution apparatuses that we used and you can see one and two is DI water and positions, it looks like nine and ten to the far right of that page are 120 minutes, so that would be 2 hours in the AGF.

Q. Now, Mr. Allphin, when did you do this formulation and dissolution testing work?

A. In 2009, but if you were to scroll to the next page, I could tell you the exact date.

MR. CALVOSA: And, Mr. Lewis, could we please go to the next page, it says JTX264.11.

A. Right. So that's the exact date, is September 3rd, 2009.

BY MR. CALVOSA:

Q. And what is the "MOK" next to that mean?

A. Oh, sorry for the -- that's release rate okay. That's my handwriting. And what that represents is my statement that I came in the next morning, everything looked fine so the release rate was okay, that was just my practice.

Q. Are the dissolution results recorded anywhere from this experiment?

A. Yes, I maintained a very large Excel workbook that had all the results.

Q. Could you please go to tab JTX237 in your binder.

A. 237?

Q. Actually it's 237A.

A. 237 -- okay.

Okay. I'm there.

MR. CALVOSA: Your Honor, at this time we'd like to move both JTX237 and 237A into evidence.

MS. DURIE: No objection.

THE COURT: JTX237 and JTX237A are admitted.

(Exhibit admitted.)

BY MR. CALVOSA:

Q. And Mr. Allphin, can you please tell us where the results of the deionized water testing for your MAMM formulation --

A. **Yes, so in that notebook reference deionized water was one and two. So that would correspond to columns G and H. And if you were to go further down the page -- I don't know if I have it in my copy here, but it would be --**

Q. **Let me help you out.**

MR. CALVOSA: Mr. Lewis, could we pull up the spreadsheet.

A. **So you can see the -- well, no, never mind. Maybe I didn't see it properly. Right there in column G is the summary of the DI water.**

BY MR. CALVOSA:

Q. **And what is the --**

A. **You'd have to scroll up to see the results.**

Q. **And let me ask you first: These tabs on the bottom, what does that represent?**

A. **Oh, yeah, so whenever I would do a dissolution test, the results would have popped into this notebook, all my calculations and everything is right in here and I would name the tab of the workbook according to the date that the test was completed.**

So, you know, you can see here 090901, for example, would have been something I did on September 1st and 090903 would have been something I did on September 3rd.

Q. **Which one of the tabs correspond to what we just looked at in your notebook?**

A. **That would be 090903.**

Q. **And can you tell us where we would see the percent release of the GHB in deionized water?**

A. **Yes, I believe it's right -- if you scroll up on the page there, it would be right -- okay, stop. Right there, column G and, I guess, row 56, where it says, "DI water."**

Q. **And in column G, line 58, what is percent release of the oxybate to 1 hour?**

A. **1 hour, it just says 2 percent.**

Q. **And how does it relate to the lag time we talked about before?**

A. **Oh it complies with the directions I was given before.**

Q. **And why is that?**

A. **Because it releases little or no oxybate in the first hour.**

Q. **And what is the release percentage at 4 hours?**

A. **At 4 hours, it's 44 percent.**

Q. **And that's in column G, line 72; is that right?**

A. **72, it looks like.**

Q. **And I think I was wrong before. I said 58. But it appears it's 68 for the -- for the 1 hour, my sight is a bit off apparently.**

And what is the release rate at 6 hours?

A. **At 6 hours, if you scroll a little bit further down.**

At 6 hours, it's 82 percent there.

Q. **And does this spreadsheet, if we scroll, I guess, over some, does it also show the percent releases in that AGF 120 testing?**

A. **Yes, I think it does. So that would be column O.**

MR. CALVOSA: And can we scroll back on this, Mr. Lewis, please.

BY MR. CALVOSA:

Q. **And what is the release rate at percentage of 1 hours in the AGF 120 testing?**

A. **Yeah, that looks like 2 percent also.**

Q. **And what is the release rate at 4 hours?**

A. **That's 38 percent.**

Q. **And how about the release percentage at 6 hours?**

A. **At 6 hours, it looks like 86 percent.**

Q. **Okay. Did you draw any conclusions, if any, about how this release testing showed whether you achieved the sustained release you were looking for?**

A. **Yeah, my conclusion was this was a good profile.**

Q. **And do you have a demonstrative that shows the comparison of the AGF 120 to the DI water testing?**

A. **Yes, I think one was prepared.**

MR. CALVOSA: And can we pull that up, Mr. Lewis. The demonstrative, the one you just pulled up. This is PDX3-1.

BY MR. CALVOSA:

Q. Can you tell the jury what we're seeing here.

A. Sure. If you remember on that spreadsheet we were looking at before, there were a couple of graphs.

What this is is just pulling out the graphs pertaining to those two conditions only, and plotting them on the same graph.

What you see here is the DI water, which is the dotted line in blue and the AGF 2-hour condition which is the red line there, it's solid.

Now what you see is that the red line and the blue line exhibit very similar profiles. And I would conclude this was a good result. It means that the DI water condition properly represents what you would see in testing under more, what would say, conventional conditions.

Q. And if you could, please, just flip back to JTX003, the '488 patent.

A. JTX003, you say?

Q. Yes.

A. Okay, I see it.

Q. Do you see in the first page, a little less than halfway down, there's a 22 on the left-hand side?

A. First page, halfway down. 22. Yes, I see that.

Q. And do you see this says this patent was filed on July 2, 2018?

A. **Yes.**

Q. **If you keep going down, do you see related US application data?**

A. **I do.**

Q. **And do you see it says, "This is a continuation of Application Number 13/071,369 filed on March 24, 2011"?**

A. **Yes, I see that.**

Q. **Okay. Had you completed your work on that MAMM formulation before March 24, 2011?**

A. **Yes. As I said earlier, the work was done in 2009.**

Q. **And a quick question for you: The work that we looked at in the dissolution testing, was that done in a USP Type 2 apparatus?**

A. **That work, the experimental work was done in a USP Type 7 apparatus.**

Q. **Okay. Had you also done testing, in your experience, in USP Type 2 apparatus?**

A. **Yes.**

Q. **And had you compared testing between a USP Type 2 apparatus and USP Type 7 apparatus?**

A. **Yes.**

Q. **And had you seen any difference?**

A. **No.**

Q. **One other thing you mentioned was that enteric polymers are pH sensitive?**

A. **Yes.**

Q. **At the time you were doing this work, did you understand that the pH of deionized water could vary?**

A. **I think most people understand that it will fluctuate, yes.**

Q. **And because the enteric polymers are pH sensitive, would that affect the dissolution profile in any appreciable way?**

A. **Not at all.**

Q. **Why not?**

A. **Deionized water, because it has no ions, it has no, what we would call, buffering capacity, which means that that pH doesn't really mean anything. As soon as anything comes into it that has buffering capacity or is acidic or basic, it will drive the pH to whatever it wants to be.**

Q. **All right. I'd like to move on now, if I may, Mr. Allphin, to your work on the '782 patent. Can you please turn in your binder to JTX006.**

MR. CALVOSA: And, Your Honor, at this time I'd like to move that exhibit into evidence.

MS. DURIE: I have no objection.

THE COURT: JTX006 is admitted.

(Exhibit admitted.)

BY MR. CALVOSA:

Q. **Is JTX006 another one of your patents?**

A. **Yes, it is.**

Q. **And do you have a co-inventor on this patent as well?**

A. **I do.**

Q. **And --**

A. **Scott Bura.**

Q. **And is it all right with you if I call this the '782 patent?**

A. **Sure.**

Q. **Can you please briefly describe for the jury the work of yours that's reflected in the '782 patent?**

A. **Sure. This work is sort of a continuation of the core-shell concept that I had described before and is patented prior to this where, in particular for this work, we focused on the multiparticulate option for the core. Now, the core can be a tablet. It can be multiparticulate. In this particular case, what are the unique challenges that come if you were to consider a multiparticulate?**

Q. **And what were those challenges that you faced?**

A. **Well, there are three of them. First is: What is the right format to present it to the patient in? The second is: How would you make sure that in that format it would be takable by the patient in a reasonable amount of time? And the third one is: How would you make sure that the product will be stable enough so that it will not, what we call, "dose dump" if taken not right away?**

Q. **All right.**

A. **Those were the three technical challenges that we overcame.**

Q. **And did you find a solution for those challenges?**

A. **I did.**

Q. **All right. Let's start with the first one, the format. What was the solution you arrived at for the format?**

A. **I felt a sachet was the optimal place to go for this.**

Q. **And what about the solution for the takable in an appropriate period of time problem?**

A. **Yeah, if you dump the pellets from the sachet into a dosing cup and add water, the problem is the pellets are very dense. You need to have a viscosifier or a viscosity-modifying agent in there that would allow the particles to be suspended enough for them to be swallowed or drunk.**

Q. **And what about the stability problem? What was your solution to that?**

A. **Yes, for the specific case of if you have in that core-shell any enteric component, these enterics, they have a pH trigger. What my calculations suggested is that you could breach that enteric just by virtue of the immediate-release portion of the dose. That would be very bad, and so the solution to prevent that would be to add an**

acidulant, we called it, or an acid to the formulation so that it kept the pH low under those circumstances.

Q. And I forgot to ask you earlier, Mr. Allphin, but what time period were you doing this work on the '782 patent?

A. This would be work that I had done in 2015 going into maybe early 2016.

Q. And so we heard about before the work you did with that MAMM formulation in 2009. Why the gap between 2009 and 2015?

A. Sure. Well, remember I told you earlier that that first product that we worked on was for an indication called fibromyalgia. We didn't get approval in that indication. And we had to take a step back and realize that for our narcolepsy patients for which we currently had sodium oxybate as the product, that perhaps reducing the sodium load would be a better use of our resources and better for our patients. So we spent those intervening years figuring out how to do that.

Q. Why didn't you pursue both the modified-release oxybate and the low-sodium oxybate at the same time?

A. Well, we were a smaller company back then, and especially people in my role, what we call CMC, our group is relatively small. We just didn't have the bandwidth to do, you know, multiple things like that. And like I said, we

really did believe that reducing the sodium burden was the best thing for our patients.

Q. Now, at the time you restarted your work on modified-release oxybate, were you aware of a company called Avadel?

A. Yeah, I think they were called Flamel back then.

Q. And do you know at that time whether Flamel was working on oxybate?

A. Back then?

Q. Yes.

A. In 2009, you ask?

Q. No, I apologize. When you restarted the work around 2015.

A. Oh, yeah, of course, we knew.

Q. And how did you know that?

A. I think they issued a press release in 2014 sometime.

Q. Did Flamel's work on oxybate contribute at all to you wanting to restart the oxybate -- modified-release oxybate program at Jazz?

A. Well, I wanted to restart it all along. Okay? Once we had finished with Xywav, I was ready for something else and I figured this would be it. But I have to say, it definitely made it much easier to get other people to agree to restart the program, having someone already there ahead of us.

Q. **And what process did you have to go through to get Jazz to restart the program?**

A. **We delivered presentations first to CMC management, my function, and then later to program management, who are involved in making decisions about which programs get green lit.**

Q. **Can you please turn to PTX1242 in your binder?**

A. **I'm sorry. What -- 12-...**

Q. **1242.**

MR. CALVOSA: And, Your Honor, I'd like to move that exhibit into evidence.

THE WITNESS: I see it.

MS. DURIE: I have no objection.

THE COURT: PTX1242 is admitted.

(Exhibit admitted.)

BY MR. CALVOSA:

Q. **Is this one of those presentations to management that you were talking about?**

A. **It is.**

Q. **And when did you make this presentation?**

A. **Well, it says here the date was November 24th, 2015.**

Q. **And if you could please turn to page 8 of PTX1242.**

A. **Okay. I see that.**

Q. **Did you prepare this slide of the presentation?**

A. **Yes.**

Q. **Can you please explain to the jury what you were presenting here?**

A. **Sure. What I'm presenting here, as I said before, in early development you like to consider all of your options and whittle them down. And so these are the options, first, that I considered. There are three platforms mentioned here: Reservoir in column 1 is another word for core-shell; matrix; and an osmotic. I have tentatively ruled out matrix and osmotic for the reasons said there, and I felt the reservoir systems, or core-shell, was a great approach to move forward with.**

And within that, there is a special case of resinate, which is a unique kind of oxybate salt with unique properties, and I felt that was worth considering as well as a more conventional core-shell-coated bead. And so that -- that's where I landed with that matrix.

MR. CALVOSA: And, Your Honor, I'm being told I'm encroaching into lunchtime. I have about ten minutes left.

THE COURT: You have about ten minutes left?

MR. CALVOSA: Yes, Your Honor.

THE COURT: Well, let's finish.

MR. CALVOSA: Okay. Thank you, Your Honor.

BY MR. CALVOSA:

Q. **Now, did you describe in this presentation any of the**

solutions to the problems that we talked about before?

A. **Yes, I think I did.**

Q. **Okay. Can you turn to page 11 of the -- 13 of the presentation. And I want to focus on the "Dose Delivery" part.**

Can you explain to the jury what you're presenting there?

A. **Yes, under "Dose Delivery," you see the second bullet point there is a sachet with a viscosity-modifying agent and additionally a flavoring agent, which I think would be a nice thing for the patient as well.**

Q. **Did you have an idea for a sachet with a viscosity-modifying agent before this November 5th, 2015, presentation?**

A. **Sure.**

Q. **Did you ever tell anyone else at Jazz about your ideas?**

A. **Yeah, all the time.**

Q. **Why did you do that?**

A. **Well, what I've learned is that when you cast a wide net and come up with a lot of options -- I'm not the patient. I don't live with the patient, and I don't interact with the patient. I need to have a rounded voice to see what are the options that really do make sense, not just what I think make sense. And so generally, I would**

bounce my ideas off of a cross section of people.

Q. Can you please turn to PTX963 in your binder?

A. 963.

MR. CALVOSA: And, Your Honor, I'd like to move that exhibit into evidence at this time, please.

THE COURT: All right. Any objection?

MS. DURIE: I have no objection.

THE COURT: PTX963 is admitted.

(Exhibit admitted.)

BY MR. CALVOSA:

Q. And if you could turn to page 3 of 963, do you see an e-mail there from yourself to several others sent on July 6th, 2015?

A. I do.

Q. Who are those others, just generally in the to and cc line?

A. Those are those people who would know more about oxybate from a broader perspective than I would.

Q. Were they Jazz employees?

A. Yeah, all of them are Jazz employees.

Q. And if you turn to the next page, page 4 of PTX963, do you see there's several bullet points there?

A. Yes, I do.

Q. And can you please describe to the jury what's in those bullet points there?

A. **Well, so I -- like I said, I cast a wide net. And so what I did for their benefit was to list some of the ideas that I had for how we could present the product to those patients, and some of them are less conventional than others. I like the pharma bar. It's like a Hershey bar that you break off the dose that you want. But getting more serious, if you'd scroll down, you'll see, the second from the last, a stick-pack for aqueous suspension, which is a sachet.**

Q. **And had you had the idea for using -- for formulating oxybate beads in a sachet even before this 2015 presentation?**

A. **Sure.**

Q. **When's the first time you can remember having that idea?**

A. **I think we talked about it going way back to when we had a meeting with PII.**

Q. **Who is PII?**

A. **Oh, sorry. That is the CDMO that we used for that earlier program back in 2010, early, I think, we engaged them.**

Q. **And just so everybody is on the same page, what is a CDMO?**

A. **CDMO is contract development and manufacturing organization.**

Q. **And what does a CDMO do?**

A. **They make the drug product that ultimately you'll put into clinical trials.**

Q. **And do they do that at your direction, or do they do it on their own?**

A. **Well, at our direction, of course.**

Q. **Sticking with PTX963 before we move on, I want to focus on the last paragraph of your e-mail, and it begins, "Another issue that arose as Scott and I were thinking through this: Beads prepared for suspension in water could carry a safety risk that other options don't."**

I want to ask you about that safety risk, but first, who is the Scott you mentioned in the e-mail?

A. **Oh, that's Scott Bura, my co-inventor.**

Q. **And then what is that potential safety risk that you're referring to?**

A. **Yeah. So oxybate is a unique product, and this one is hard to understand, but patients are directed to take it right before they go to bed. And I mean right before they go to bed. And it is the last thing that they do in the day. The problem is that if you have a formulation that can't be taken right away -- so, remember, I said that there's a viscosity-modifying agent. What if it doesn't work quickly enough? Well, then they can be distracted, something at -- life happens and maybe a baby is crying,**

there's some other emergency, they may not come back to it right away. They may come back to it an hour or two later, perhaps. Well, in that hour or two later, the drug could prematurely release from the dosage form, and that's something we call in the industry "dose dumping." That would be a very bad thing.

Q. And why would that be a bad thing for oxybate?

A. Because more of the dose is taken up front rather than slow and steady. There are safety ramifications for that potential.

Q. And did you come up with a solution to that -- to that potential safety risk?

A. I did.

Q. What was that?

A. That would be to incorporate the viscosity-modifying agent as a loose powder in the formulation, separate from the pellets or beads.

Q. So we saw your work with the sachet and the viscosity enhancing agent for the particles.

Did you record your work related to the acid and the particles anywhere?

A. Yes, I did.

Q. And where would you have recorded that?

A. I formally recorded it in a memo that I wrote detailing out a particular -- the delayed release option.

Q. **And could you please turn to PTX87 in your binder?**

A. **I'm sorry, what was the number again?**

Q. **87.**

A. **87. Okay.**

Q. **Is this the memo you're referring to?**

A. **It is.**

Q. **Can you please turn to page 11 of PTX87.**

A. **Okay.**

MR. CALVOSA: And, Your Honor, at this time I'd like to move PTX87 into evidence.

MS. DURIE: No objection.

THE COURT: PTX87 is admitted.

(Exhibit admitted.)

BY MR. CALVOSA:

Q. **And on page 11, under administration with IR, there's some numbers in a table.**

Can you explain to the jury what we're looking at in that section?

A. **Sure. Remember I said earlier that the portion of the dose is immediate release. What these numbers represent is for that immediate-release portion of the dose, how much the pH in your stomach could increase when you take the dosage form.**

So the stomach -- what I modeled is under physiological conditions -- it's acidic, but the drug

oxybate is actually somewhat basic. And so it neutralizes the stomach acid. And this is a safety problem potentially.

So what these calculations here show is that at a reasonable dose, so 4 or 5 grams, that the pH in the stomach, if we didn't correct for it, would be about pH 6.

Q. **And did you come up with a solution for correcting for this problem?**

A. **Sure. And I'd also like to add, just to remind you, that pH 6 is close to the activation point for an enteric, and you want to avoid that if you can. So the solution was to add an acid to the formulation to drive that pH reliability lower than the activation pH.**

Q. **And if we could turn, please, to page 12 of PTX87.**

I'd like to focus on the second sentence below the graph. It says, "To accomplish this, tartaric acid can be added to the diluent blend, along with beads in the sachet."

Can you explain to the jury what you're saying there?

A. **Sure. Well, first I'm saying tartaric acid is a great acid to work with. But more importantly, adding it to the diluent blend, for the same reason that we added the polymer separately as a blend, you add the acid separately because you really want it to take effect quickly.**

Q. **So the acid would also be separate from the --**

A. **Separate from the pellets or beads, yes.**

Q. **When is this memo dated?**

A. **I see printed on March 18, 2016.**

Q. **Had you done the calculations and came up with your conclusion about adding the acid separate from the particles in a sachet before February of 2016?**

A. **Yes.**

Q. **How do you know that?**

A. **Because the calculation of pH 6 is in our patent application.**

Q. **And that's the patent application for the '782 patent we looked at earlier?**

A. **Yes.**

Q. **Can you go back to the '782 patent quickly, it's JTX006.**

A. **006.**

Q. **And, again, I want to look at the front page.**

A. **All right.**

Q. **The 22 number on the left-hand side?**

A. **Mm-hmm.**

Q. **You see it says filed March 23, 2021?**

A. **I do.**

Q. **And if we go down to related US application data, right below that, the second to the last line says that this is a continuation of Application No. 15/047,586 filed on**

February 18, 2016.

Do you see that?

A. **I see that.**

Q. **Had you done all the work we just looked at before February 18, 2016?**

A. **Yes.**

Q. **Mr. Allphin, one more question about your work for the '782 patent. We saw your actual physical experiments for the work that went into the '488 patent.**

Did you do physical experiments with the sachet and viscosity enhancing agent and acid?

A. **No, I didn't think I needed to.**

Q. **Why not?**

A. **Well, I considered those to be late-stage development activities. And what I had identified was the components and how to include them in the formulation, but the details about specifically which components and what the final formulation we like to call it, those are the details that generally are hashed out in later stages of development.**

Q. **Now, we talked about that company Flamel that became Avadel before. At any time did you learn about a Flamel patent application?**

A. **Yes.**

Q. **Okay. And did you review that Flamel patent application?**

A. **I would have, I'm certain -- certainly I did, yes.**

Q. **And did you have any reaction when you saw that application?**

A. **I remember when I analyzed it that first I -- as a formulator, I'd like to know what approach they used. And they used the same approach that I used, that is of a core-shell approach. And I also noticed that their approach was an enteric pore former, which was pretty similar to what I had done earlier.**

Q. **And if we could turn to PTX2016 in your binder.**

A. **2016. Okay.**

MR. CALVOSA: And, Your Honor, I'd like to enter this exhibit into evidence.

MS. DURIE: No objection.

THE COURT: All right. PTX2016 is admitted.

(Exhibit admitted.)

BY MR. CALVOSA:

Q. **Is this the Flamel patent application that you saw?**

A. **Yes.**

Q. **And when did this application become public?**

A. **It says the publication date was 25, January, 2018.**

MR. CALVOSA: Pass the witness, Your Honor.

THE COURT: All right. At this time, we're going to break for lunch. So we can take the jurors out. We'll break for lunch for 45 minutes.

(Whereupon, the jury left the courtroom.)

THE COURT: All right. Mr. Allphin, you can step down. You're still under oath so you can't talk to counsel at this time while you're on the stand. All right.

All right. So we'll break until 2:00 p.m.

MR. SILVER: Your Honor, before the break, apologies, I want to go back to the door opening for a minute, because on redirect, Mr. Honerkamp was asked a question and he testified -- and this is a quote -- "we're not in the business of pulling drugs from the market."

And that is directly contrary to the fact that Jazz is seeking an injunction. It's directly contrary to Jazz's case against the FDA in which they are seeking to have our drug approval rescinded.

And so I would encourage Your Honor to at least look at the transcript.

THE COURT: On redirect he testified "we're not in the business of pulling drugs from the market."

MR. PORTER: In reference to his own drugs, Your Honor, Xyrem.

THE COURT: So what is the point that Avadel wants to make? That they're trying to -- they're also seeking to take Lumryz off the market?

MR. SILVER: The point, Your Honor, is they're trying to convey themselves to the jury as a patient-centric

company that wants the patients to have choices. When in reality, that's not what they want at all, they want our product off the market. And --

THE COURT: Okay. I don't need the argument, I wanted to hear what the factual point is you're trying to make.

MR. SILVER: The factual point is that they are seeking an injunction to take our product off the market and that they've sued the FDA in order to take our product off the market a second way. Those are the things that Jazz moved to exclude, and that in our view, they have now opened the door to.

THE COURT: Well... let me hear from Jazz on that. So let me hear from you.

MR. PORTER: Your Honor, his statement was "we're not in the habit of pulling the drugs off the market" regarding our own drugs, it was Xyrem, that's what he was talking about, it's contextual.

Because the question was about -- remember they had gone through this long examination about, well, you -- even though you have the low sodium, you still sell Xyrem you made a billion dollars off of Xyrem. That was their point, they were trying to suggest that we really, I guess, don't care about the low-sodium product because we're still making money off of Xyrem, which is the high-sodium product.

And what Mr. Honerkamp is saying, which is true, is that we're not in the business of pulling our products off the market. And because he stated repeatedly "while we are educating the market and seeking to get them" -- "seeking to educate to get people to move to the lower sodium." That is still a conversation that needs to be had between the patient and the provider. And so we're not going to pull that off the market for people who have been using this for 20 years. That is an education.

This is just a back-door attempt for them to try to -- to try to turn something out of nothing. He didn't say what they said. He -- there was nothing about pulling any other drug off the market. Why would he testify to that? He can only speak to what he could do as a Jazz employee.

But there was no suggestion that we're not in the business of pulling -- it wasn't even -- we're literally talking apples and oranges here, because it wasn't even anywhere close to the context in which they're trying to squeeze this into.

So it's really -- it's difficult for me to respond to it because of that, but that's the response that I have, Mr. Honerkamp is simply talking about our product, Xyrem, and why we don't pull it off in response to their suggestion that, you know, we're making billions off of

Xyrem so we don't care about the low sodium.

THE COURT: So let me hear from Mr. Silver.

MR. SILVER: Your Honor, I think it's -- first of all, the words that I read to Your Honor were an exact quote that I wrote down from the realtime transcript.

THE COURT: But wasn't he talking about his own product?

MR. SILVER: He may have been, Your Honor, but it's the second time he raised the issue about pulling products from the market. In the first instance that we raised earlier, he said, "All we're seeking is our fair share" --

THE COURT: His response was in response to the questioning about the difference in revenue.

MR. SILVER: Correct, Your Honor. But, again, what Jazz is doing is presenting themselves to the jury in an angelic light where they are not going to pull drug out of patient's mouths. They answered it with regard to their own product, Xyrem. But when it comes to our product, they are not letting the jury see who Jazz really is and what they really want out of this case.

THE COURT: So, the factual point that -- in addition to seeking money damages, Jazz is attempting to get relief in the form of pulling Xyrem from the market is the factual point you want to make.

MR. SILVER: Yes, Your Honor. I'm sorry, Lumryz from the market.

THE COURT: Lumryz from the market.

MR. SILVER: I was with you, everyone else was --

THE COURT: Lumryz from the market, that's the point you want to make?

MR. SILVER: Yes, Your Honor.

THE COURT: So, why don't the parties meet and confer and try to come to some agreement on some statement that could be read to the jury that says just that factual point but that they're not being asked to decide that issue.

MR. PORTER: Because, and I think the problem is -- excuse me, the problem, Your Honor, excuse me, the problem, Your Honor, is that -- the problem with that is because that's -- we think that that has -- that is going to be highly prejudicial to us, that has no place whatsoever in this trial.

And the question was asked about the -- in the trial, that was specific -- I mean, I -- I -- I'm really surprised that counsel is trying to squeeze what he's trying to squeeze out of the question -- the question that was asked was contained within the trial and that is what we're here for the next five -- four days now, which is this trial.

Yeah, and it's -- and then they brought up the issue about, again --

THE COURT: Differences in the --

MR. CERRITO: -- they opened the door on cross and then expect us not to respond and if we do, then we've opened the door, that's not fair, Your Honor.

THE COURT: I hear you. Again, I don't think that this door has opened.

MR. PORTER: Thank you, Your Honor.

THE COURT: If the parties can reach some agreement on a limited statement, I was going to allow that, but I don't think that the door has been opened based on that.

MR. PORTER: Thank you, Your Honor.

THE COURT: All right. So we're going to resume at 2 o'clock.

DEPUTY CLERK: All rise.

THE COURT: All right. You may be seated.

So with respect that the Court reviewed the parties supplemental briefing on the inventorship issue on unasserted claims, so on this issue, the Court is finding in favor of Avadel. There was sufficient disclosure both in Avadel's final invalidity contentions and in Dr. Charman's invalidity report disclosing that all of the '782 patent claims are invalid for lack of proper inventorship.

And, in fact, Dr. Charman specifically dismisses Claim 19 there. The Court has reviewed *Fox* and *Sunoco* and believes those cases are in sufficiently distinguishable than the circumstance present here.

Here, Avadel is attempting to invalidate Claim 24, which is asserted, and it's relying on Claim 19 for that, but the legal result, that's a question of law. If one claim is invalidated for improper inventorship, then the entire patent is invalid.

So, in addition, Avadel has made -- has a copying defense so that there's still a case of controversy with respect to Claim 19, as well, with respect to Avadel's copying defense, so for all of those reasons, the Court is finding for Avadel on that issue.

All right.

MS. DURIE: Thank you, Your Honor.

(Whereupon, the jury entered the room.)

THE COURT: All right. You may.

MS. DURIE: Thank you, Your Honor.

Good afternoon, ladies and gentlemen.

CROSS-EXAMINATION

BY MS. DURIE:

Q. **And good afternoon, Mr. Allphin. I know that we have spent a couple of days together before, but I'm Daralyn Durie, one of the lawyers representing Avadel.**

A. **Pleased to meet you.**

Q. **Now, Mr. Allphin, you learned about Avadel's Micropump technology back in 2010, correct?**

A. **I don't recall specifically when, but I believe I did learn in 2010 sometime.**

Q. **You have a binder, a very thick binder in front of you that we provided you. If you could set aside the binder from Jazz's counsel and pull that down, there should be a tab in there that is DTX1361.**

A. **1361.**

Q. **1361.**

A. **Can you tell me approximately where it is.**

Q. **They should be in order. There is a DTX1361 and they are in order. It's about half-way through.**

A. **Bear with me for a second.**

Getting close. All right. I see that.

Q. **Do you have that?**

A. **1361, yes.**

Q. **1361.**

Now, this is an e-mail that you forwarded to a fellow Jazz employee in 2015, correct? At the top?

A. **Yes, it says May 29, 2015.**

MS. DURIE: We offer 1361.

MR. CALVOSA: Objection, Your Honor, this document is hearsay.

MS. DURIE: It is an e-mail exchange among Jazz employees, we have a stipulation with respect to business records for such documents.

MR. CALVOSA: Your Honor, this isn't a business record, the bottom part of it is from an outside source. I don't think they have established that it's a business record.

THE COURT: Is this an e-mail that Mr. Allphin received?

BY MS. DURIE:

Q. **Mr. Allphin, is this an e-mail that you received in the course of your regular business activities at Jazz?**

A. **Are you referring to the e-mail from Mike DesJardin.**

Q. **Yes. The e-mail -- yes, exactly.**

A. **It says, "Just FYI," so I don't know how to answer your question. I've obviously received the e-mail.**

Q. **And did you receive that e-mail in the course of your duties as a Jazz employee?**

A. **Well, I would say, from his title "FYI," it probably wasn't germane to my job because it's merely provided for my --**

THE COURT: Were you employed at Jazz at the time?

THE WITNESS: Yes, I was, sir.

THE COURT: Overruled.

MS. DURIE: Thank you, Your Honor.

BY MS. DURIE:

Q. **If we could publish DTX1361 and take a look at the first page and if we could blow that up.**

The bottom portion of this is an e-mail that was sent in 2010 and then forwarded to you on June 4th, 2010, correct?

A. **Yes, that's correct.**

Q. **And the e-mail at the bottom indicates that there had been a request to Flamel, you understand that to be Avadel, right?**

A. **Yes.**

Q. **"To follow up with a summary presentation outlining the applicable benefits of their technology for sodium oxybate," and you, then, re-forwarded that e-mail to one of your colleagues in 2015, correct?**

A. **Yes. Or at least I think I did, is that... yes, I forwarded it to Finn Bartlett, yes.**

Q. **But it's safe to say you had it in your possession at least as of June 2010 when it was forwarded to you, right?**

A. **As I have many documents in my possession, yes.**

Q. **So let's take a look at that document, if we can go to DTX, if we can go to the next page, DTX1361.2 and then 3, this was a presentation that Flamel had put together for Jazz Pharmaceuticals regarding the use of its Micropump**

technology for controlled-release sodium oxybate, correct?
A. That's correct.
Q. And if we go to 1361.4, the next page, we see here that Flamel was telling Jazz that it thought Micropump had certain advantages to improve sodium oxybate administration, correct?
A. That's the title of the presentation, so, yes, I would assume that's correct.
Q. Right. Flamel was explaining that it believed its, "Micropump technology would allow for the combination of immediate release and delayed release in a single administration, such as at bedtime," right?
A. Um, yeah, that would appear so.
Q. And it indicated that, "Micropump technology is compatible with various dosage forms including a sachet," right?
A. Yes, I see a "sachet" there.
Q. Right.

And when we talk about a "sachet," we're talking about something like you can buy vitamin C in, right, it's like a little single-use pack, if you will?
A. Yes.
Q. Now, if we turn to 1361.9, further on in the presentation, Avadel was indicating here that it thought this Micropump system was the perfect fit for sodium

oxybate, right?

A. That's what the slide says.

Q. And when it talks about here a "multiparticulate system," that's talking about little beads, right?

A. "Multiparticulate" means little beads, yes.

Q. And then Avadel said, "thanks to Micropump's unique properties, one single bedtime administration of sodium oxybate would lead to this double-trigger release, an immediate and a delayed effect several hours later," right?

A. That's what it says.

Q. Now you then learned in 2014 that Flamel/Avadel had actually pursued this development effort, right?

A. I learned, yes.

Q. And at that point in time, you were not convinced that Flamel was going to be successful, right?

A. I don't think anybody could be convinced until it actually happens.

Q. Let's -- if you can turn in your binder to DTX250, 2-5-0. So it should be earlier in your binder.

DTX is Jazz, correct?

A. Yes.

MS. DURIE: We offer DTX250.

MR. CALVOSA: No objection, Your Honor.

THE COURT: All right. DTX250 is admitted.

(Exhibit admitted.)

BY MS. DURIE:

Q. **And if we could start with DTX250.3 just for orientation, this is a Jazz presentation titled "Flamel Market Intelligence: Once-nightly sodium oxybate Micropump formulation from August of 2014," right?**

A. **Yes, that's what the slide says.**

Q. **And if we could please turn to DTX250.7, there's a pretreatment. 250.7.1. This is number -- slide numbered 5, but if you'll see across the bottom, there are page numbers. DTX250.0007, that's going to make it easier for you to follow along and it's also what Mr. Jared's going to use.**

So here there was a discussion of Flamel/Avadel's technology, right?

A. **Yes.**

Q. **You were involved in preparing this, right?**

A. **I assume so, I see my initials there. Although I don't remember, it's safe to assume that's me.**

Q. **That's C.A., that's you?**

A. **Yes, mm-hmm.**

Q. **And it says, "Historically, drug formulation issues have challenged the development of multiparticulate bead formulations."**

And that was true, right?

A. **Yes.**

Q. **And it says, "Other drug developers, e.g., Shire,**

have pursued development of a sodium oxybate delayed-release bead but discontinued efforts."

You were aware of that earlier effort to try to develop delayed-release beads that had failed, right?

A. At this point in time, yes, I think I had dug into the Shire work.

Q. And you said, "One of the working assumptions was that sodium oxybate poses unusual challenges for bead formulations," and that was true, right?

A. Yes.

Q. It was not a trivial matter to make beads with sodium oxybate?

A. I think that's safe to say.

Q. If we can now go to 250.9 and there's a pretreatment, 250.9.1.

So it says current -- it's talking about current assumptions and it says what we know, "Jazz has been attempting to develop once-nightly sodium oxybate for many years and has not been successful."

That was true as of 2014, right?

A. That is correct.

Q. And it referenced two earlier products -- programs that had been discontinued at earlier stages. One of those we just mentioned was Shire. That was an effort to develop beads, right?

A. **That's correct. I don't see where you're mentioning the two programs. Are you --**

Q. **It says: What we know: Two once-nightly sodium oxybate programs, e.g. Shire/Jazz --**

A. **Oh, okay.**

Q. **-- discontinued at early stages.**

A. **That's correct.**

Q. **So we talked about Shire. There had also been an earlier Jazz program that had been discontinued in its earlier stages, right?**

A. **That's correct.**

Q. **So I want to talk to you about that program, because that was the program that led to the '488 patent involved in this lawsuit, right?**

A. **That's right.**

Q. **Okay. Now, you're aware that in 2018 Jazz submitted claims to the Patent Office to a formulation that included methacrylic acid-methyl methacrylate, right?**

A. **I'm not sure of the year, but I know that we submitted claims along those lines, yes.**

Q. **You know that it was certainly many years after the development work had been done, right?**

A. **Yes, that's true.**

Q. **And you submitted -- those claims were submitted including certain very specific testing requirements in a**

USP 2 dissolution testing, right?

A. Yes.

Q. And you signed an oath of inventorship when Jazz submitted those new claims, right?

A. Yes.

Q. And you told the Patent Office that that was an invention that you had made --

A. It certainly was.

Q. -- right?

But you're not sure how that requirement for having methacrylic acid-methyl methacrylate in the claims came into being, right?

A. I'm not sure of the meaning of your question. Certainly I understood the work that I had done with MAMM.

Q. But you don't know how the specific requirement of that copolymer in the patent claim wound up there, right?

A. Well, I would have been working with counsel for that. But I don't know specifically how that arrived.

MR. CALVOSA: I just want to make sure we don't get into privileged information.

MS. DURIE: I -- I agree with that.

MR. CALVOSA: Okay.

BY MS. DURIE:

Q. And let me see. Mr. Allphin, you remember that I took a -- what's called a deposition of you in this case,

right?
A. Mm-hmm.
Q. We actually spent a couple of days together.
A. Mm-hmm.
Q. And I asked you -- I had an opportunity to ask you questions, right?
And you were there as what is called a Jazz corporate representative?
A. Yes.
Q. Do you remember that?
A. Mm-hmm.
Q. So in advance of that deposition, we had provided your counsel with a series of topics, right?
A. That's correct.
Q. And you were designated to testify on some of those topics, right?
And you spent about two and a half -- I mean two and a half days, I think you said, with Jazz's counsel getting ready for that deposition, right?
A. That's correct.
Q. You reviewed documents, right?
A. Yes, I was not allowed to review any privileged documents, though.
Q. Understood.
And do you recall that at your deposition I

asked you whether you had an understanding as to how the specific requirement of a methacrylic acid-methyl methacrylate copolymer came into being, and your answer was "I don't recall." Do you remember that?

MR. CALVOSA: Objection, Your Honor.

Can we get a page and line number --

MS. DURIE: It is volume 1 at 177:6-16.

BY MS. DURIE:

Q. But my question to you, sir, at the moment is just: Do you remember that?

A. I remember that.

THE COURT: All right. Let's give them an opportunity to look.

MR. CALVOSA: What page?

MS. DURIE: 177:6-16.

BY MS. DURIE:

Q. Now, Avadel's patent application published on January 25th, 2018, right?

A. If you say so.

Q. Does that sound about right?

A. Yeah.

Q. And you read Avadel's published patent application around that time, right?

A. It's safe to assume somebody forwarded it to me shortly after it was published.

Q. **And that patent application laid out the details of Avadel's formulation, right?**

A. **Yes.**

Q. **And Jazz -- you and Jazz paid close attention to that information at the time, right?**

A. **Yes, we would have analyzed the patent.**

Q. **I would ask you to turn in your binder to DTX483.**

A. **483. Yes, I'm there.**

Q. **You have seen this document before, right?**

A. **I think I have.**

Q. **It is a --**

A. **It's not refreshing my memory, though.**

Q. **It is a Jazz PowerPoint presentation, correct?**

A. **Mm-hmm.**

MS. DURIE: We offer DTX483.

MR. CALVOSA: No objection, Your Honor.

THE COURT: All right. DTX483 is admitted.

(Exhibit admitted.)

MS. DURIE: And if we could please publish -- I apologize -- 483.1.

BY MS. DURIE:

Q. **So this is a Jazz PowerPoint presentation from March 23rd of 2018, right?**

A. **Yes.**

Q. **So about a couple of months after Avadel's patent**

application published; sound about right?
A. Okay, yes.
Q. And if you could please turn to the page that says 19 -- DTX483.19.1.
We see here a page from the Jazz PowerPoint -- I apologize. It's also, Mr. Allphin, up on your screen --
A. Oh, okay.
Q. -- and whichever is easier, you should feel free to use.
A. I see that.
Q. 2018/0021284, that's the Avadel/Flamel patent application, right?
A. I assume so.
Q. And there's a couple of tables that are pulled out here. Those are tables from the Avadel patent application, right?
A. They look like that, yes.
Q. And there's some highlighting there on the formulation hydrogenated vegetable oil methacrylic acid copolymer type C, methacrylic acid copolymer type B, right?
A. Yes.
Q. One of those is MAMM, right?
A. That's correct.
Q. And if we can blow that back out, there was a notation that had been made discussing that formulation and

asking a question about it, right?

A. I'm sorry --

Q. EtOH-rugged, question mark?

A. Oh, yes. That's the formulation. Okay.

Q. So you were identifying what Avadel's formulation was and internally asking some questions about it, right?

A. Yes.

Q. And then if we can go to slide 21, it's 483.21.2, there's a discussion here of some of the key formulation highlights of our formulation, right?

A. Okay. I'm not sure that I follow where you are.

Q. Well, at the top -- at the top, it's still discussing our patent application, right?

A. Okay.

Q. Avadel's patent application.

And then it's talking about the -- it says "DR core," and it says, "Use a mix of two enteric polymers plus hydrogenated vegetable oil," and it's again talking about --

A. Right.

Q. -- those formulation characteristics and the pH dissolution trigger point, right?

A. Right.

Q. And then let's go down to "final composition." It says, "there's an acidulant to buffer dose water."

That's an acid, right?

A. **That is an acid, yes.**

Q. **And it's saying there is a suspension agent to hold the microparticles in solution, right, so they don't all fall to the bottom before you drink it, basically?**

A. **Right.**

Q. **Okay. And this was an analysis, again, that Jazz was doing in 2018 about a couple of months after Avadel's patent application published?**

A. **Yes.**

Q. **Okay. And then after reading all about Avadel's formulation, Jazz submitted new claims to the Patent Office, right?**

A. **Yes, I think so.**

Q. **And if we take a look in the '488 patent, it's JTX003, and you'll have that -- you should have that in your binder. Unfortunately, because it's JTX, it's actually going to be towards the back of your binder, but we'll also put it up on the screen, JTX003 at page 30, .30. If we could just blow up Claim 1. So 3.30, perfect. And again, it's on -- if it's easier, it's on your screen.**

A. **Great, okay.**

Q. **So this is a claim that Jazz asked the Patent Office to issue after having seen Avadel's formulation, right?**

A. **Okay, yes.**

Q. **And that claim includes these methacrylic acid-methyl**

methacrylate copolymers and then this particularized testing condition in Dissolution Apparatus 2, right?

A. **That's correct.**

Q. **Now, to know whether a particular formulation is going to release at a particular rate in a particular type of dissolution apparatus, you have to actually test it, right?**

A. **Well, or have substantial enough experience in the equivalency, but yes, you would test it to be sure.**

Q. **Why don't we take a look in your binder at DTX1268.**

A. **I'm sorry. What was the number?**

Q. **1268, DTX1268.**

A. **Okay.**

Q. **Do you have that?**

A. **Yes.**

Q. **This is an e-mail that you sent in 2021 to one of your colleagues at Jazz, correct?**

A. **Yes, it is.**

MS. DURIE: We offer DTX1268.

MR. CALVOSA: No objection, Your Honor.

THE COURT: DTX1268 is admitted.

(Exhibit admitted.)

MS. DURIE: Thank you.

And if we could publish 1268.2 and just blow up that top portion.

BY MS. DURIE:

Q. **This is an e-mail from you, and you're referring to the claims of the "Allphin/Pfeiffer family." That's -- that includes the '488 patent, right?**

A. **That's right.**

Q. **And you say, "these would cover 20-50 percent enteric," that's a reference to that 20-50 percent MAMM requirement, right?**

And then you say -- you're referring at the top to JZP-324. That is a project that was underway at Jazz in 2021 to try to develop a once-nightly formulation, right?

A. **That is correct.**

Q. **And you're talking about a formulation from JZP-324 and you'd say you'd want to test the claim -- you'd want to test the dissolution in D.I. water since our claims have dissolution limits in various forms that specify D.I. water.**

So you were saying, essentially, in order to know whether this formulation that we're developing now is covered by the patent, we would need to test it?

A. **That's true. But earlier you were asking about USP 2 versus 7.**

Q. **Just -- you would need to -- my only point is you would need to test it -- do the dissolution testing in order to know whether it was covered by the claims?**

A. **It's always good to have that data, yes.**

Q. **Okay. And in this case, obviously you knew what the formulation was already, because it was a Jazz formulation, right?**

A. **Yes.**

Q. **Okay. Now, in connection with the prosecution of the '488 patent, the Patent Office raised some concerns about whether that precise dissolution testing was something that you had actually done, right?**

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

Q. **Why don't you take a look in your binder at JTX104.**

A. **Okay. JTX --**

Q. **I think the Js are in the back.**

A. **Okay, I'm there.**

Q. **JTX104 is a declaration that you submitted to the Patent Office in connection with the '488 patent, right?**

A. **That is correct.**

MS. DURIE: We offer JTX104.

MR. CALVOSA: No objection, Your Honor.

THE COURT: JTX104 is admitted.

(Exhibit admitted.)

MS. DURIE: Please publish 104.2.

BY MS. DURIE:

Q. **So this is the first page of your declaration, right?**

A. **That's correct.**

Q. **And we don't need to go there, but if we go to the**

last page, you signed it under oath, right?
A. Mm-hmm.
Q. We can actually take a look at paragraph 14, it's on page 6.
And I just want to say, you understood that it was very important that you be completely straightforward with the Patent Office, right?
A. That everything I said is complete and true, yeah.
Q. Absolutely.
And you knew the Patent Office would be relying on this declaration?
A. Mm-hmm.
Q. In making a decision about whether to issue the '488 patent, right?
A. That is correct.
Q. And if we can go to the previous page to paragraph 13, at the bottom of the previous page.
MS. DURIE: And just blow up paragraph 13.
BY MS. DURIE:
Q. You said, "Figure A of the appendix shows that the dissolution profile -- shows that the dissolution profile of a sustained release portion of a GHB formulation meeting the... claims."
Right?
A. Mm-hmm.

Q. That's what you said?
A. Yes.
Q. Okay. And then you provided some information about some dissolution testing that had been done of a formulation that included 28 percent MAMM, right?
MS. DURIE: You can leave that up.
BY MS. DURIE:
Q. And this is dissolution testing --
MS. DURIE: Sorry, can we get that back up. 13. Great.
BY MS. DURIE:
Q. This is dissolution testing that had been done back in 2009, right?
A. Right.
Q. And you wrote, "Its dissolution profile was tested in a dissolution apparatus in deionized water," but you didn't specify the dissolution apparatus in which the testing had been done, right?
A. I would beg to differ.
Q. Well, you didn't say in a USP 7, did you?
A. No, I wouldn't have to.
Q. Okay.
A. Can I explain -- should I explain why?
Q. I think I know what you're going to say. It says a dip rate of 30 per minute, right?

A. **And intervals --**

Q. **Right.**

A. **-- which are specific terminology of USP 7.**

Q. **And that -- what that tells you, a person of skill in the art, is that this was a USP 7 dissolution testing methodology, right?**

A. **It tells me and anyone familiar with the field.**

Q. **Okay. Now, the '488 -- but you didn't say -- just to be clear, you didn't say tested in a USP 7 dissolution apparatus?**

A. **No, it does not say USP 7.**

Q. **Now, if we go to the claims --**

MS. DURIE: And if we can pull up pretreatment "JTX3.30.2", which is Claim 1 of the '488 patent.

BY MS. DURIE:

Q. **What Claim 1 requires is testing when tested in a Dissolution Apparatus 2, right?**

A. **Yes.**

Q. **In the claim, it actually specifies in those words -- it also says, to be clear, a paddle speed of 50 RPM?**

A. **Yes.**

Q. **Now, paddle speed of 50 RPM is Dissolution Apparatus 2 as opposed to a dip rate of 30, which is dissolution Apparatus 7, right?**

A. **That's correct.**

Q. **Okay. But it was clear in the claim Dissolution Apparatus 2, and the results that you gave the Patent Office were not about Dissolution Apparatus 2, right?**

A. **They were not about Apparatus 2, that's correct.**

Q. **Okay. Now, I think you heard -- I heard you say in your direct examination that results between USP 2 and USP 7 don't really differ that much; is that right?**

A. **In my experience, and also in this program.**

Q. **Okay. Let's take a look at that. Can you turn in your binder to JTX105.**

A. **I see that.**

Q. **JTX105 is a memorandum that you wrote, correct?**

A. **Mm-hmm. Yes.**

Q. **It's from you?**

A. **Yes.**

Q. **Okay. And if you -- and if you take a look there, you wrote this in 2011?**

A. **That sounds right, I don't see the date here, though.**

Q. **Okay.**

MS. DURIE: We offer JTX105.

MR. CALVOSA: No objection, Your Honor.

THE COURT: JTX105 is admitted.

(Exhibit admitted.)

MS. DURIE: And if we could please publish JTX105.3. And if we could blow up --

BY MS. DURIE:

Q. **First of all, that's the memorandum from you, right?**

A. **Correct.**

MS. DURIE: And then let's blow up the bottom portion of the page, multiparticulate sodium oxybate.

BY MS. DURIE:

Q. **Now, this is reporting on dissolution testing that you did on multiparticulates, right?**

A. **I remember this, actually, yes.**

Q. **And you say, "Unfortunately, the coated granules exhibited agitation effects, as evidenced by remarkably faster dissolution in USP 2 versus USP 7, right?**

A. **That's correct.**

Q. **You didn't tell the Patent Office that, right?**

A. **Well, that wouldn't have been germane, this particular example. I'm happy to explain why, but...**

Q. **That's okay.**

Now, you also told the Patent Office in 2018 that your invention included microparticles that specifically included MAMM, and that you had made that invention back in 2011, right?

A. **Um...**

Q. **So if you could turn in your binder to DTX236.**

A. **I'm sorry, you said 236?**

Q. **236, thank you, sir.**

A. **DTX?**

Q. **Do you have it? Oh, sorry.**

A. **Sorry, not yet. I'm at 236.**

MR. CALVOSA: Is it JTX --

BY MS. DURIE:

Q. **DTX236.**

A. **Yes. I found it.**

Q. **I have it. Your binder does not have it?**

MR. CALVOSA: I thought you said JTX.

MS. DURIE: No. Sorry, DTX236.

BY MS. DURIE:

Q. **Did you find it?**

A. **DTX236.**

Q. **Yes.**

A. **A memo, yes.**

Q. **And this is a technical memorandum that you wrote in 2016, correct?**

A. **Yes.**

MS. DURIE: We offer DTX236.

MR. CALVOSA: No objection, Your Honor.

THE COURT: DTX236 is admitted.

(Exhibit admitted.)

BY MS. DURIE:

Q. **And if we could start, please, by going to page 4, 236.4.3.**

This is a review that you put together of Jazz's efforts to come up with a once-nightly sodium oxybate formulation, starting with a collaboration with Shire back in 2002 and continuing through 2015, correct?

A. **Yes.**

Q. **Now, we talked -- I think you talked in your direct testimony about how there was a hiatus at some point; is that right?**

A. **I'm not sure what "hiatus" means, but there was a period of time when I was a one-man show, as I put it.**

Q. **Okay. But work was being done at Jazz on trying to come up with once-nightly in 2006, 2009, 2011, 2011, 2011, 2012, 2013, 2014, and 2015, right?**

A. **Yes.**

Q. **Okay. Now, you have referred to once-nightly oxybate as the Holy Grail, right?**

A. **I don't think I referred to the product as a Holy Grail. I think I meant something different when I said that.**

Q. **Not our product specifically, I agree with that. But the concept of a once-nightly oxybate, you referred to that --**

A. **I don't recall specifically referring to once-nightly as a Holy Grail, but I may have.**

Q. **Why don't you take a look at DTX1274 in your binder.**

DTX1274.

A. 1274. Should I put a pin in --

Q. Yeah, I think that's a good idea. And --

A. It would be great if we had stickies or something.

MS. DURIE: Your Honor, permission to approach.

THE COURT: You may.

THE WITNESS: Oh, thank you.

BY MS. DURIE:

Q. This will help.

A. That was 1274.

Q. 1274. I'm realizing that is tiny, tiny print. So I apologize because --

A. That's all right, I can try to -- I can squint.

Q. Okay. There's an e-mail from you in the middle of the page, Monday, August 18, 2014.

Do you see that?

MR. CALVOSA: Do you --

MS. DURIE: Why don't I put in -- I'll offer DTX1274.

MR. CALVOSA: No objection. That way everybody could see it.

THE COURT: All right.

MS. DURIE: And then why don't we put it up.

THE COURT: DTX1274 is admitted.

(Exhibit admitted.)

BY MS. DURIE:

Q. **And it's not, even as we've done it here, easy to read, but it's talking about Flamel, right?**

A. **Yes. Okay.**

Q. **And it says: If they have actually figured that out then, yes, would be interesting and potentially useful to us, kind of a Holy Grail in our business and to my knowledge hasn't been conclusively shown by any platform.**

That's what you wrote, right?

A. **I remember this and I'm not referring to success in once-nightly here, I'm happy to explain because it's a fascinating topic but I'm not referring to "once-nightly."**

Q. **Well, we have a limited amount of time so I'm going to move along and not get a lengthy explanation of a fascinating topic. If your counsel wants to ask you --**

A. **Okay, fair enough.**

Q. **-- they certainly can.**

Let's go back to DTX236. And let's put back up 236.4.6. So if we go down to 2009, there's a reference there to "PLE-2 (SR tablet)," right?

A. **Yes.**

Q. **And "SR" stands for sustained release, correct?**

A. **Or the core-shell approach that we used.**

Q. **And you would agree that the goal -- and this was the program that led to the filing of the '488 patent, right?**

A. That's correct.
Q. And you would agree that the goal of that program was a single daily dose of tablets, correct?
A. No, I wouldn't agree with that.
Q. All right. If we could please go to your deposition testimony. It's volume 2, 373:19-374:8.
A. When you say "volume 2" --
Q. You'll get to hear it, we're going to actually play it.
A. Oh, okay.
Q. I was just letting your counsel know where we were going to be playing from.
MR. CALVOSA: What was your question, I'm sorry?
MS. DURIE: The goal of the PLE program was a single daily dose of tablets.
And if we could please play that video, that's pretreatment IP2.
(Video clip played.)
BY MS. DURIE:
Q. For the moment, I'm just talking administering a single daily dose to a patient. And so my question is: When is it that you believe that you first invented any formulation that could be administered to a patient for treating disease as a single daily dose?
A. Well, the objective of the PLE-2 program and in the

Allphin-Pfeiffer patent was a single daily dose of tablets.

(End of video played.)

MR. CALVOSA: I object, Your Honor, improper impeachment, it's not the same question.

MS. DURIE: He said the goal of the program was --

MR. CALVOSA: That's not what he said.

MS. DURIE: -- interval daily dose of tablets.

THE COURT: So, all right, the jury has heard it, so we'll -- they'll decide what to make of it.

MR. CALVOSA: Thank you, Your Honor.

BY MS. DURIE:

Q. **Now, you thought about trying to make beads or microparticles back in 2009 as part of that PLE-2 program, right?**

A. **That's correct.**

Q. **Turn in your binder, please, to DTX665.**

A. **Okay. I'm there.**

Q. **Exhibit 665 is a PowerPoint presentation from your files captioned "PLE-2 Formulation Review," correct?**

A. **That's correct.**

MS. DURIE: We offer DTX665.

MR. CALVOSA: No objection, Your Honor.

THE COURT: All right. DTX665 is admitted.

(Exhibit admitted.)

MS. DURIE: Please publish 665.2, and if we can now go to 665.8.

BY MS. DURIE:

Q. **You indicated here that you had rejected several platforms without screening, so a bit hard to read but at the top it says, "Platforms rejected without screening," right?**

A. **That's correct.**

Q. **And one of those platforms that was rejected without screening was the multiparticulate beads/pellets, correct?**

A. **It appears so, yes.**

Q. **And in fact, at that time, you didn't have the equipment in your lab to make oxybate pellets, right?**

A. **That's correct.**

Q. **You also didn't have the equipment to coat pellets in a way that you thought was acceptable, correct?**

A. **Correct, especially given the earlier experiment that you referenced, that was proof that we didn't have the correct coating technology for the job.**

Q. **And so as part of the program that led to the '488 patent, you didn't do what you considered to be any valid experiments with sodium oxybate beads or pellets, correct?**

A. **Well, I thought I did experiments that were translatable to bead or pellet, but we didn't do physical experiments with beads or pellets.**

Q. **You did experiments with tablets?**

A. **That's was the medium we chose for the core, that's correct.**

Q. **Now, let's take a look at your '488 patent, JTX003 in evidence. And go to "Pretreatment" 3.18.8.**

So this is on page 18 at the top of column 3. You talk about a piece of prior art called Liang, right?

A. **Yes.**

Q. **And you say, "The delayed release -- " that was an effort to make a sodium oxybate bead formulation, right?**

A. **That's correct.**

Q. **And you say: "The delayed-release component of the formulations taught in Liang, however, function in a pH dependent manner."**

You said, "however," because you are suggesting that was a potential problem with that prior art, right?

A. **Not necessarily. That it differs from what we did.**

Q. **We'll see. There are examples in your patent, right?**

A. **There are.**

Q. **You provided those examples, right?**

A. **I did.**

Q. **All the examples are tablets, right?**

A. **That's correct.**

Q. **None of the examples have MAMM, right?**

A. **That's true.**

Q. **Now, MAMM is activated in a change in pH, right?**

A. **MAMM itself is, that's correct.**

Q. **None of the examples in your patent were triggered by a change in pH, right?**

A. **Not the written examples, correct.**

Q. **Okay. The things that are called examples?**

A. **Examples, correct, mm-hmm.**

Q. **Right?**

And in fact, you thought that having a pH trigger was less desirable than other approaches, right?

A. **I think that's fair for the implications and the sensitivities that could come.**

Q. **Now, you showed us some experiments from your lab notebook that you testified about on direct. Those experiments are not in your patent, right?**

A. **No.**

Q. **You did not include those examples as examples in your patent, right?**

A. **That's true.**

Q. **That's true even though you had done that experimental work before you had filed your patent, right?**

A. **Yes.**

Q. **And in fact, you don't recall ever coming to the conclusion that it would be acceptable to have a pH trigger, right?**

A. **Well, I don't recall anybody coming to that conclusion, whether it was acceptable or not, all that I recall from the program is that it was less desired than nonenteric approaches.**

Q. **So let me be clear: You don't recall ever coming to the conclusion that it would be acceptable to have a pH trigger, correct?**

A. **I think that is correct, yes.**

Q. **And --**

A. **But I also would like to add, I wouldn't say that it was unacceptable, just that we didn't decide that, yes, this is okay.**

Q. **In fact, you never came to the conclusion that it might be acceptable to have a pH trigger, right?**

A. **Um, I didn't, no.**

Q. **Okay. Now, the examples in your patent use something called ethylcellulose, right?**

A. **That's correct.**

Q. **Ethylcellulose is not a pH trigger, right?**

A. **That's true.**

Q. **And the fact that you could use ethylcellulose to control release doesn't necessarily tell you that any other ingredient could be used successfully as part of a controlled-release formulation, correct?**

A. **I'm not sure of the meaning of your question, are you**

referring to ethylcellulose in its role as a base polymer?

Q. The examples using ethylcellulose would not necessarily tell you whether any of the other polymers that you talked about in your patent application could be used successfully as part of a controlled-release formulation, correct?

A. That's fair, yes.

Q. So you don't know whether the examples teach that you would have a successful controlled-release formulation using MAMM?

A. I think one skilled in the art would probably infer that from what we say elsewhere, but you're right, the examples themselves don't show that.

Q. So, just to be clear, the examples would not tell you it would be possible to have a successful controlled-release formulation that caused methacrylic acid-methyl methacrylate?

A. The examples show the roadmap for how you would characterize it and with ethylcellulose and water-soluble pore formers that would be an example of that, but they don't show exactly what you would get with MAMM.

Q. I'm going to play for the witness his deposition at volume 1, page 125, line 16 through 126, line 2. It's IP 15.

(Video clip played.)

BY MS. DURIE:

Q. Now, none of the examples that you gave in the provisional patent application involve methacrylic acid-methyl methacrylate, right?

A. That is correct.

Q. Would any of those examples tell you that it would be possible to have a successful controlled-release formulation that caused methacrylic acid-methyl methacrylate?

A. I don't know.

(End of video clip.)

BY MS. DURIE:

Q. Now, your original application had a long list of ingredients that might be used as part of a controlled-release formulation, right?

A. I'm sorry, could you ask me that again?

Q. Sure.

Your patent had a long list of potential ingredients, right?

A. In different roles within the formulation.

Q. Sure.

A. Yes, okay.

Q. And when you filed your patent application in 2011, you didn't know which of those other ingredients, other than the ones in the examples, could be used as part of a successful controlled-release formulation, right?

A. **Well, let me explain something.**

Q. **Sir, I would just like if you can, please, a yes-or-no answer to my question.**

A. **Well, I don't know what you mean by "successful," that's the problem. Could you explain to me what you mean by "successful"?**

Q. **Let me see if I can refer to your deposition testimony. This is 12 -- volume 1, 123, line 19-124, line 2.**

"QUESTION: Do you know which, if any of these constituents could be used for a functional coating that would be part of a successful controlled-release formulation for oxybate?

"ANSWER: I don't know."

MR. CALVOSA: Your Honor, I'm trying not to interrupt too much, but this is several times now, that was not the same question. I'll just make my record for objection, but it's not impeachment by any means.

THE COURT: Okay. Well, it's -- well, I'm not saying that -- it's proper cross-examination, he did not answer the question that was asked. And she used his deposition testimony to refresh his recollection. So you'll have a chance to redirect.

MR. CALVOSA: Understood, Your Honor. Thank you.

THE WITNESS: Can I -- now that my recollection has been refreshed, can I answer that question?

BY MS. DURIE:

Q. **That's fine. I -- again, I've got a limited amount of time, so I want to keep trying to --**

A. **Okay.**

Q. **-- to move through stuff.**

When you worked with MAMM -- you did a little bit of work with MAMM in 2009 -- you found some of the results hard to explain, right?

A. **With MAMM?**

Q. **Yeah.**

A. **I wouldn't be surprised. I don't remember, but I wouldn't be surprised.**

Q. **And because you did a limited amount of experimental work with MAMM, you didn't know whether a study would have a reasonable chance of success with a formulation that included MAMM, right?**

A. **I wouldn't know that for certain.**

Q. **Okay. Now, in the '488 patent, you said that you had invented controlled-release formulations that offered consistent oxybate delivery and reduced the likelihood of variances.**

Does that sound right?

A. **I think I remember seeing that passage in the patent,**

yes.

Q. Let's take a look at JTX003. This is the '488 patent.

And if we can actually start on page 1, so JTX003 at 1. The title of your patent up at the top is "Controlled-Release Dosage Forms," right?

A. That's what the title is.

Q. And you said in your direct testimony "controlled release" means "delivering the right drug to the right place at the right time," right?

A. Yeah, in layman's terms, yes.

Q. And if we can now go to page 20, it's pretreatment J3.20.8 column 8 at 31, J3.20.8. This is at column 8.

Your patent says that "controlled-release formulations... offer consistent GHB" -- that's sodium oxybate, right? -- "delivery and reduce the likelihood of undesirable intra- and inter-patient inconsistencies."

Now, was it true that the formulations that you described in the patent reduce the likelihood of undesirable intra- and inter-patient inconsistencies?

A. I don't know. Compared to what?

Q. Okay. In fact, you don't know whether there's any information in your patent that would support that claim, right?

MR. CALVOSA: Your Honor, could we have a

sidebar for a second, please?

THE COURT: Okay.

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

MR. CALVOSA: So the issue with this, Your Honor, is that this is suggesting the claim -- supports his claim was her exact question. There's nothing about patient variability in the claim. If Your Honor remembers this is a DI water dissolution claim, and she just said is that -- is there anything to support your claim for that.

MS. DURIE: I'll use the word different in the claim. I meant assertion, the statement in the patent. I'll use a different word. I'll rephrase it.

MR. CALVOSA: I have been trying to sit down and watch, but this is where she's suggesting there's safety and efficacy limitations in the claims.

THE COURT: Well, the Court has already ruled that there's not safety and efficacy requirements in the claim.

MS. DURIE: Correct.

THE COURT: So let me hear how you're going to rephrase it.

MS. DURIE: So I'm just going to say, "You say in the patent that the formulations you describe will reduce the likelihood of undesirable intra- and inter-patient," and

I want to ask him whether that statement is true.

His credibility as an inventor is obviously at stake, so I just want to ask him whether he will stand by the statements that were made in the patent.

I will also note that one of the unasserted claims relevant to inventorship is specifically about blood levels, so the asserted claims -- none of the claims have safety and efficacy; I agree with that. One of the unasserted claims we're going ask about specifically has to do with blood levels.

MR. CALVOSA: Not in this patent, not relevant to the '488 patent, and if we could get an instruction to the jury that there's no safety and efficacy claims, I have no problem with that.

MS. DURIE: Well, that's -- I think we take that up in the context of jury instructions.

MR. CALVOSA: Well, no, this is being done throughout the trial, and they need to know because they got claim constructions at the beginning and this is a claim construction and they were not instructed on that, because it didn't come up until the *Daubert* motions, Your Honor.

THE COURT: So -- okay. If you want to --

MS. DURIE: We can meet and confer about an instruction.

MR. CERRITO: Not in the middle of an

examination.

THE COURT: Because what Jazz is saying is by asking this question, you're trying to imply that there's safety and efficacy.

MS. DURIE: Let me see if I can make that clear to the jury.

MR. CALVOSA: I'd rather that Your Honor instruct on what the claim means. They didn't have the benefit of that claim construction.

THE COURT: Well, I'm not going to do that unless she gives me a reason to do that.

MS. DURIE: Very good. Thank you. I appreciate it.

(Whereupon, the discussion held at sidebar concluded.)

BY MS. DURIE:

Q. Now, I want to be clear, Mr. Allphin. I'm not asking you about your claims here, right? I'm asking you about this language that appears in the specification and what you told the Patent Office in the description. And you said here that the controlled-release formulations could "reduce the likelihood of undesirable intra- and inter-patient inconsistencies."

You don't know whether there's any information in the patent that would support that assertion being made

in the specification, right?

A. I don't know.

Q. Sorry?

A. That's correct.

Q. All right. And if we take a look at table 5 of your patent, this is pretreatment J3.29.3, we do see some data that's reported in here, right?

A. Yes.

Q. This is data from a human study, right?

A. Yes.

Q. So people were given these tablets and then levels of their blood were measured over time, right?

And if we go to figure 12 of the patent, 3.14, it's pretreatment figure 12A. Figure 12 shows these results, figure 12A. And this is basically showing a graph of what the blood levels of drug look like over time, right?

A. Correct.

Q. And what we see here with the two spikes is Xyrem, right?

A. I --

Q. One dose peak, drops. Middle of the night, second dose peaks, drops, right?

A. That's right.

Q. And if we go to figure 12B, the other line shows the tablets that people were given as part of the study, right?

And this was basically what you were hoping for, right?

A. **Yes, something close to it.**

Q. **Now, this data that you reported in the patent related to people who had fasted for ten hours before they took the drug, right?**

A. **It was fasted state. I don't recall whether it was ten hours, but, yes.**

Q. **And not eating for ten hours before you go to bed is not realistic for most people, right?**

A. **That's true, yes.**

Q. **Okay. Now, when Jazz filed the patent application, it had other data from this study that it didn't give the Patent Office, right?**

A. **I'm not sure when we filed, but, yes, we had other data.**

Q. **And that other data was for people who had eaten before they took the drug, right?**

A. **That's correct.**

Q. **If you can turn in your binder to DTX1406.**

A. **1406, you say?**

Q. **1406.**

A. **I'm there, yes.**

Q. **DTX1406. Are you with me?**

A. **Yes.**

Q. **This is a PowerPoint presentation -- an internal Jazz PowerPoint presentation from October of 2010 called "PLE-2 Formulation Options," right?**

A. **That's right.**

MS. DURIE: We offer DTX1406.

MR. CALVOSA: No objection, Your Honor.

THE COURT: DTX1406 is admitted.

(Exhibit admitted.)

BY MS. DURIE:

Q. **And if we can go to 1406.9 and start with pretreatment 1406.9.1. This is showing the results of that same study that was partially reported in the patent, right?**

A. **The green line, you mean?**

Q. **This data.**

A. **I don't know if it's showing the same results.**

Q. **Well, what we see is the green lines, we see two peaks. That's Xyrem, right?**

A. **That looks like Xyrem, yes.**

Q. **We see another line that is relatively smoother. Now, this is an individual subject, but relatively smoother. If we can go to .2, 1406.09, that's a fasted state, right?**

A. **Okay.**

Q. **And then if we go to 1406.09.3 this is the fed state data, right?**

A. **Looks like it.**

Q. **This is what happened when this patient had eaten before they took the drug, right?**

A. **Yes, I believe they would eat a full breakfast and 30 minutes later be dosed.**

Q. **And what this shows is that they would get peak dosage of the drug about the eight-hour mark, right?**

A. **That is what that one shows, yes.**

Q. **So you would take the drug -- you would take the drug, go to bed, and eight hours later, the drug -- you'd have a peak load of the drug and be extremely sleepy or -- if not asleep, right?**

A. **For some patients such as this one.**

Q. **Okay. And that's really bad, right?**

A. **That would be undesirable, yes.**

Q. **Yeah. Right. And if we can take a look in your binder, sir, at DTX246.**

A. **Okay. I'm there.**

Q. **246, this is an e-mail you wrote in 2013, correct?**

A. **Yes.**

MS. DURIE: We offer DTX246.

MR. CALVOSA: No objection, Your Honor.

THE COURT: DTX246 is admitted.

(Exhibit admitted.)

MS. DURIE: If we can publish 246.2 and if we can blow up portions of that e-mail.

BY MS. DURIE:

Q. This is from you, right, and you're reporting on what Jazz had tried before unsuccessfully, right?

A. Yes.

Q. And I want to say clearly, it's blacked out and I'll represent that's how we received it. I -- we didn't do any of the blacking out.

A. Okay.

Q. And it says, "ER film-coated tablet." That's a reference to the tablets in the '488 patent, right?

A. Yes.

Q. And it says, "Bizarre and completely unacceptable results in fed state (not publicly disclosed)."

That's a reference to data that you did not include in your patent application, right?

A. That's correct.

Q. And if we can now turn in your binder to DTX1412.

A. Okay. I think I'm there.

Q. 1412 is an e-mail that you sent to a colleague in 2019, correct?

A. Yes.

MS. DURIE: We offer DTX1412.

MR. CALVOSA: No objection, Your Honor.

THE COURT: DTX1412 is admitted.

(Exhibit admitted.)

MS. DURIE: And if we could please put up pretreatment 1412.1.3 or just blow that up. That's perfect.

BY MS. DURIE:

Q. **This is in 2019, and you are conducting a retrospective look at Jazz's once-nightly efforts, right?**

A. **Yes.**

Q. **Yes?**

A. **Yes.**

Q. **And number 2, Jazz PLE-2 sustained-release tablet, that's that project that led to the '488 patent, right?**

A. **I'm sorry. I lost my place there for a second.**

Q. **Sorry.**

Number 2, "Jazz PLE-2 SR tablet" --

A. **Yes.**

Q. **-- that's the project that led to the '488 patent --**

A. **It is.**

Q. **-- right?**

And then number 6, "Tris (resinate)," that's trying to make about -- make little resinate beads, right?

A. **That's correct.**

Q. **We're going to talk more about that.**

A. **Sure.**

Q. **And then in the middle, you say, "Flamel (looks okay, but we'll see how efficacy reports)," right?**

A. **Right.**

Q. **Okay. So let's talk about that resinate project. That was actually the project not -- before it became Tris that led to the '782 patent, right?**

A. **Well, Tris is a very specific program that we did. Resinate was work that I did earlier that later we engaged Tris to do some work for us, if that's what you mean.**

Q. **Perfect. So let's shift to the '782 patent.**

A. **Okay.**

Q. **And I want to start -- this is JTX6 in evidence at 19 at Claim 24. And if we can pull up pretreatment JTX6.19.6.**

So this is the asserted claim of the '782 patent. And because it's what we heard referred to as a dependent claim, it's Claim 14 plus that additional requirement in Claim 24, right?

A. **Right.**

Q. **Now, you're not sure whether you are an inventor of that formulation that is in Claim 24, right?**

A. **I am pretty sure that I am. I may have said something differently a year and a half ago, but I have all those elements and I have reviewed documents that suggest I knew all of those things at that time.**

Q. **Well, going back to a year ago or so, when you gave your deposition, again, you understood that you were testifying on behalf of Jazz?**

A. **Mm-hmm.**

Q. **As Jazz's corporate representative, right?**

A. **Yes.**

Q. **You understood that was our opportunity to learn from you what you thought your inventive contributions were, right?**

A. **(No response.)**

Q. **And as you said, you looked at documents to get ready for that deposition, right?**

A. **I looked at some, many documents.**

Q. **Right. Over the space of two and a half days, right?**

A. **Yes.**

Q. **You did your best to get ready for that deposition, right?**

A. **And I have to confess, I'm not as good a crammer as some people are.**

Q. **Well, as good a crammer, I mean, whether you invented one of the claims of your patent is not something -- is that something you need to cram up on?**

A. **No. However, I have done a lot in the intervening years and I forget things.**

Q. **Let's take a look at what you said in your deposition. It's volume 1 --**

MR. CALVOSA: Objection, that is not proper impeachment whatsoever. He said he said something different. Once they say that, you can't go to the

deposition transcript.

MS. DURIE: This is --

THE COURT: Let's limit the argument before the jury.

MR. CALVOSA: I apologize.

THE COURT: You have an objection, say objection, we'll see if we can come to sidebar.

Let's -- let me see the deposition excerpt before we deal with this issue.

MS. DURIE: Yes, it is volume 1 -- do you want to see it here, I can bring it.

THE COURT: Okay.

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

MS. DURIE: This is the witness's 30(b)(6) deposition testimony. Topic 20 is that claim. And I asked him, "Do you consider yourself to be an inventor of the formulation?"

He said, "I don't know."

THE COURT: All right. Okay.

MS. DURIE: It's 30(b)(6) testimony, that was the company's position. He's now saying something different. I can impeach him with his inconsistent testimony and his 30(b)(6) testimony.

THE COURT: Yes.

MR. CALVOSA: Your Honor, when he says "I said something different" --

THE COURT: But she can still ask him. You'll get a chance to redirect, but she gets to make the point.

MR. CALVOSA: Okay. I understand. Thank you, Your Honor.

(Whereupon, the discussion held at sidebar concluded.)

MS. DURIE: If we could please play pretreatment IP 21.

(Video clip played.)

BY MS. DURIE:

Q. **Turning to topic 20, which references a formulation of GHB with immediate-release particles and modified-release particles with certain characteristics as set forth in topic 20, do you consider yourself to be an inventor of the formulation that is described in topic 20?**

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

(End of video clip.)

BY MS. DURIE:

Q. **And just to make the record clear, Mr. Allphin, topic 20, if you turn in your binder to 234.1 -- 234, sorry, to Exhibit 234.**

A. **Is it DTX or --**

Q. **DTX234.**

You see that DTX234 is the topics from your deposition? Sorry.

A. **Sorry. I'm almost there. Yes.**

Q. **And if you turn to topic 20, it's on page 8 -- or sorry, on page 9.**

A. **Okay.**

MS. DURIE: And if we can put back up, please, pretreatment J6.19.6, that's Claim 24.

BY MS. DURIE:

Q. **Topic 20 was experiments conducted on a formulation of GHB comprising a plurality of immediate-release particles comprising GHB, a plurality of modified-release particles comprising GHB, a viscosity enhancing agent, and an acid, wherein the viscosity enhancing agent and the acid are separate from the immediate-release particles and the modified-release particles.**

That was topic 20, correct? That was topic 20 as to which at your deposition you said you did not know whether you were an inventor, correct?

A. **I don't recall what I said at the deposition.**

Q. **We just played it, right?**

A. **I thought you were referring to Claim 14 earlier, but okay, that's fine.**

MS. DURIE: And, Your Honor, I offer now as substantive evidence under FRE 613 the deposition excerpt at

56:24 to 57:7, because the witness had been given an opportunity to explain and it is a prior inconsistent statement.

MR. CALVOSA: I got to get that Your Honor, I apologize.

THE COURT: Any objection?

It's admitted, let's go.

(Exhibit admitted.)

MS. DURIE: Thank you.

BY MS. DURIE:

Q. **Now, sir, with respect to topic 20, which is Claim 24, you don't know when you first thought about that formulation that is Claim 24, correct?**

A. **I don't know exactly when I thought of that, that's true.**

Q. **Okay. You don't know whether you first thought of the formulation that is Claim 24 before or after you learned that Avadel had filed for a patent on it, correct?**

A. **I don't recall when I came up with this idea, but it would have been before 2016.**

MS. DURIE: Your Honor, I'm going to play from the witness's deposition at page -- volume 1, page 58, 11-18.

And could I ask the Court to turn the volume up a little bit, would that be possible? I think the Court

controls the volume.

THE COURT: Okay. We -- they control the volume, right?

MS. DURIE: Could we turn it up a little? Just in general. I was finding it at least hard to hear.

Could we please play pretreatment IP 20.

(Video clip played.)

BY MS. DURIE:

Q. Did you first contemplate the formulation that is described in topic 20 before or after you acquired a general understanding that Avadel had filed for patent claims on such a formulation?

A. I don't recall.

(End of video clip.)

MS. DURIE: Now, if we can go back to pretreatment J.6.19.11, Claim 24, and put that back up.

BY MS. DURIE:

Q. In Claim 24, the acid is separate from the immediate-release particles and the modified-release particles, right?

A. Yes.

Q. Now, none of the examples in the '782 patent include an acid and that viscosity enhancing agent separate from the immediate-release and modified-release particles, right?

A. That's right.

Q. **Okay. And at the time of your deposition, you didn't know what the purpose of having an acid in the formulation even was, right?**

A. **I couldn't recall, my memory was fuzzy, that's correct.**

Q. **Now, you included examples in your patent, right?**

A. **Yes.**

Q. **And you had some concepts, right?**

A. **That's true.**

Q. **But you had not experimentally proven those concepts, right?**

A. **Not all of them.**

Q. **Okay. Well, let's take a look at JTX6.9, JTX6 in evidence. '782 patent at page 9.**

MS. DURIE: And let's pull up at column 6 -- pull that up. Let's go to column 6 around line 43, starting about halfway down the page.

BY MS. DURIE:

Q. **In your specification --**

MS. DURIE: Just blow up that whole paragraph, that's fine.

BY MS. DURIE:

Q. **-- you say -- you talk about the invention providing a formulation which delivers a controlled-release profile, right?**

A. **Okay, yes.**

Q. **And if we take a look at Claim 19 of your patent, pretreatment J.6.19.5, one of the claims that you submitted was a unit dose wherein eight hours after administration of the formulation provides a blood concentration ranging from 15 milligrams per liter to about 30 milligrams per liter.**

Now, there's no data in your patent showing any blood levels, right?

A. **That's correct.**

Q. **Much less a particular concentration after a particular point in time, correct?**

A. **That's correct.**

Q. **And you're not aware of any data in your patent from which you could figure out those blood levels, right?**

A. **Not in this patent, no.**

Q. **In fact, the only place in this patent that talks about specific blood levels is example 3, right?**

A. **I don't --**

Q. **Let's take a look at example 3, it's pretreatment J.6.18.5, it's page 18 and it's column 23.**

So example 3 is talking about sampling blood, right?

A. **Mm-hmm.**

Q. **This is not an experiment that you actually performed, right?**

A. **This is what we call a prophetic example, yes.**

Q. **Right. That means you didn't do it?**

A. **Yes, it's how we would do it if we did.**

Q. **So you don't know what the results of this experiment would have been because you didn't do it, right?**

A. **Well, yes, we're stating what our expectation was. But until you actually do something, you don't really know for sure.**

Q. **Right. Well, and you don't provide any results, right?**

A. **That's correct.**

Q. **You don't provide the results because you didn't have the results, right?**

A. **We didn't do the experiment, that's true.**

Q. **Right. So now I want to talk briefly about the work you did do back in 2015.**

You were looking for a way to make a bead-based solution for sodium oxybate, right?

A. **That was one of the things we were looking at, yes.**

Q. **And you started that work after you learned that Avadel was already working on beads, right?**

A. **That sounds about right, yes.**

Q. **And if we could, please, have you -- if we can actually put up DTX236, which I believe is now in evidence, and put up pretreatment 236.7.1.**

You are discussing here in the technical memo that -- you wrote that, "In 2014, Flamel," that's Avadel, "announced acceptable PK results with a multiparticulate approach," that's beads, right?

A. **That's correct.**

Q. **And you wrote, "This triggered a reassessment of conventional sodium oxybate delivery options and, in particular, reconsideration of the root cause of PLE-2 failure."**

That's the failure of the program that led to the '488 patent, right?

A. **Correct, although it says "cause," but that's correct, yes.**

Q. **Now, and you decided to try and go back and figure out why that project had failed, right?**

A. **Reconsidering, yes, means that, reflecting on it.**

Q. **Turn in your binder, please, to 248.**

A. **Okay. I'm there.**

Q. **248 is an e-mail that you sent on October 12th of 2014.**

A. **October 13th, 2014, yes.**

MS. DURIE: We offer 248.

THE COURT: Any objection?

MR. CALVOSA: No objection, Your Honor.

THE COURT: All right. DTX248 is admitted.

(Exhibit admitted.)

BY MS. DURIE:

Q. And if we -- sorry.

MS. DURIE: If we could please publish 248.2.

BY MS. DURIE:

Q. So there's an e-mail here at the bottom from you to one of your colleagues, "Re: Flamel Patent."

And you say, "My thinking on what -- I looked at the PK data on PLE-2 again," and then you say, "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."

This was in October 2014.

A. Yes.

Q. And you knew that Avadel had already been working on sodium oxybate beads for probably years, right?

A. I assume so, although I didn't know for a fact they were working on it.

Q. And so in late 20- -- late January of 2015, you were ordering materials and thinking about preparing a prototype, does that sound right?

A. What date did you say?

Q. Sorry? January of 2015.

A. 2015? That seems about right when we would have done the work with resinates.

Q. **And you started doing some work with resins and you discovered that resins are a lot more complicated than you thought, right?**

A. **Well, I didn't discover, I -- yes, I reasoned that they were complicated and I explored the ways that those complications could be exploited.**

Q. **Please take a look in your binder at DTX55.**

A. **55, okay. I'm there.**

Q. **DTX55 is an e-mail that you wrote in February of 2015, correct?**

A. **Yes.**

MS. DURIE: We offer DTX55.

MR. CALVOSA: No objection, Your Honor.

THE COURT: DTX55 is admitted.

(Exhibit admitted.)

MS. DURIE: Please publish 55.1.1.

BY MS. DURIE:

Q. **And if we look at your e-mail dated February 1, 2015, and just blow up that bottom portion, you say, "Resins are a lot more complicated than seem at first glance."**

Right?

A. **Mm-hmm, yes.**

Q. **And you actually wrote right under that, "there's a decent risk the approach might not work."**

Right?

A. **There are interesting things about resinate that, um, yes, there's a chance that it wouldn't work.**

Q. **And this is February 1, 2015, you filed your provisional patent application two and a half weeks later, right?**

A. **Yes.**

Q. **Now, if you can please turn to PTX1174. "PTX" this time, 1174.**

A. **You said 1174?**

Q. **Yeah, 1174, it's a lab evaluation chart oxybate SR. Do you see that?**

A. **I see that.**

MS. DURIE: We offer PTX1174.

MR. CALVOSA: No objection, Your Honor.

THE COURT: PTX1174 is admitted.

(Exhibit admitted.)

BY MS. DURIE:

Q. **And if we take a look at 1174.1, you were doing work trying to layer things on sugar beads, right?**

A. **It looks like that, yes.**

Q. **And you couldn't get it to work, right?**

A. **No.**

Q. **So you abandoned that approach, right?**

A. **Did not have the right equipment to do that.**

Q. **And in fact, you couldn't even make immediate-release**

beads, right?

A. I think that's fair to say, immediate-release beads that would be suitable for coating, we didn't have a way to do that.

Q. Okay. And in fact, even after you filed that provisional patent application, you thought a resinate approach was unlikely to be successful as a mechanism for obtaining a sustained-release formulation, right?

A. My thinking on the resinate evolved during my analysis of that problem. I'm sure that at some point I thought it was not likely to work and other times, I thought it was more likely.

Q. But even after you filed that provisional patent application, for a period of time, you thought it was unlikely to work, right?

A. I thought it was likely enough to work that we funded the work to actually do it.

Q. You thought it had a relatively low probability of success but not vanishingly low.

Does that sound familiar?

A. Yeah, that sounds like what I said, enough chance of success that it's worth spending money on.

Q. And as of February 11th, 2016, when you then filed the formal patent application, you had a theory that you could use a resin to slow down release, right?

A. That's correct.
Q. You didn't have any data about how a resinate formulation would release in water, right?
A. I'm not sure what you mean. In analyzing resins, I think we went through this with the deposition, we do release it in water.
Q. You didn't have dissolution data when you filed --
A. Right.
Q. -- the patent application --
A. That is correct.
Q. -- in February of 2016?
If you can please turn in your binder to DTX675.
A. 675. It would have been nice if you gave me two binders.
Q. I know. 675.
A. Bear with me one second, I think I've got it. Okay I'm there.
Q. DTX675 is an e-mail you sent in January of 2019?
A. Yes.
MS. DURIE: We offer DTX675.
MR. CALVOSA: No objection, Your Honor.
THE COURT: DTX675 is admitted.
(Exhibit admitted.)
MS. DURIE: Please publish 675-1.
BY MS. DURIE:

Q. **Let's take a look at the top and blow that up. January of 2019, you wrote that, "Jazz only got into once-nightly because Flamel went there first so Jazz had to follow," correct?**

A. **Yes.**

Q. **Okay.**

MS. DURIE: Your Honor, we have a number of exhibits to admit through this witness, I provided the list to counsel for Jazz, I believe there is no objection. It is -- I will read the list of numbers.

It is DTX661, DTX50, DTX1423, JTX251, PTX906, PTX1167, DTX1707, JTX242, DTX1367, DTX1454, DTX1396 and DTX1673.

MR. CALVOSA: Your Honor, perhaps there was a misunderstanding beforehand. I thought she was at least going to show the documents to the witness, that's what the pretrial order says you have to do.

MS. DURIE: We actually had an explicit discussion about that. These are documents, Your Honor, for which this witness has the foundation in the sense that they are documents he wrote, the experts are going to talk about them substantively.

THE COURT: Okay. So Jazz is saying that they didn't just stipulate that they would be admitted, so he's saying that you have to show him the document.

MS. DURIE: So --

THE COURT: Is that what you're saying?

MR. CALVOSA: I said ahead of time that we wouldn't have objections to them but I thought you still had to show them.

MS. DURIE: So I think what I had said was I wanted to bulk admit these to lay the foundation. I'm happy if they get admitted through the expert in question, whoever talks about them, but I would like an agreement that this witness has laid a foundation for the documents so I don't have to spend a lot of time putting each of them in front of the witness saying, "This is an e-mail that you wrote."

MR. CALVOSA: Yeah, I think that's -- yeah, for otherwise not having an objection, that's fine.

MS. DURIE: Very good.

MR. CALVOSA: But hopefully it goes both ways because it seems like a timesaver.

MS. DURIE: It does seem like a timesaver.

THE COURT: What's good for the goose is good for the gander, so I will assume that we do this -- for this witness for Avadel, Avadel will be fine with Jazz doing the same?

MS. DURIE: Absolutely.

MR. CALVOSA: Thank you, Your Honor.

MS. DURIE: Thank you, Your Honor.

Mr. Allphin, thank you for your time, pass the witness.

THE COURT: All right.

Redirect examination.

So that I'm clear, are we admitting these documents?

MR. CALVOSA: Yes, Your Honor.

THE COURT: So DTX661, DTX50, DTX1423, JTX251, PTX906, PTX1167, DTX1707, JTX242, DTX1367, DTX1454, DTX1396 and DTX1673 are all admitted.

(Exhibit admitted.)

MS. DURIE: Thank you.

REDIRECT EXAMINATION

BY MR. CALVOSA:

Q. **Hello, Mr. Allphin.**

A. **Hi.**

Q. **I'll try to be as quick as I can but there was a lot there and there was a lot of flipping through documents without giving you a chance to actually answer in certain instances.**

So do you remember when counsel put up Claim 24, the '782 patent, on the screen and asked you if you were the inventor of that claim?

A. **I think so.**

Q. **And you said yes.**

A. **Mm-hmm.**

Q. **And then she referred to some deposition testimony with this Topic 20, do you remember that?**

A. **Yes, I'm -- yes.**

Q. **Did you see her put Topic 20 up on the screen?**

A. **No, that's what confused me, I did not.**

Q. **Let me read Topic 20 to you, it's, "Experiments conducted on a formulation of GHB --"**

MS. DURIE: Your Honor, I object, that is an incorrect reading of Topic 20, if I could please have the DTX number.

MR. CALVOSA: DTX234, "Experiments Conducted."

(Discussion held between counsel off the record.)

THE COURT: All right. So you withdraw the objection?

MS. DURIE: I do, thank you.

BY MR. CALVOSA:

Q. **Now we can hear what it actually says: "Experiments conducted on a formulation of GHB comprising a plurality of immediate-release particles comprising GHB, a plurality of modified-release particles comprising GHB of a viscosifying enhancing agent and acid where the viscosifying and enhancing agent and acid are separate from the immediate-release particles and the modified-release**

particles."

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?

A. Well, experiments conducted, you don't invent experiments, so I was confused about what exactly was being asked from me.

Q. Okay. I want to go next to something else that might have been confusing. Counsel kept using words like "success" and "acceptable" and "worked," and you said you didn't understand what that means. When you were answering questions at your deposition, what did you understand success to mean?

A. Well, in my deposition, I took a very high standard, and success to me in that context meant did you prove it, did you actually go all the way with it.

So, for example, if I have a particular formulation that was successful in vitro in a lab in small experiments, it's not necessarily proven to be successful when you scale it up. And so in some respects, I took a high standard with that.

Q. And when you mean "scale it up," are you taking about efficacy studies?

A. Going all the way, yes, efficacy studies or at least going far enough that you're absolutely sure that you can

commercially manufacture that formulation.

Q. Do you remember counsel asking you --

A. If I can add that in some cases, I remember answering questions with two specific ingredients, and those I was absolutely sure because we had scaled them up all the way.

Q. When -- do you remember counsel asking you questions about you looking at Avadel's patent application and then filing claims?

A. I remember -- it's been a long -- almost two hours --

Q. Sure. Why don't I show you that, because then she showed you some documents afterwards where you were breaking down that formulation.

A. Mm-hmm.

Q. Can you pull up DTX483, please. Let me get the exact page number that she referenced. Let me ask my colleague to help and I'll ask you another question.

MR. CALVOSA: May I just step back, Your Honor?

THE COURT: Yes.

(Discussion held off the record between counsel.)

MR. CALVOSA: All right. Let me move on to something else and then I'll come back to that, I promise.

Can we please pull up JTX104. And can we please go to page 5. And let's go to page 6, actually.

BY MR. CALVOSA:

Q. **And do you remember counsel asking you this question about a declaration you put in to the Patent Office?**

A. **Yes.**

Q. **And she said, Were you honest when you signed that declaration?**

A. **Yes, and I was.**

Q. **Okay. Have you ever lied to the Patent Office?**

A. **Absolutely not.**

Q. **Would you ever lie to the Patent Office?**

A. **No.**

Q. **Why not?**

A. **I have too much respect for patent examiners and the office in general. I wouldn't do that.**

MR. CALVOSA: Let's go back to the previous page, and let's blow up paragraph 13, please.

BY MR. CALVOSA:

Q. **Do you remember counsel implying that you didn't tell the patent examiner that you used USP Type 7 apparatus in here?**

A. **Yes, I remember that.**

Q. **Can you explain to the jury why -- why you feel you told the patent examiner you used USP Type 7?**

A. **Yeah. I may not remember everything that was said in that interview. There was so many interviews. But I remember that patent examiner. I remember him well, and**

that guy was super sharp. There's no way I could pull the wool over his eyes even if I wanted to, and I wouldn't do that. He certainly knew the field very well, and I'm absolutely sure he knew that 30 dips per minute and intervals, that meant USP 7.

Q. And why does 30 dips per minute at intervals mean USP Type 7 and not USP Type 2?

A. Well, because they only apply to USP Type 7. When you say, for example, USP Type 2, you usually also say the paddle RPMs. You say the paddles and the stir rate because those are the parameters that describe that.

When you say USP 7, you don't need to say it. If you say dip rate of 30 per minute and intervals, those are the parameters that describe that test. Everybody knows that that's USP 7.

Q. And the examiner that you were meeting with, is he somebody in the field?

A. Absolutely. A pretty sharp guy.

Q. And now, I promised, let's go back to DTX483.

A. Okay.

MR. CALVOSA: And let's go to page 19 of that exhibit, please, Mr. Lewis.

BY MR. CALVOSA:

Q. And do you see where they said you were breaking down Avadel's formulation?

A. **Yes.**

Q. **Okay. And that formulation, the 2018, what does that signify at the top?**

A. **I don't know what you mean.**

Q. **I'm sorry. The US 2018.**

A. **Yeah, that looks like -- that must be their patent application.**

Q. **The one we looked at before that published in 2018?**

A. **Yes.**

Q. **And that published after you had filed your patents?**

A. **Yes.**

Q. **And that published after all the work we looked at that you did?**

A. **Long after, yes.**

Q. **Do you remember counsel showing you a document from 2010, very beginning of your -- of your cross-examination?**

A. **I think I know what you're referring to, yeah.**

MR. CALVOSA: Let me see if we can find it. Can we pull up DTX361 -- 1361.

BY MR. CALVOSA:

Q. **Now, you see this e-mail originally came from a Brent Clough at InnerVation LLC?**

A. **Yeah, I don't know who that is, but I see that.**

Q. **That e-mail is not a Flamel e-mail address, is it?**

A. **No.**

Q. **That e-mail is not an Avadel e-mail address, is it?**

A. **No.**

Q. **Okay. Would you expect that if Avadel's accusing you of taking something from them, they would bring this Brent Clough to trial?**

MS. DURIE: Objection, Your Honor. Argumentative. There's no accusation.

MR. CALVOSA: You said during your opening "they took it from us."

THE COURT: Hold on. Hold on.

MS. DURIE: Not in 2010.

MR. CALVOSA: I'll withdraw the question, Your Honor.

THE COURT: All right. The question is withdrawn.

BY MR. CALVOSA:

Q. **Last question for you, Mr. Allphin. We saw your work. We saw your thinking and your ideas. Counsel is pointing out that not everything that was in your patent is an example. Would it be possible to put all of your work into the patent as examples?**

A. **I suppose it might be possible, but it would be one hell of a long application, not practical.**

Q. **Based on your experience in the pharmaceutical industry, do scientists often not put all of their work into**

the examples of the patent?

A. **That's fair to say. What we do is we put the teachings, the learnings from the works, and the approaches, we describe those well. But with a limited amount of white space that we have in a patent, you write examples for what you are immediately going forward with.**

Q. **And I said the famous last words that that was my last question. I got one more from the back here.**

A. **Okay.**

Q. **Can we please go to DTX1274. Remember this small document, the small print?**

A. **Yes.**

Q. **Originally counsel didn't put it up on the screen, and I invited her to put it up and blow it up.**

A. **Okay.**

Q. **All right. She asked you about the Holy Grail, remember?**

A. **Mm-hmm.**

Q. **And she implied that you were after the Holy Grail, once-nightly oxybate.**

A. **Yeah, she implied that, yes.**

Q. **And you wanted to explain.**

A. **Yeah, no, Holy Grail -- in drug delivery, one of the hardest things to do is deal with drugs that have a limited absorption window. If it doesn't absorb well throughout the**

GI, you only have a little bit of space to deliver that drug. One of the strategies that people have used is to try to slow down the rate that it goes through your intestines, and it turns out that it is incredibly hard to do that. Nobody to my knowledge has actually proven that they've done that, proven it with scintigraphy studies. And I think there was an article from Davis, who is the DTX1274, Green Buildings advisor, basically saying so, that we were skeptical of Avadel's claims that they had done that, but if they had done that, what I meant was kudos to them because that's something that's very difficult to do in the field.

Q. So you --

A. It's not about once-nightly. It's really more about the platform technology and what a wonder that would be if it actually delivered that promise.

MR. CALVOSA: Thank you, Mr. Allphin.

I have no further questions, Your Honor.

THE COURT: All right. Mr. Allphin, you may step down. Thank you, sir.

All right. Jazz, you may call your next witness.

MR. CALVOSA: Your Honor, I just noticed 3:50, and I know you had said we were going to break usually at 3:50.

THE COURT: We're good -- no, because we started

at 2:10, we got that started, so we're going to go a little longer.

MR. CALVOSA: Okay. Understood, Your Honor. Plaintiffs call Herve' Guillard.

THE COURT: All right. Mr. Guillard, you may take the stand.

HERVE' GUILLARD, having been called on the part and behalf of the Plaintiff as a witness, having first affirmed to tell the truth, testified as follows:

CROSS-EXAMINATION

THE COURT: All right. Distribute the binders.

MR. CALVOSA: May I approach, Your Honor?

THE COURT: Yes.

BY MR. CALVOSA:

Q. Good afternoon. Your name is Dr. Herve' Guillard, right?

A. Yes.

Q. And even though Jazz has called you as a witness, you are a former Avadel employee, right?

A. Yes.

Q. Okay. And before Avadel, you worked at Flamel, right?

A. Yes.

Q. And then Flamel became Avadel?

A. Yes, that's correct.

Q. **So today is it okay if I just refer to both as "Avadel"?**

A. **Yes.**

Q. **You were a scientist at Avadel, right?**

A. **Yes.**

Q. **And you worked in the research and development department at Avadel, right?**

A. **That's correct, yes.**

Q. **And specifically, the formulation department?**

A. **Yes.**

Q. **And you worked on a project called FT-218?**

A. **That's correct, yes.**

Q. **And FT-218 was work on a once-nightly formulation of sodium oxybate that was done at Avadel, right?**

A. **Yes.**

Q. **And internally at Avadel, the FT-218 project went by the code name Project Dodo, right?**

A. **Yes.**

Q. **Avadel's work on FT-218 began in 2012?**

A. **Yes.**

Q. **The work you did on FT-218 is summarized in a formulation development report that you were the author of?**

A. **In fact, we wrote several development reports. So, yes, there were several reports summarizing all the work.**

Q. **And if you could please turn in your binder to**

JTX230.

MR. CALVOSA: And, Your Honor, move to enter that into evidence.

MR. BRAUSA: No objection.

THE COURT: All right. JTX230 is admitted.

(Exhibit admitted.)

BY MR. CALVOSA:

Q. JTX230 is the earliest development report that you authored, right?

A. Yes, it is the first one.

Q. Okay. And it says right there, "sodium oxybate CR, granules for oral suspension," right?

A. Yes, that's correct.

Q. And "CR" there stands for controlled release?

A. Yes.

Q. And even though it says "formulation development report 2013," the date of your report is June 11th, 2014?

A. Yes.

Q. And if you could please turn to page 2 of the report. The first author listed there is yourself, right?

A. Yes.

Q. And that's your signature there?

A. Yes.

Q. And, again, that's on June 11th, 2014?

A. Yes.

Q. **And your signature on this document means that you -- you had authored the document and it was approved by your superiors and you all agreed on it?**

A. **Yes, it is the final version, yes.**

Q. **Can you please turn to page 38. And I'm looking at figure 24. And not to scale, but figure 24 is a representation of the modified release microparticles that you were working on?**

A. **Well, in fact, we developed three different prototypes, and the development work is summarized in that development report. And one of the three prototypes contains modified-release microparticles, sorry, and they are all depicted there on the screen.**

Q. **Okay. And in that modified-release microparticle, you use a methacrylic acid-methyl methacrylate copolymer, right?**

A. **Yes, we used two different polymers, yes.**

Q. **Sir, in that figure, you use a methacrylic acid-methyl methacrylate copolymer, right?**

A. **Yes.**

Q. **Okay. And that -- can I call that MAMM just so it's easier for everybody?**

A. **Sorry?**

Q. **May I call the methacrylic acid-methyl methacrylate copolymer MAMM?**

A. **Yes, it would be easier.**

Q. **Yes, much easier.**

And the MAMM copolymer in that modified-release particle is Eudragit S100, right?

A. **You said the MAMM?**

Q. **The MAMM.**

A. **Well, to be honest, the chemical names are so complicated, as you've seen. In fact, both are very -- chemicals with very related, very close structure. So, in fact, there's a mixture of two -- MAMMs that chemical structure is very, very close. And they are both enteric polymers.**

Q. **Okay. You don't know which one of those two is the MAMM copolymer?**

A. **Well, to be honest, the methacrylic acid ethyl acrylate, MAMM and methacrylic acid-methyl methacrylate. I never remember, so I'm sorry, it's so complicated, which one is which one, but there is a mixture of both.**

Q. **The one that says 26.7 percent Eudragit S100, Eudragit S100 is a polymer of carboxylic acid, it's a copolymer of methacrylic acid-methyl methacrylate, right?**

A. **Yes.**

Q. **So that's the MAMM?**

A. **Yes.**

Q. **And, again, you use it at 26.7 percent, right?**

A. **Yes, in the Micropump II layer, yes.**

Q. **And that's the -- in the functional coating?**

(Reporter asks for clarification.)

THE WITNESS: Yes, in the Micropump two layer. Which is the functional coating.

BY MR. CALVOSA:

Q. **And you tested the formulation of FT-218 in dissolution testing, right?**

A. **Well, in fact, yes, all the formulations have been tested, yes.**

Q. **Okay. And dissolution testing is in vitro testing, right?**

A. **Yes, in vitro meaning not in real conditions on human, but in the lab.**

Q. **And dissolution testing in vitro, the idea is that allows you to have an approximate simulation of what takes place in vivo?**

A. **Well, in fact, you can never know by using tests performed in the lab what will occur in vivo, of course. But, in fact, we try and give some insight of what can happen in vivo using information.**

Q. **Dr. Guillard, do you remember I took your deposition in this case? Do you remember we were over the computer, I asked you questions, you answered?**

A. **Yes.**

Q. **At that deposition you said you didn't speak English well and needed an interpreter?**

A. **Yes.**

Q. **Okay. You're speaking English here today?**

A. **Not on a daily basis but I understand.**

Q. **I'm sorry?**

A. **You asked me if I speak English sufficiently well, that was the question.**

Q. **Okay. Do you understand my questions when I'm asking them to you today?**

A. **Yes, I understood your question.**

Q. **And you told the truth at your deposition, right?**

A. **Yes.**

Q. **And you had a chance to review your deposition answers afterward and fix anything you wanted to, right?**

A. **Yes.**

Q. **Okay. If I could direct you in your binder to your deposition transcript.**

A. **Yes.**

Q. **You have that pulled up?**

A. **I'm sorry, is the deposition in the binder?**

Q. **There's a deposition in the binder, it's the last one, it should be.**

A. **Which tab? So sorry.**

THE COURT: There's no deposition transcript in

the binder.

BY MR. CALVOSA:

Q. The dissolution testing that you conducted in this development report was all at buffered pH, right?

A. Well, we perform several kinds of dissolution profiles but they were all performed, yes, in different buffer level.

Q. Okay. And that means a pH is held at a certain level, right?

A. Yes.

Q. And for the dissolution testing of FT-218, you were responsible for a team that conducted that testing, right?

A. Well, in fact, we were conducting the test and, in fact, some were analyzed by the analytical lab, so it was work performed with another team. But, in fact, I conducted some of the experiments.

Q. Sir, you were responsible for a team of technicians that conducted the testing?

A. Yes.

Q. You did not conduct the testing yourself?

A. Not myself, personally.

Q. The technician who conducted the dissolution testing recorded the experiments and the results and signed the laboratory notebook that they're in, right?

A. Yes. Each experiment was -- in fact, the results

they were all filed and written in a lab notebook, yes, and signed by them.

Q. And you later signed that same lab notebook, right?

A. Yes.

Q. And when you signed it, it meant that you had reviewed the experiment protocol and it was in line with what had been agreed, right?

A. Yes.

Q. And it also meant, your signature, that you had reviewed the results and understood the results?

A. Yes.

Q. And your signature meant that you believed the information in that notebook was accurate, right?

A. Yes. A mistake is always possible, but, yes. In fact, there is no -- yes, I think it was correct if I signed it, yes.

Q. At the time of this development report we're looking at in June of 2014, you had not conducted any dissolution testing in deionized water of FT-218, right?

A. Yes, that's correct.

Q. Aside from working in formulation at Avadel, you also had responsibilities for drafting patent applications, right?

A. Well, in fact, I was in involved in drafting applications, the part of these applications relating to the

formulation work because I was a formulator at that time.

Q. Could you please turn to JTX260 in your binder.

MR. CALVOSA: And Your Honor, move to admit JTX260 at this time.

MR. ZUBICK: No objection.

THE COURT: JTX260 is admitted.

(Exhibit admitted.)

BY MR. CALVOSA:

Q. This is a patent related to FT-218 where you are a named inventor, right?

A. Yes.

Q. And if you look down at the Application No. 15/655,924, you were involved in drafting the application that led to this patent, right?

A. Well, I have written the experimental section, the examples, and some sections relating to the formulation.

Q. And you understand that the application consisted of the specification that is part of this document we're looking at now that is JTX260?

A. So what do you mean by "specification"?

MR. CALVOSA: May I approach?

THE COURT: Yes.

BY MR. CALVOSA:

Q. Just before I ask again, the JTX260 is the '062 patent?

A. **Yes.**

Q. **If you turn to page 116 of the deposition transcript I just gave you, line 4 to line 7.**

"QUESTION: --

A. **Can you please repeat which page, sorry.**

Q. **Page 116, line 4 to line 7.**

"QUESTION: And you understand that the application consisted of a specification that is part of this '062 patent that we're looking at?"

And you answered "yes," right?

A. **Yes.**

Q. **And just so we're all on the same page, you understand that the patent specification that you drafted, that's the part of the patent up until the claims that's supposed to provide a description of the invention, right?**

A. **Yes.**

Q. **At the time your patent application was filed with the United States Patent Office, you believed everything in there to be true and accurate, right?**

A. **Yes.**

Q. **And you still believe that, sitting here today?**

A. **Yes, of course.**

Q. **Let's go to page 74 of JTX260. And I'd like to look at table 1a.**

Table 1a gives the composition of the

immediate-release microparticles of FT-218, right?

A. **Yes, that's correct.**

Q. **And sodium oxybate is a component of those immediate-release particles, right?**

A. **Yes.**

Q. **And sodium oxybate is the active pharmaceutical ingredient in FT-218, right?**

A. **Yes, the drug, yes.**

Q. **I'd like to go down now to table 1b. Table 1b gives the composition of the modified-release particles in FT-218, right?**

A. **Yes.**

Q. **And table 1b in your patent says that the IR microparticles are the core of the MR microparticles, right?**

A. **No, what is said is that the function is the core of the MR microparticles, that is what is written, it's their function.**

Q. **Is the function, they function as the core?**

A. **Yes.**

Q. **Part of your responsibilities in the R&D group at Avadel was monitoring competitors' patent applications, right?**

A. **Yes, in fact, we monitored all the competitors in that field.**

Q. **Yup, perfectly fine to monitor competitors, correct?**

A. **Yes.**

Q. **And one of the competitors that you were monitoring was Jazz?**

A. **Jazz was one of them.**

Q. **And one of the Jazz patent applications that you were monitoring was a publication that published on March 24, 2012, right? I apologize, I got the date wrong.**

Why don't we do it this way. Why don't I show it to you, and I'm sure you'll recall it.

If you can turn to PTX312 in your binder?

MR. CALVOSA: And Your Honor, move to admit that into evidence.

MR. ZUBICK: No objection.

THE COURT: All right. PTX312 is admitted.

(Exhibit admitted.)

BY MR. CALVOSA:

Q. **And PTX312 is United States Patent Application Publication Number US 2012/0076865, right?**

A. **Yes.**

Q. **And this was published on March 29th, 2011, right?**

A. **Yes.**

Q. **And if you look down, it says, "Application Number 13/071369," and that was filed on March 29th, 2012?**

A. **Yes.**

Q. **And the lead inventor is Clark Allphin?**

A. **Yes, he's one of the inventors, yes.**

Q. **And we had talked about the dissolution experiments that you had done in the formulation development report. Those were all at buffered pH?**

A. **Yes.**

Q. **If you could please turn to PTX060.**

MR. CALVOSA: And, Your Honor, move to admit PTX060.

MR. ZUBICK: No objection.

MR. CALVOSA: And also we have another exhibit which counsel has agreed we can use as a demonstrative, it's the French notebook, PTX060 is the translation, but just to show the cover of the notebook.

MR. ZUBICK: No objection, Your Honor.

THE COURT: All right. At the appropriate time, we'll take a break, so let me know when it's appropriate.

MR. CALVOSA: Now is a good time if you'd like to take one.

THE COURT: Let's give the jury a break.

Members of the jury, we're going to end a little early because one of the jurors has to leave, so we're going to end a little early, so we're going to take a 10-minute break instead of a 15-minute break.

(Whereupon, the jury left the courtroom.)

THE COURT: All right. We'll be in recess for

10 minutes.

(Break taken.)

THE COURT: All right. You may be seated until the jury comes.

(Whereupon, the jury entered the room.)

THE COURT: All right. You may continue, Mr. Calvosa.

MR. CALVOSA: Thank you, Your Honor.

BY MR. CALVOSA:

Q. **Dr. Guillard, we were on PTX60 and I believe it has been admitted into evidence so we can bring it up. And we can use PTX751, side by side.**

This is an Avadel laboratory notebook, right?

A. **Yes.**

Q. **And if you turn to page 2 of PTX60, this is an Avadel laboratory notebook for the FT-218 or Project Dodo project, right?**

A. **Yes.**

Q. **And your signature is down on the line manager line, right?**

A. **Yes, that's correct.**

Q. **And above that are the technical manager signatures, right?**

A. **Yes.**

Q. **And the technical managers were the ones who actually**

carried out the work that's in this notebook, right?
A. Yes, exactly.
Q. And then you reviewed that work and agreed with the results, right?
A. That's correct, yes.
Q. And your signature indicates that you believe the information in this notebook to be accurate, right?
A. Yes.
Q. Believed it then, back then when it was done?
A. Yes.
Q. And you believe that now, right?
A. Yes, that's correct.
Q. Good. All right. Let's turn to page 5 of the notebook. And there is a title there that's listed "Dissolution in deionized water according to the Jazz Patent," right?
A. Yes.
Q. And one of these dissolution -- sorry, you tested several different prototypes in this dissolution testing, right?
A. Yes, we have tested the formulations corresponding to the three prototypes, the first three prototypes that we have tested in the first clinical studies, yes.
Q. And one of these formulations is the one that's actually in Avadel's Lumryz product today, right?

A. **Yes, one corresponds to the final FT-218 formulation, yes.**

Q. **And the one that you tested that corresponds to the final formulation is 864369 -- I lost my place. Sorry.**

The ones that you tested that correspond to the final formulation are represented in columns 1, 2 and 3, right?

A. **Yes, in fact, there are nine dissolution vessels, so it means that we have performed the dissolution testing in -- for each formulation in three dissolution vessels and the formulation corresponding to FT-218 was tested in the first three dissolution vessels, so, yes.**

Q. **That's easier than me reading the numbers, thank you, I appreciate that.**

And the pH level for the dissolution testing that you measured once the formulation was in -- if you go up a little bit more -- was 6.09, right?

A. **Yes.**

Q. **And this testing was done on October 27th, 2015, right?**

A. **Yes.**

Q. **Before this time, your practice was to always conduct dissolution testing in buffered liquid, right?**

A. **That's correct, yes.**

Q. **This is the first time you conducted dissolution**

testing in deionized water in 2015, right?

A. Yes.

Q. And you only did this dissolution testing in deionized water in 2015 because you had knowledge of the Jazz patent application that published and we looked at before, right?

A. Yes, there was dissolution that -- in such a medium, yes.

Q. So based on Jazz's patent that we looked at before, you carried out the dissolution testing that we see here in Avadel's laboratory notebook, right?

A. Yes. The formulation was completed and --

Q. Dr. Guillard, please, if your counsel wants to redirect --

A. Yes. So the answer is yes.

Q. Thank you.

The results of that dissolution testing for positions 1, 2 and 3 were averaged for each time point and reported in your patent, right?

A. Yes, the average of each, yes.

Q. And if we turn to page 6 of the laboratory notebook, we see the GHB release reported in this table on page 6, right?

A. Yes. You have, for each sampling time, the amount of sodium oxybate released and so you have the dissolution

profile for each dissolution vessel, yes.

Q. And here, one -- the results for one, two and three, "quantity dissolve percentage," for each of those, it was the average that you reported in your patent, right?

A. Yes.

Q. Going back to your patent, JTX260, and if we go to page 76, column 52.

The average of those 3 percent released for GHB across the batches, that's reported in table 2d, right?

A. Yes.

Q. And if you go right above that, you were able to tell that the immediate-release fraction of sodium oxybate was solubilized in 15 minutes, right?

A. Yes, it is the first sampling point so we can see half of the dose is released, yes.

Q. Okay. And because half of the dose is released, you were able to tell that it came from the immediate-release portion, right?

A. Yes.

Q. And you were able to tell the modified release portion doesn't release until after that first hour, right?

A. Yes, because we can see that it is very steady. During the first 4 hours, it remains at 50 percent at most, so there is almost no release of the drug by the modified release portion during those first 4 hours, yes.

Q. **Okay. And you compared the dissolution profile to what you saw in Figure 2 of Jazz's published 865 application, right?**

A. **Yes, that's correct, yes.**

Q. **And the only difference that you point out is that Figure 2 does not exhibit a lag phase after dissolution of the immediate-release part, right?**

A. **No. It is written that -- it shows below the table, we don't see it on the screen, but... it is written, it shows that the dissolution profiles are different, so it is a general conclusion.**

Q. **The specific conclusion you made, Dr. Guillard, beginning at line 65, going to line 67 is the formulation described in United States Patent Publication 2012/0076865, Figure 2, does not exhibit a lag phase after the dissolution of the immediate-release part, right?**

A. **It is one of the differences.**

Q. **And if you turn to Figure 6 in your patent, which is on page 7. At 6 hours, the release -- let me ask you first: The Figure 6 is a comparison between the formulation of FT-218 in deionized water and the formulation of Figure 2 of deionized water in Jazz's patent, right?**

A. **Yes.**

Q. **And in that 6 hours, the dissolution of deionized water is almost identical, right?**

A. **Yes.**

Q. **And in your formulation, you had a formulation made up of 50 percent IR particles and 50 percent MR particles?**

A. **Yes.**

Q. **Jazz's formulation that you compare it to had a formulation made up of about 20 percent or so IR particles, and the rest were MR particles, right?**

A. **In my memory, from what I remember, it was not a particulate formulation. It was a tablet formulation, I may be wrong, but...**

Q. **That wasn't my question, sir.**

In the formulation that you compared, the immediate release was only a percentage of 22 percent and the rest was modified release, right?

A. **Yes.**

Q. **And that was my next question: You thought it was valid to make a comparison between your microparticle formulation and the specific tablet that you compare it to in Jazz's patent, right?**

A. **Yes.**

Q. **Dr. Guillard, the acid that's part of -- you were here during openings, right?**

A. **Yes.**

Q. **And you heard your counsel say you came up with this invention of using an acid separate from GHB?**

A. **Yes.**

Q. **The acid that's in the product that Avadel sells and that you formulated is malic acid, right?**

A. **Yes.**

Q. **You're not the first person to use malic acid with GHB, right?**

A. **No.**

Q. **Jazz did that before you did your formulation work, right?**

A. **Yes.**

Q. **I'd like to take you -- same patent, JTX260 -- to page 110. And I'd like to focus in on Claim 79 and specifically the acidifying agents that are listed there.**

You were not -- take your time to review them.

A. **(Witness reviews document.)**

Q. **You were not the first person who used oxybate or GHB with many of those acidifying agents, right?**

A. **Yes.**

Q. **"Yes," you're not?**

A. **Yes, we were not the first -- the first ones to use a -- an acidifying agent, sorry, with sodium oxybate -- sodium oxybate, yes.**

Q. **Again, that was Jazz?**

A. **In the Xyrem formulation, they have malic acid, yes.**

Q. **And before you're part of this crew that is accusing**

Mr. Allphin of taking something from you, did you check to see whether the acids that Mr. Allphin claims are the same that Jazz had always been using?

A. Well, in fact, we knew that there was some malic acid inside Xyrem.

Q. What about the other acids that are in Mr. Allphin's claim? Did you check to see if Jazz had already been using those?

A. Well, in fact, we -- we have tested other acids, but I don't remember having looked at other acids inside Jazz's Xyrem patents.

Q. Don't you think that's something you should have checked before making accusations?

MR. ZUBICK: Objection, Your Honor. He's a fact witness. I'm not aware of any accusations he's made.

THE COURT: He's not testifying as a 30(b)(6), right?

MR. CALVOSA: I'll withdraw the question, Your Honor.

THE COURT: All right.

BY MR. CALVOSA:

Q. You tested other acids as part of your development work, right?

A. Yes.

Q. I looked through the 110-so pages of your '062

patent. The only acid included in an -- in examples is malic acid, right?

A. Yes.

Q. Yet you're claiming you're the inventor of using all these other acids?

A. Yes, in fact, during development work, we have tested other acids and we have seen that they also work, so we can use other acid instead of malic acid.

Q. And even though you tested all those other acids and you're claiming them as the inventor, you didn't include all of them as examples in your patent?

A. Well, in fact, they're all in the development report, so the final one was malic acid.

Q. Sir, I'm asking about the examples in your patent.

A. From that I remember, there are only examples with malic acid, yes.

Q. So you believe you could claim an invention using all these acids, but you don't need to put all the work and all the different experiments you did in your patent as examples, right?

A. So I was a formulator, so I made some formulations. I haven't written the claims.

Q. Sir, it's a yes-or-no question.

Do you believe that you could call yourself the inventor using all these different acids even though you

only put examples of using malic acid in your patent?
A. Well, I am not a patent engineer, so I can't give an answer to that question.
Q. I'm asking, do you believe you're the inventor here?
A. Yes, of course.
Q. And do you believe your patent is valid even though you didn't include examples of using all the acids you're claiming?
A. Now you are talking about validity, so I was a formulator, so I can't give an answer about something --
Q. So you have no idea whether your patent is valid or not?
MR. ZUBICK: Objection, Your Honor. I think this question has been asked and answered the same way three times, and the witness is not a patent lawyer.
MR. CALVOSA: Your Honor, they're making allegations here.
THE COURT: Go ahead.
BY MR. CALVOSA:
Q. So you have no --
THE COURT: You were saying?
MR. CALVOSA: Okay.
THE COURT: They're making allegations --
MR. CALVOSA: They're making allegations here, and I'll discuss it over there if you want, if you would

like, but that Mr. Allphin didn't invent certain things, even though he did the work, because the examples aren't in his patent. We have the same thing here with the person they're saying is the real inventor. And he should be able to testify -- just like they did, the credibility of the inventor, he should be able to testify whether he believes his patent is valid or not.

THE COURT: Okay. So you've asked him the question, and he's given you his answer. He said he doesn't know because he's --

MR. CALVOSA: I didn't hear the "I don't know." I'm sorry, Your Honor.

THE COURT: Well, he said -- so go ahead. I'll hear you.

MR. ZUBICK: I think -- I'm with you, Your Honor. I think you have it right. I mean, he was asked. He gave an answer. It wasn't a yes or no, but it was a fully responsive answer, which is: I'm not a lawyer.

I don't remember that being asked of Mr. Allphin. Mr. Allphin was asked about what's in this patent, what's not. So was Dr. Guillard; he answered completely and truthfully.

THE COURT: All right. So you can ask him the question one more time. I think he gave you a response.

MR. CALVOSA: If he said "I don't know," that's

fine. I'm -- I'll just -- I'll accept an "I don't know."

BY MR. CALVOSA:

Q. Do you think your patent is valid even though you don't include all of these acids in the examples yet you claim them?

A. I don't know.

MR. CALVOSA: Pass the witness.

THE COURT: All right. Redirect?

MR. ZUBICK: May we disperse the binders, Your Honor?

THE COURT: Yes.

MR. ZUBICK: Good afternoon. My name is Marc Zubick. I'm one of the attorneys for Avadel.

May I proceed, Your Honor?

THE COURT: Yes.

MR. ZUBICK: Okay.

REDIRECT EXAMINATION

BY MR. ZUBICK:

Q. Good afternoon, Dr. Guillard.

A. Good afternoon.

Q. Let's step back for a second. Is this your first time in the United States?

A. No, it's the second. I have been to Boston. It was a long time ago, ten years ago. So the second time.

Q. What were you doing in Boston?

A. **Well, I -- I was attending a scientific workshop in the field of dissolution profiling and pharmaceuticals.**

Q. **You were asked a number of questions by Jazz's counsel about your work on FT218. What was your role on that project?**

A. **Well, in fact, I was a formulator, so it means that I started from the drug, so sodium oxybate. In fact, my work was to develop the final dosage form, so the final dosage form was a sachet, and so my work was to, in fact, do all of the different steps from just the drug to the product marketing.**

Q. **And let's go even further back for a minute. We're calling you "Dr. Guillard." What is your doctorate in?**

A. **So I have a PhD in polymer materials.**

(Reporter clarification.)

THE WITNESS: So in polymer materials.

(Reporter clarification.)

THE WITNESS: In applied chemistry. Yes, polymer. Sorry for my accent.

BY MR. ZUBICK:

Q. **Where did you learn to speak English?**

A. **School, so I tried to. I hope you can understand me, so...**

Q. **Now, you were asked some questions by Jazz's lawyer about reviewing some of Jazz's patents and patent**

applications. Do you remember being asked about that?
A. Yes.
Q. So what, if anything, did Jazz's public patents and patent applications tell you about formulating a once-nightly sodium oxybate product?
A. Well, in fact, there were no useful information in the applications from Jazz that we used for the development of FT-218.
Q. Okay. And we'll come back to that DI water testing.
Let me ask you right at the outset, Dr. Guillard, how, then, were you able to successfully formulate a once-nightly sodium oxybate product?
A. Well, in fact, we used technology that was developed in the company. You have seen the name Micropump, so -- Micropump II, so it relates to a technology, a general one, that can be applied to many, many, many drugs, and it was previously used for other drugs and we used it for sodium oxybate for FT-218.
Q. Something you testified about with Jazz's counsel was that the name of the project was Project Dodo. It's D-O-D-O. Do you remember saying that?
A. Yes.
Q. Where did that name come from?
A. Well, it is just an internal name. FT-218 is a bit formal, so we named it something a bit more fun, I should

say. We called it "Dodo." And Dodo -- dose for a dose, the first two letters, and also in French, "Dodo" has a special meaning. It means a small -- it means a "nap." So if you have a kid, you want him to have a small nap. In French, you say, "It's time for you to go to bed for a small Dodo," so it is just a little funny, let's say.

Q. Dr. Guillard, can you turn in your binder to the tab DTX638.

Do you recognize this document, Dr. Guillard?

A. Yes.

MR. ZUBICK: At this time we offer Exhibit DTX638.

MR. CALVOSA: No objection, Your Honor.

THE COURT: DTX638 is admitted.

(Exhibit admitted.)

MR. ZUBICK: And can we publish Exhibit DTX638.

BY MR. ZUBICK:

Q. Dr. Guillard, can you tell us what we're looking at here?

A. Well, this is a slide deck of -- of a meeting -- for a meeting which is named "kick-off meeting."

Q. What was the date listed on this technical kick-off meeting?

A. So August the 1st, 2022.

Q. What was the purpose of this kick-off meeting?

A. **Well, the purpose of that meeting -- sorry for the noise -- in fact was to -- for each team involved, in fact, in the work to gather and collect all the information they had to develop, in fact, the FT-218.**

Q. **Now, by the time of this technical kick-off meeting, it already says "sodium oxybate." How is sodium oxybate selected as a drug candidate?**

A. **Well, in fact, someone in the company -- I don't know who -- but had a member of his family who was suffering from narcolepsy, and the treatment that the person had to take was not very convenient because -- well, if a person had to take a first formulation at bedtime and then she had -- or he -- he had to take the second formulation during the night, he had to wake up. And so clearly there was a real -- there was something to improve. And that's how, in fact, the idea of developing a once-nightly formulation came to us at Avadel.**

Q. **Now, what input, if any, did you and the formulation group have on the selection of sodium oxybate?**

A. **Well, in fact, as formulators, we -- in fact, we have been asked to assess, in fact, the formulation liability of the once-nightly formulation, is it feasible or not.**

Q. **And what conclusion, if any, did you come to?**

A. **Well, in fact, the drug, it was very challenging to develop a new formulation because of the dose, which is very**

high and other characteristics of the drug. And we knew that, others tried to develop it and that failed, but while we -- we made the assessment and we said, yes, it was worth trying it and there is some chance of success.

MR. ZUBICK: Can we turn, please, to slide 5, Exhibit DTX638.

BY MR. ZUBICK:

Q. And I want to focus your attention, Dr. Guillard, on the first bullet. And can you explain to the jury what the primary, at least preliminary, objective was of the FT-218 project?

A. Well, so the objective was to develop a new formulation as a powder of the drug, so sodium oxybate, using the platform, the technology, Micropump, as I mentioned before, and the Micropump II technology.

Q. Okay. So let's talk a bit about the Micropump II, which you've mentioned and is listed up here. What is Micropump II?

A. Well, so it is a technology with a platform that can be applied to many drugs, and in fact, the technology is based on -- is going to provide specific release of the drug, is designed to provide specific release of the drug in the body, so meaning that -- you had some explanation this morning about the fact that the pH, which you remember is not the same in the stomach or in the intestine, you have --

it is much more acidic in the stomach, and in the intestine, the pH is more neutral. And, in fact, that technology is used to -- is designed, in fact, to release the drug in specific areas of the body, and mainly when the formulation would go to the stomach, to the intestine, in fact, to release the drug in the intestine, so in the specific area of the body.

Q. When did Flamel develop this Micropump II platform that you just described?

A. Well, when I was hired at Avadel in '2004, it was in '2004 -- in -- I said '2004, yes -- it was developed in around 2000.

Q. So we've heard a lot about sodium oxybate. We're going to hear a lot more, but did you develop any other drugs with the Micropump II platform?

A. Yes, before FT-218, we worked on many, many drugs, and we worked in particular on one drug and the commercial name is Coreg. It's a product we developed for GSK, which is a big pharmaceutical company. And while we managed to develop using that technology a formulation to switch from a twice-daily formulation to a once-daily formulation, so almost the same formula as for FT-218.

Q. How did Flamel select the drugs that it wanted to try and formulate with Micropump II?

A. Well, in fact, that technology arose to -- in fact,

to improve, could I say, the dosing schedule, in fact, of the drugs by reducing, for instance, the number of intakes. So instead of taking the drug twice daily, it is possible to take it only once.

So from the patient point of view, it's much better because it's much more convenient to have the drug only once. And that's -- we were focusing on that kind of drugs where there is really -- there was something to improve.

Q. So can we please look at the third bullet on slide 5 of the kick off meeting. And, Dr. Guillard, it says, "Finish product: Two types of sachets."

Can you tell us what you're talking about here?

A. Yeah, so it is the final finished form, which was contemplated. So the sachet or, like, your sugar pack or sugar packets, so you have your powder inside, and it is very convenient because you just have to open it, and after pour it into a glass of water or something. And after, you just have to swallow, in fact, the content of the glass.

Q. How did you come up with the idea of using a sachet for your formulation of sodium oxybate?

A. Well, in fact, there are -- you can -- you can formulate as a capsule or as a tablet. But, in fact, considering the very, very high dose of drug, since the maximum dose is 9-gram per day, so it's a very huge amount

of drug, it's really not realistic to imagine taking tablets or capsules because it means swallowing a huge number of tablets or capsules, and very, very big ones.

So, clearly, for that kind of drug, a sachet is very convenient because you only have a powder, you pour it in a glass of water, and you drink it. So it's clearly a convenient way.

Q. How long did you end up spending on the formulation of sodium oxybate until you had a prototype that could go into humans?

A. Well, in fact, it took about one year to develop the three prototypes, the early prototype that were -- that have been tested in clinical study on human beings.

Q. Was that just you working on the formulation for that year?

A. No. In fact, we had seen -- I was working with some technicians in the lab books, so I worked with three to four technicians to develop the prototypes.

Q. So if we go back to the first bullet on slide 5, the objective bullet. It was mentioned that Micropump II is protected by a patent expiring in 2025.

Did you come to review the Micropump II patent in the course of your formulation work on sodium oxybate?

A. Yes, it requires the technology, so, yes, I reviewed the patent.

Q. **Could you please turn, Dr. Guillard, to tab DTX750 in your binder.**

MR. ZUBICK: At this time we offer Exhibit DTX750.

MR. CALVOSA: No objection, Your Honor.

THE COURT: DTX750 is admitted.

(Exhibit admitted.)

MR. ZUBICK: Can we publish Exhibit DTX750?

BY MR. ZUBICK:

Q. **And Dr. Guillard, do you recognize this exhibit?**

A. **Yes.**

Q. **What is it?**

A. **It is a patent covering the Micropump II technology.**

Q. **Dr. Guillard, do you know when the application that led to the Micropump II technology patent was filed?**

A. **Yes, in fact, the French application, the first application was filed in 2001, October.**

Q. **What types of formulations were disclosed in the Micropump II patent?**

A. **Well, what is disclosed are microparticles using the Micropump II technology.**

Q. **What does the Micropump II patent say is done with these microparticles?**

A. **Well, it describes, in fact, the structure and the nature of the coating of the microparticles, we discussed a**

lot about the coating, so it discloses the composition of the Micropump II.

Q. And generally what is in the Micropump II coating composition?

A. Well, it is a mixture of different ingredients, and the choice of these ingredients allows to obtain the dissolution profile. And after the release in the body, we discussed before, with no release in the stomach. And after, when the particles go inside the intestine, the release of the drug, so it is the composition of that coating that allows such a release.

Q. Can we please turn to column 10, lines 28-35, Exhibit DTX750.

Dr. Guillard, what's -- when this comes up, I'm going to ask you -- here we go -- what's being described in this section of the Micropump II patent?

A. Yeah, so the drug is contained between very, very tiny microparticles, lots of microparticles, very tiny. And after the microparticles, or microcapsules, means the same, can be put in capsules or tablets or in the sachet. So it was described in that application.

Q. What formulation did you end up using for sodium oxybate or FT-218?

A. As we discussed before, considering the dose, we used a sachet for the final dosage form.

MR. ZUBICK: Can we put up Exhibit JTX230 into evidence.

BY MR. ZUBICK:

Q. **And Dr. Guillard, you have this in your binder as well.**

You were asked some questions about this document by Jazz's counsel earlier. What sodium oxybate formulations had you made at the time of this formulation development report?

A. **Well, in fact, we had developed three prototypes, different prototype that have been tested then in the first clinical study on human.**

Q. **Let's look at one of those that Jazz's counsel asked you about, which is Figure 24 on page 38.**

MR. ZUBICK: Can you blow it up a little bit, please.

BY MR. ZUBICK:

Q. **Dr. Guillard, you explained something about the MAMM in this prototype, but could you walk us through the three different, I guess, concentric circles shown on the screen?**

A. **Well, like I said before, the drug, in fact, is contained in many, many, many microparticles. And you take it and cut it in the middle, and you'll have -- see, in fact, that structure. So there is a first layer, it's the centermost portion, in fact, of the microparticle, and which**

is called a "middle core" or a "neutral core," because it does not comprise any drug.

So there is a commercial name of this product, which is a cellet, so there is no drug in it. On top of it, you have -- there it is written -- drug layer, meaning it comprises the drug, the sodium oxybate. And on top of it, the last layer is the Micropump II layer, which is selected to release the drug, as I described before.

Q. **So I'll draw your attention to the Micropump II layer, you were asked about one of the three items listed there.**

But thinking about all three, where did you get the idea to use those three ingredients in the Micropump II layer?

A. **Well, in fact, they are disclosed in the Micropump II patent covering the general technology, the patent we have seen before.**

Q. **What ended up happening to this prototype formulation we see in Figure 24?**

A. **Well, in fact, we were rather lucky because this prototype gave very good results in the first case study. And so it was then further selected for further development. And, finally, it was the final FT-218.**

MR. ZUBICK: Can we please put up page 55 of Exhibit JTX230. And there's a subheading 5.4.3.

BY MR. ZUBICK:

Q. **And Dr. Guillard, can you walk us through, summarize maybe, all the words on this page?**

A. **Yes. In fact, you have half the dose, which is contained in the immediage release microparticles, so release the drug at once. And half of the dose in the release of microparticles.**

So the formulation is a powder, so you have to put the power in tap water before swallowing -- swallowing the formulation. And, in fact, due to the fact that there is this immediate release portion for stability purposes, there is -- there is acidic excipient, as it is written, to make sure the formulation is stable once you put it in water.

MR. ZUBICK: Can we please put up page 56 of JTX230, halfway down the page. Yep, that's it, full compositions.

BY MR. ZUBICK:

Q. **And Dr. Guillard, why is the entry for malic acid listed separately from the IR microparticles and the CR microparticles?**

A. **Well, because the acidic ingredient is intended to go into solution once you pour it into water. And so to have this effect of stabilization, I mentioned before, so there was no reason to put it inside the microparticles. It is a**

powder, the microparticles are in powder form, and you mix, in fact, all these powders to have the final product.

Q. Now --

THE COURT: So Mr. Zubick, I promised this jury that we would end today at 5 o'clock, so unless you have five minutes or less, we're going to stop now and adjourn for the evening.

MR. ZUBICK: I'm sure everyone would love to start with malic acid tomorrow, Your Honor, but how about three questions and then I'll sit down.

THE COURT: Okay.

MR. ZUBICK: Okay.

BY MR. ZUBICK:

Q. So Dr. Guillard, a few questions.

Jazz's counsel asked you about malic acid coming from Jazz, do you remember those questions?

A. Yes.

Q. And you said that you thought malic acid had been used in Xyrem, right?

A. Yes.

Q. Is Xyrem a microparticulate formulation?

A. No.

Q. Is Xyrem a controlled release formulation?

A. No.

Q. Is the malic acid that you used, did you use it for

the same reason that you understood it to be used in Xyrem?
A. No.
MR. ZUBICK: I guess we'll stop for today.
THE COURT: All right. Ladies and gentlemen of the jury, we're going to adjourn for the evening.
Before you go, there's a couple of instructions: One, don't talk to anyone about the case, not your family members, not your friends, not even among each other. You know, continue to keep an open mind.
Two, remember not to do any independent research, only decide this case based on what you hear here in the courtroom. So no Googling, no Internet, none of that. No social media, none of that.
Leave your notes in the jury room.
And we'll see you tomorrow morning between 9:10 and 9:20, okay.
(Whereupon, the jury left the courtroom.)
THE COURT: All right. Dr. Guillard, you're still under oath so you can't talk to your counsel while you're still under oath. We'll see you tomorrow morning. All right. Thank you.
All right. We'll continue with Dr. Guillard in the morning with his redirect. So the Court will expect the joint submission this evening by the time you guys agreed to. And we will remember less than six, we'll start at

9:00 a.m., six or more, we start at 8:45.

MR. ZUBICK: Your Honor, quickly, we do have a bit more with Dr. Guillard on what I suppose is cross but our direct before he goes up on redirect.

THE COURT: Okay.

All right. SO you called him as cross, right?

MR. CALVOSA: Yes.

THE COURT: All right. So you're on redirect, right?

MR. ZUBICK: Okay, understood.

THE COURT: So all right.

All right. So we'll continue with Dr. Guillard in the morning.

MR. CALVOSA: Understood.

THE COURT: All right.

(Recess taken.)

(Whereupon, the following proceeding concluded at 5:04 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