IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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

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Wilmington, Delaware
Wednesday, February 28, 2024
Trial Day 4

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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-

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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 8:45 a.m.)

THE COURT: Good morning.

ALL COUNSEL: Good morning, Your Honor.

THE COURT: All right. You may be seated.

All right. So I'm going to deal with the Rule 50 motions first. Jazz seeks judgment as a matter of law under Federal Rule of Civil Procedure 50 on several grounds. First, with respect to Claim 19 of the '782 patent, Jazz seeks judgment as a matter of law with respect to invalidity. Jazz contends that Avadel has admitted that the limitations of the claim are met and thus the claim is not invalid.

With regard to enablement, Jazz contends that Dr. Charman said that for both patents, the '488 patent and the '782 patent, that the experimentation necessary would be extensive. Jazz contends that under the case law, that is not good enough for Avadel to meet its burden of showing clear and convincing evidence of undue experimentation. Therefore, for both invalidity under sections 102, 103, and 112 written description and section 112 enablement in

Claim 19, Jazz contends that Avadel has not met its burden and JMOL should be granted. Avadel, in response, contends that it is entitled to pursue theories of invalidity under sections 102 and 103 and invalidity under section 112 in the alternative.

Avadel also argues that the standards that apply to invalidity under sections 102 and 103 are different from the standards that apply to written description and enablement under section 112. Avadel contends that there is sufficient evidence of record to support a jury verdict in its favor on invalidity of Claim 19 under sections 102, 103, and/or 112. Among other things, Avadel contends that the evidence presented shows that the data set forth in Allphin 2012 concerning the blood plasma levels is unreliable and only partial and that there was data that was withheld from the PTO by Jazz that renders the data provided unreliable for purposes of Jazz's attempt to show possession of the invention.

With respect to the other asserted claims of the '782 patent and the '488 patent, which are Claims 7 and 11 of the '488 patent, which were dealt with collectively and generally by Jazz concerning enablement, Avadel contends that Dr. Charman's testimony is sufficient evidence of record to support a jury verdict in its favor; that the law does not require an expert to specifically use the words

"undue experimentation"; and that the amount of experimentation required to meet the undue experimentation standard is a factual determination for the jury for purposes of enablement.

Now, with respect to Jazz's motion for judgment as a matter of law on Avadel's defenses of invalidity under sections 102 and 103, with respect to Claim 19 of the '782 patent and the other asserted claims of the '782 patent and the '488 patent, the Court finds that there are genuine disputes of material fact for a jury to decide. Viewing the evidence in the light most favorable to Avadel as the nonmoving party and giving Avadel, as the nonmovant, the benefit of all reasonable inferences, there is sufficient evidence of record to support a jury verdict in favor of Avadel on those defenses.

With respect to Jazz's motion for judgment as a matter of law on Avadel's defenses of invalidity under section 112 lack of written description and section 112 lack of enablement, with respect to Claim 19 and the other asserted claims of the '782 patent and the '488 patent, the Court finds that there are genuine disputes of material fact for the jury to decide. Viewing the evidence in the light most favorable to Avadel as the nonmoving party and giving Avadel, as the nonmovant, the benefit of all reasonable inferences, there's sufficient evidence of record to support

a jury verdict in favor of Avadel on those defenses.

Next moving to Jazz's motion for judgment as a matter of law on infringement. Jazz moves for judgment as a matter of law under Rule 50 on the issue of infringement of the asserted claims of the '782 patent and the '488 patent. With respect to the remaining asserted claim of the '782 patent, Claim 24 of the '782 patent, Avadel has -- Avadel and Jazz filed a stipulation where Avadel admitted infringement of Claim 24 of the '782 patent to the extent that claim is not found to be invalid.

With respect to the '488 patent, Jazz contends that it has carried its burden to show that Lumryz infringes the core limitation and the deionized water limitation of the asserted claims. Jazz also contends that Avadel has not carried its burden of proving by clear and convincing evidence invalidity with respect to the asserted claims, Claims 7 and 11 of the '488 patent and/or Claim 24 of the '782 patent concerning section 102, section 103, section 112 lack of written description and section 112 lack of enablement.

In response on infringement with respect to the '488 patent, Avadel contends that it has presented the jury with ample evidence that Lumryz does not have a core that contains drug. Avadel contends that the testimony of the experts as well as the figures and text in Avadel's patents

show that Lumryz does not have a core that contains drug. Avadel contends that the purported admissions relied upon by Jazz do not mean what Jazz contends they mean, and there remain genuine disputes of material fact for the jury to decide on those issues.

With respect the invalidity of the '488 patent based on enablement, Avadel again contends that it has presented legally sufficient evidence to meet its clear and convincing evidence burden through Dr. Charman and otherwise and that, at the very least, there remains genuine disputes of material fact for the jury to decide.

The Court agrees that with respect to the issues of infringement or noninfringement of the '488 patent, the Court finds that there are genuine disputes of material fact for the jury to decide. Viewing the evidence in the light most favorable to the nonmovant and giving the nonmovant the benefit of all reasonable inferences, there is sufficient evidence of record to support a jury verdict in favor of the nonmovant on those issues.

Thus, both Jazz's motion for judgment as a matter of law on infringement and, if any, Avadel's motion for judgment as a matter of law on noninfringement are denied.

With respect to Jazz's JMOL judgment as a matter of law on Avadel's defenses of invalidity of the '488 patent

with respect to lack of written description and/or lack of enablement, the Court finds that there are genuine disputes of material fact remaining for the jury the decide. Viewing the evidence in the light most favorable to Avadel as the nonmovant and giving Avadel the benefit of all reasonable inferences, there is sufficient evidence of record to support a jury verdict in favor of Avadel on those issues.

Thus, Jazz's motion for judgment as a matter of law on Avadel's defenses of invalidity of the '488 patent with respect to lack of written description and/or lack of enablement is denied.

Moving on to inventorship. Jazz seeks a judgment as a matter of law with respect to Avadel's claims of inventorship or improper inventorship, contending that Avadel has failed to provide sufficient evidentiary basis to support a jury verdict in Avadel's favor on the issue of inventorship with respect to the claims at issue in the '488 patent and/or the '782 patent. Jazz points to the testimony of Clark Allphin, Dr. Guillard, laboratory records, and certain exhibits admitted and other evidence to support its argument on the inventorship issue including conception, possession, and derivation with respect to the claims at issue in the '488 patent and the '782 patent.

In sum, Jazz contends that Clark Allphin conceived of the invention in or around September 2009.

Jazz also argues that the '782 patent is an AIA, American Invents Act, patent as opposed to the '488 patent, which is a pre-AIA patent, and that all that matters with respect to an AIA patent is who filed first.

In response on the issue of inventorship/improper inventorship, Avadel contends that it has presented a legally sufficient basis to support a jury verdict in its favor on inventorship, including that Mr. Allphin did not conceive of the invention in September 2009, as Jazz claims; that Mr. Allphin and others at Jazz did not meet the conception and/or possession requirements; and the evidence shows that Avadel was the true inventor of the invention with respect to the claims at issue in the '488 patent and the '782 patent. Avadel points to certain lab reports and other exhibits, testimony by Mr. Allphin, including admissions that he did not consider himself to be the inventor of Claim 1 of the '782 patent, the testimony of experts about the copying of the language from Avadel's patent application by Jazz, and other evidence to support its argument.

With respect to Jazz's argument that the '782 patent is an AIA patent and all that matters is who filed first, Avadel responds that inventorship is still a defense post-AIA and it -- and there remains a question for the jury to decide under the circumstances of this case whether the

true inventor is Jazz or Avadel. With respect to derivation, Avadel contends the analysis is essentially the same as inventorship and there remains, at the very least, a question for the jury to decide.

Having considered the parties' respective arguments and the record, the Court finds that there are genuine disputes of material fact for the jury to decide on the issues of inventorship/improper inventorship and derivation. Viewing the evidence in the light most favorable to Avadel as the nonmovant and giving Avadel, as the nonmovant, the benefit of all reasonable inferences, there is sufficient evidence of record to support a jury verdict in favor of the nonmovant on those issues.

Accordingly, Jazz's motion for judgment as a matter of law on the issues of inventorship/improper inventorship and derivation are denied.

Moving on to Jazz's motion for judgment as a matter of law on damages. Jazz moves for judgment as a matter of law on damages contending that the only conclusion the jury could reach is that Jazz is entitled to a 27 percent royalty rate for past infringement. Jazz points to the expert testimony of Dr. Rainey to support its argument and the fact that Avadel did not cross-examine Dr. Rainey on the appropriateness of the 27 percent royalty rate and did not present a damages expert of its own.

Avadel, in response, contends that Dr. Rainey's testimony and his opinion was not as clear-cut as Jazz contends. Rather, Avadel contends that Dr. Rainey's opinion is that depending upon the period of time a reasonable royalty rate could fall anywhere from 3.5 percent to 27 percent. Avadel contends that there is a sufficient legal basis to support a jury verdict that 3.5 percent is a reasonable royalty award if infringement is found or anywhere between 3.5 percent and 27 percent reasonable royalty if infringement is found.

The amount of the reasonable royalty is a determination for the jury if infringement is found, and thus the issue will go to the jury and the judgment -- and the motion for judgment as a matter of law on damages is denied.

Given the parties previously -- given that the parties previously stipulated to infringement of Claim 24 of the '782 patent, if it is found not to be invalid, the motion -- Jazz's motion for judgment as a matter of law of infringement on Claim 24 of the '782 patent, to the extent it is not found to be invalid, is granted.

All right. So that deals with the JMOL motions.

With respect to the remaining time, let me give you that. All right. Yesterday Jazz used an hour and 38 minutes. Avadel used 3 hours and 34 minutes. The Court

did not charge either side for the argument and times on the JMOL motions. Thus, Jazz has 2 hours and 48 minutes remaining. Avadel has 4 hours and 23 minutes remaining.

Again, remember to consider the time for your closings.

All right, anything else we need to deal with before we bring the jury in?

MR. CERRITO: A couple of housekeeping matters, Your Honor. I'd like to have one of my new associates present housekeeping matters to Your Honor. He's not admitted to this Court. Defendants don't oppose his presentation, if the Court permits it.

THE COURT: Okay. All right. Introduce him to the Court.

MR. FERGUSON: Brendan Ferguson for Quinn Emmanuel.

THE COURT: Sorry, I didn't hear you.

MR. FERGUSON: Brendan Ferguson for Quinn Emmanuel.

THE COURT: Good morning, Mr. Ferguson.

MR. FERGUSON: Good morning. This morning we have to make a correction for the record for an exhibit that was incorrectly admitted, JTX266 should be PTX266. Thank you.

THE COURT: All right.

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

THE COURT: We're making some progress, Mr. Cerrito might even let Mr. Schuler touch his arm today.

(Laughing.)

MR. CERRITO: Depends on how the day goes, Your Honor, we'll see.

MR. SILVER: Thank you, Your Honor, that was good.

So we have no objection to that correction. We'll probably have a number of corrections that we'd like to make as well, but we'll coordinate with chamber staff and do all of that before the exhibits go back to the jury and we go off the record at the appropriate time.

I'd like to talk about the discussion we had a sidebar yesterday concerning PTX815, which are the contentions that Jazz used with Dr. Charman. We had the discussion and we said we'd confer --

THE COURT: About the truncated --

MR. SILVER: Yeah, what would come into evidence. The parties have since conferred and have agreed that PTX815 will not be moved into evidence in any form.

THE COURT: Okay. All right.

MR. SILVER: Thank you, Your Honor.

THE COURT: All right. So PTX815 is not an

exhibit.

MR. CERRITO: Your Honor, just want to check in on some timing issues, right. We understand the timing we have left, obviously. We have a couple of witnesses, a few witnesses this morning. We think that will take us to roughly about lunch, I don't know how long cross-examinations will go, of course. And then we go into a charge conference.

What I'm trying to gauge is are we going to be doing closings today or tomorrow and when are we charging the jury. Obviously, Plaintiffs would prefer the charge comes at the same time as the closings. And to do that, it sounds like Friday is a more logical point of view, from our side. But we wanted to check with Your Honor's preference.

THE COURT: So would both sides prefer that closings and charging occur tomorrow?

MS. DURIE: From my point of view, Your Honor, we're prepared to proceed whenever we have the time to proceed. So if we're able to get through the testimony, get through the charge conference and we've got sufficient time in the day for both closings today, I think we ought to use the time and go ahead and do that.

THE COURT: Okay.

MS. DURIE: If we're not in a position to do that, then obviously we're not in a position to do that, and

we'll have closings presumably first thing tomorrow.

MR. CERRITO: Just again, charging, we prefer it comes with the closings so they are not separated by the evening, so they hear closings, get the charge and go and deliberate.

We'd also like the opportunity, obviously we're going to put on some witnesses today, to incorporate that into our closing. Won't have time to do that, obviously, today.

THE COURT: All right. So given that you have a couple -- you have how many witnesses?

MR. CERRITO: Three, Your Honor.

THE COURT: Three witnesses. And, you know, those three witnesses with cross-examination, and then we have to do the charging conference, which, you know, it's unlikely we're going to have enough time to do all of that today, so I think you're probably in good position that it will happen tomorrow. What I will ask the jury is can we start at 9 o'clock tomorrow instead of 9:30.

MR. CERRITO: That would be great, Your Honor.

THE COURT: But in the event, unexpectedly, we breeze through everything today and we're done with the charge conference -- with everything in the charge conference by, you know, noon, 1 o'clock, we got at least four hours, then that's a different story, but it's unlikely

that's going to happen.

MS. DURIE: Understood.

MR. CERRITO: Mr. Schuler and I hopefully will be able to be noncombative today.

THE COURT: All right.

MR. SILVER: Your Honor, last thing, just to note for the record about the charge conference. If it's okay with Your Honor, we're going to have some of our more junior team members present argument on the disputed jury instructions at the conference.

THE COURT: That's fine.

MR. SILVER: Thank you, Your Honor.

THE COURT: All right. Anything else?

MR. SILVER: One logistical matter, court reporter, it looks like the live stream has turned off.

(Discussion held off the record.)

(Whereupon, the jury entered the room.)

THE COURT: All right. Good morning, ladies and gentlemen of the jury. We're going to continue with the evidence presentation. And the evidence presentation is likely to be concluded today.

All right. We'll see where we are. All right.

MR. NIMROD: Thank you, Your Honor. Good morning.

THE COURT: Good morning.

MR. NIMROD: Your Honor, Jazz calls its next witness, Mr. Robert Stoll.

ROBERT STOLL, having been called on the part and behalf of the State as a witness, having first affirmed to tell the truth, testified as follows:

DIRECT EXAMINATION

BY MR. NIMROD:

Q. **Good morning.**

A. **Good morning.**

Q. **Would you please introduce yourself to the jury?**

A. **Hi, my name is Robert L. Stoll.**

Q. **Okay. And would you please explain to the jury your experience with the United States Patent and Trademark Office?**

A. **I worked at the U.S. PTO for 29 years.**

Q. **When did you retire?**

A. **I retired in December 2011.**

Q. **Okay. At the time of your retirement, what position did you hold in the Patent Office?**

A. **I was the commissioner for patents at the U.S. PTO.**

Q. **Okay. How did you obtain that position, commissioner for patents?**

A. **I was appointed by the Secretary of Commerce.**

Q. **Could you explain to the jury what your responsibilities were as the commissioner?**

A. **I was responsible for the entire patent corps, that was 8,000 people, including all of the examiners; and examination; and the procedures and processes dealing with examination of patents.**

Q. **Okay. What was your position when you started at the Patent Office?**

A. **I was a patent examiner.**

Q. **Can you explain to the jury what your responsibilities were as a patent examiner?**

A. **Yes, when the applications came in, you review the applications to make sure it comports with all the statutory requirements, which include anticipation, obviousness, written description, and enablement. And if it does, you issue the patent; and if not, you make a rejection, which you communicate to the applicant.**

Q. **Were you ever promoted from a patent examiner to a different position?**

A. **Yes. I was promoted as a supervisory patent examiner.**

Q. **What were your responsibilities in that job?**

A. **I supervised about 15 examiners, and I very closely worked with those that were new, and more sporadically with those that were more experienced.**

Q. **How many years were you an examiner, either beginning or supervisory?**

A. **Around 12.**

Q. **Okay. And how many applications did you examine during that time period personally?**

A. **My name appears on 2,000 issued patents as either an examiner or supervisory examiner. And I had many multiples of that that did not issue as patents.**

Q. **During your 29 years in the Patent Office, were you involved in the development of its rules and regulations?**

A. **Yes, very intimately.**

Q. **Okay. And during your time in the Patent Office, were you also involved in the development of the America Invents Act, or the AIA, as we have been hearing in this trial?**

A. **Yes, the legislation itself and the implementation.**

Q. **Okay. Now, you said you retired in 2011. What is your currently employment?**

A. **I'm a partner at Faegre Drinker Biddle & Reath and deputy chair of Intellectual Property Law Group.**

Q. **Okay. And what is the focus of your practice at the law firm?**

A. **I supervise patent prosecution and drafting of applications. I troubleshoot, myself, applications that have run into trouble at the PTO. I do a lot of policy work and a lot of legislative work. And, of course, I testify.**

Q. **So about how many years' experience do you have in**

total in patent prosecution?
A. About 41.
Q. Okay. Have you ever been qualified in this court as an expert in Patent Office process and procedure?
A. A couple of times.
MR. NIMROD: Your Honor, Plaintiffs move to qualify Mr. Stoll as an expert witness in the field of U.S. Patent Office practice and procedure.
MR. ZUBICK: No objection, Your Honor.
THE COURT: All right. Mr. Stoll may testify as an expert on USPTO practice and procedure.
MR. NIMROD: Thank you, Your Honor.
BY MR. NIMROD:
Q. All right. Mr. Stoll, let's go over your overall opinions first. What were you asked to analyze in this case?
A. I was asked to look at -- to talk about process and procedure at the Patent and Trademark Office, and particularly about the alleged copying of the claims as it relates to the '782 patent.
Q. Under Patent Office practice and procedure, is claim copying permitted?
A. Yes.
Q. Okay. And why is that?
A. Well, as long as you have support in the

specification as you have it, you can copy claims that are meeting the written description and enablement that's already in the specification.

Q. **So in your view, why is it fair for the Patent Office to allow someone to copy claims of another person's patent application?**

A. **Well, it's very fair because you're the first inventor, you're the one who disclosed the information to the world, and you should be able to claim it in any manner in which it's supported.**

Q. **Okay. What kind of support is necessary to copy claims, according to Patent Office practice?**

A. **You need to have full written description, that means possession, and you need to have enablement, and that means to teach someone of ordinary skill in the art how to make and use the invention.**

Q. **Okay. And you have to have that before the other person's application?**

A. **That's correct.**

Q. **In your opinion, did the examiner, in connection with the '782 patent, conduct a written description and enablement analysis in connection with the claims that Avadel says were copied?**

A. **Yes, she did.**

Q. **All right. Before we go into the details of that,**

let me direct your -- direct you first to an MPEP section that Mr. Matal, the patent expert for Avadel, testified about.

Were you in court for that?

A. I was.

Q. Okay.

MR. NIMROD: Could we please put up DTX499.3. Put up 2001.06(d), please.

(Reporter asks for clarification.)

MR. NIMROD: D.

BY MR. NIMROD:

Q. Now, you were in court when Mr. Matal stated that it was his opinion that claim copying is relevant for AIA patents because MPEP section 2001.06(d) requires applicants to tell the examiner they copied claims.

Did you hear him say that?

A. I did.

Q. Under this MPEP section, does it apply to AIA patents in any way?

A. It definitely does not.

Q. Why do you say that?

A. Because it's only related to interferences, and interferences are only available to pre-AIA cases, they are not available to AIA cases.

Q. Okay. So there's a section in here that says 37 CFR

41.202(a). And it appears twice in -- once in each of the two sentences.

Do you see that?

A. I do.

Q. What is that provision?

A. That provision relates to interferences, and both sentences are dependant upon that provision.

Q. Is there any dispute between you and Mr. Matal that 37 CFR 41.202(a) relates to interferences only?

A. No.

Q. And is there any dispute that that only relates to pre-AIA patents?

A. No.

Q. Okay. Now, during his testimony, Mr. Matal said, The first sentence up there talks about an older proceeding called "interferences" where you also have to disclose copying.

Do you recall him testifying to that?

A. I do.

Q. And do you agree with that?

A. It only refers to interferences.

Q. Right, okay. So then he said, "The most important sentence is this second one. And as you can see, it says, The information required, you know, as to the source of copied claims, is material information under the Patent

Office rules."

So where he said "the information required by, you know, as to the source," what was the you know that he left out of that?

A. **The 37 CFR 41.202(a), which is the interference provisions.**

Q. **Okay. So this second sentence, does it have anything to do whatsoever to AIA patents?**

A. **No.**

Q. **Now, why is this MPEP section still in the regulations under the AIA regime?**

A. **Because there are still interferences at the Patent and Trademark Office.**

Q. **Are there AIA patent applications still pending in the Patent Office?**

A. **There are pre-AIA patent applications still pending at the United States Patent and Trademark Office, and AIA as well.**

Q. **Thank you. Are you aware of 37 CFR 41.202(a) ever being applied to an application that is an AIA application?**

A. **No.**

Q. **Okay. Are you aware of this MPEP section ever being applied to a patent application subject to the AIA?**

A. **No.**

Q. **And in your opinion, did you see Mr. Matal provide**

any evidence or examples showing that either the MPEP section or the CFR section has ever been applied to AIA patents?

A. **No.**

Q. **So in your view, based on your 41 years of experience, is there any requirement under Patent Office procedures to tell an examiner about claim copying for AIA patents?**

A. **No, there is not.**

Q. **Okay. Let's say an examiner were advised for an AIA patent that there were copied claims from another application, how would that impact the examination process?**

A. **Not at all. The examiner is still required to do the enablement and written description analysis of the specifications.**

Q. **Okay. And is the standard -- to be clear, is the standard for written description and enablement any different for copied claims versus noncopied claims?**

A. **No.**

Q. **Okay. Now, Mr. Matal testified to the jury that perhaps, in the situation of copied claims, an examiner may take a closer look at written description.**

What is your thought on that?

A. **No. The examiner's always required to analyze the specification to see whether it provides written description**

and enablement for the claims that are present.

Q. Okay. Now, let's turn to what happened during the examination of the '782 patent. You mentioned earlier that your opinion was that the examiner of the '782 patent conducted the written description and enablement analysis for the claims at issue, right?

A. Yes, that is my opinion.

Q. And that would include Claim 24?

A. That would include all the claims, including Claim 24.

MR. NIMROD: All right. Let's turn to, Mr. Lewis, JTX12 at page 122, please. Thank you.

BY MR. NIMROD:

Q. This is an office action in the prosecution history that I took Mr. Matal to. What tells you that the examiner, in connection with the '782 patent, conducted a written description or enablement analysis?

A. Well, you can see in the middle of the page, it has a whole discussion about priority. In order to determine priority -- and that's claiming pendency back to earlier applications -- you need to make a written description and enablement analysis.

Q. Okay. Do the rules of the Patent Office require an examiner to conduct written description and enablement analyses in order to make a priority determination?

A. **Yes.**

Q. **And they're not allowed then to simply say, I find priority without that analysis, are they?**

A. **No.**

Q. **All right. Let's turn to the next page, please. And if we could just go right there.**

What was the examiner's priority determination for the '782 patent claims?

A. **She clearly said, "Therefore, the earliest priority for the claimed subject matter is February 18th of 2016, the effective filing date of 15/047,586," which is one of the parents of the '782 patent.**

Q. **And that's an application filed by Jazz in the chain that led to the '782 patent?**

A. **Yes.**

Q. **Okay. And what does the examiner's priority finding mean with respect to written description and enablement for that application from February of 2016?**

A. **It means that the -- the claims that were filed with the application were fully supported as of February 18th of 2016.**

Q. **Okay. So the examiner's determination means that the invention of the claims -- like Claim 24 was there all along, so to speak, since 2016?**

A. **Yes, all of the claims.**

MR. ZUBICK: Your Honor, objection. I'm fine with walking through the file history but that question and answer, the last one as phrased, is giving a legal conclusion. If we're talking about the examiner's conclusion, that's one thing, that's not what the answer is.

(Reporter clarification.)

MR. ZUBICK: Zubick.

THE COURT: So I'm going to sustain that, let's just keep it to the examiners' determinations.

BY MR. NIMROD:

Q. **Okay. Mr. Stoll, when an examiner makes a determination about priority, that includes a determination of written description, right?**

A. **Necessarily, yes.**

Q. **And does written description relate to whether or not there was something called possession of the invention?**

A. **Yes, it does.**

Q. **So the examiner's determination regarding this priority date, from February 2016, means she determined what with respect to when Jazz possessed the invention at issue here?**

A. **She determined that as of February 18th of 2016, the applicant possessed the subject matter of the claims.**

Q. **Okay. And that would include Claim 24?**

A. **Yes.**

Q. **At the time the examiner made her priority determination, did she have Avadel's '866 patent before her?**

A. **Yes, she did.**

Q. **How do you know that?**

A. **Because it was listed on an information disclosure statement provided by Jazz to the applicant.**

Q. **What is an "information disclosure statement"?**

A. **It's probably the best mechanism to put information in front of the examiner that might form the basis of a rejection at the United States Patent and Trademark Office.**

Q. **Okay.**

MR. NIMROD: Mr. Lewis, can we turn to page 159 at JTX12, please. Let's just highlight the information disclosure statement.

BY MR. NIMROD:

Q. **So what does this title indicate the document is?**

A. **It's an information disclosure document.**

Q. **Okay. And this was submitted by who?**

A. **By Jazz to the Patent Office.**

Q. **Okay.**

MR. NIMROD: Now, could we highlight this line right here, Mr. Lewis, the first line?

BY MR. NIMROD:

Q. **What is indicated in the line that Mr. Lewis just highlighted?**

A. **It's indicated that the '866 patent was provided to the Patent and Trademark Office and you can see that the examiner considered it because she initialled next to it.**

Q. **That's these -- the "YZ" here, is that the initials of the examiner?**

A. **They are.**

Q. **Okay. What do the initials mean when you see the examiner's initials?**

A. **That she considered the reference.**

Q. **Okay. So the information disclosure statement is sent with that column blank and then it's up to the examiner to do something with that column?**

A. **That's correct.**

Q. **Okay. And you said she "considered it," what does that mean, "considered it"?**

A. **It means she made a determination that it did not provide the basis for a rejection of claims.**

MR. NIMROD: If we can look at the bottom of the page, please. Go down. Yes. A little lower, Mr. Lewis, please.

BY MR. NIMROD:

Q. **At the very bottom there's an excerpt here. What does this refer to?**

A. **Well, first of all, that -- if you see the examiner's name there and she provides the date she considered and then**

she says, "All references considered except where line through," and she initialled that as well.

Q. Did she line through the '866 or did she consider it?

A. No, she considered it.

Q. All right. Now, Mr. Stoll, you mentioned the AIA earlier and that you were involved in its development at the time when it came to be.

A. I did.

Q. Okay. How did the AIA change the U.S. Patent system with respect to the date of invention?

A. Well, it changed the mechanism for what was given priority. The first inventor to invent was the pre-AIA standard, the first inventor to file was the post-AIA.

Q. Okay. As the jury heard in the video, the patent video, said, "Under the America Invents Act of 2011, the filing date will determine who was awarded the patent if there are competing valid applications."

Were you in court for that?

A. Yes, I was.

Q. Okay.

MR. NIMROD: Mr. Lewis, could you please go to JTX59 and put up the cover page of the patent.

BY MR. NIMROD:

Q. This is the Avadel patent; is that right?

A. Yes.

Q. **Okay. The '866 patent.**

All right. And what is the earliest priority date that the Avadel patent could have, if we scroll down a little further, right there?

A. **You can see down in Section 60, which provides the continuing information, that the earliest filing date for Avadel patent is July 22nd of 2016.**

Q. **Okay. Okay. Now, the earliest date for Avadel's patent is July 22, 2016.**

MR. NIMROD: And now let's go to the JTX6, please. This is the '782 patent and if we can bring up all of the related U.S. application data, please, Mr. Lewis.

BY MR. NIMROD:

Q. **And what was the date the examiner found for Jazz having possession of the invention?**

A. **It was February 18th of 2016.**

Q. **I'm going to pause for one second. It mentions this chain of or series of applications, and then it also says, "now abandoned" for one of them.**

What is this related U.S. application data? What does that mean when you list these all out like this?

A. **That's the continuing data, so you file an application and you file a continuing application while that application is still pending and sometimes you have a couple of them.**

Q. **Okay. And so this one here, for example, says "abandoned."**

Does that mean under Patent Office practice that you've abandoned the invention?

A. **It doesn't. It just means that that particular application, you filed a continuation and you continued processing the inventions that were contained in the parent application.**

Q. **So you have one serial number and then you move to the next serial number?**

A. **That's correct.**

Q. **Okay. And that's common practice?**

A. **Yes.**

Q. **Okay. Now, under the AIA first inventor to file system, which application was filed first here, Jazz's or Avadel's?**

A. **Jazz's by five months.**

Q. **Okay. Under the AIA, which party should be awarded the invention?**

MR. ZUBICK: Objection, Your Honor. That's calling for a legal conclusion.

THE COURT: Calling for a legal conclusion.

MR. NIMROD: That's fine, Your Honor.

THE COURT: Sustained.

BY MR. NIMROD:

Q. **Okay. Mr. Stoll, let's talk a little bit about your personal practice now.**

Since 2011, you've been in private practice. Have you ever copied claims into an application for your client that you were prosecuting?

A. **As long as I had written description and enablement support, yes.**

Q. **Okay. In your own practice for AIA applications, when you copied claims, do you ever identify the source of the claims pursuant to the MPEP Section 2001.06(d)?**

A. **No.**

Q. **And why is that?**

A. **It's not required.**

Q. **And is it relevant to anything in the patent?**

A. **No.**

Q. **Okay. In your own practice, have you ever drafted claims to cover competitor's products?**

A. **Many times.**

Q. **And do you and Mr. Matal agree on that acceptable practice?**

A. **Yes.**

Q. **Okay. And why is it fair to be able to copy claims -- excuse me, to draft claims based on competitors products?**

A. **Because you're the first inventor to provide the**

information to the public, you should be able to claim it in any manner that you see fit.

MR. NIMROD: Thank you, I'll pass the witness, Your Honor.

THE COURT: All right. Cross-examination?

MR. ZUBICK: May we approach with binders, Your Honor?

THE COURT: Yes.

MR. ZUBICK: Thank you. May I proceed, Your Honor?

THE COURT: Yes.

MR. ZUBICK: Thank you.

CROSS-EXAMINATION

BY MR. ZUBICK:

Q. Good morning, Mr. Stoll.

A. Good morning.

Q. We've not met before but my name is Marc Zubick and I'm one of the lawyers for Avadel.

A. Nice to meet you.

Q. Likewise.

A. I think.

Q. I hope so.

You mentioned that your name appears on approximately 2,000 issued US patents.

Let me ask you this: Do you know how many

patents issued from the United States Patent Office last year?

A. **I'm going to estimate about 500,000.**

Q. **Okay. I think that's about right.**

And do you know how many applications the Patent Office received last year?

A. **I don't, but I know the backlog exceeds 800,000.**

Q. **Okay. And if you think it's about 500,000 patents issued, logically more than 500,000 applications went in, right?**

A. **It depends on the year.**

Q. **Okay. You said you watched the patent video that was shown to the jury. You were in court for that; is that right?**

A. **I don't remember if I've seen here in this court or if I have seen it before or I saw it -- I just know I have seen it several times.**

Q. **Maybe I misunderstand your testimony, but you've seen that video?**

A. **I have.**

Q. **Okay. I'm going to read you a quote from that video.**

"In 2012, the PTO received nearly 600,000 patent applications."

Any reason to disagree with that?

A. **No, I don't know the number, but it sounds like it**

could be.

Q. Okay. You'd agree the job of examining that many applications is challenging, correct?

A. That's why we have about 9,000 examiners now.

Q. Even with those examiners, that job is challenging, right?

A. Yes, it's a good job, it's -- you know, I think most of the patent examiners do a great job, so I don't know what you mean by "challenging." They are there because they like doing it.

Q. Okay. Well, I'm going to read you a direct quote from the video that was shown to the jury and you tell me if you agree.

"The job of examining so many applications is challenging."

A. I believe that was said in the video.

Q. Okay. And you agree with it?

A. I don't know what was meant by "challenging." I guess it can be challenging for some people.

Q. Okay. I think this is an easy one.

Someone applies for a patent, they need to be honest with the Patent Office, right?

A. Yes.

Q. Okay. Good.

That's important, to be honest with the Patent

Office?

A. **Yes.**

Q. **Okay.**

And the system depends on the people telling the Patent Office the truth, right?

A. **Yes.**

Q. **Now, you agree that in the course of reviewing the patent, there may be arguments and there may be facts that the examiner is not aware of, right?**

A. **Yes, it's possible.**

Q. **You agree that examiners have a lot of work to do?**

A. **They have work to do. "A lot," I don't know, but they work. They work hard.**

Q. **Okay. I'm going to read you, again, an exact quote from the patent video that was shown to the jury and you tell me if you agree or disagree. Is that okay?**

A. **Yes.**

Q. **All right.**

"Examiners have a lot of work to do and no process is perfect."

Do you agree?

A. **Yes, I agree with that.**

Q. **Okay. I should just go right to the video. You're more likely to agree with the video than you are with me, I think.**

A. **There are some things with the video, but...**

Q. **Let's turn to the prosecution of the '782 patent which is the issue in this case, okay?**

A. **Okay.**

Q. **That's what you testified about on direct?**

A. **Correct, in part.**

Q. **Okay. That prosecution of Jazz's '782 patent, that was just between the --**

In part, okay. That prosecution of Jazz's '782 patent, that was just between the patent examiner and Jazz, right?

A. **Yes, it's an ex parte process, which means it's just between the two.**

Q. **Okay. Avadel wasn't part of that process?**

A. **I don't believe so. I don't believe so.**

Q. **But you reviewed the file history, right?**

A. **I did not see any submission of an IDS by Avadel.**

Q. **In fact, that prosecution, that was not public, so Avadel couldn't have known about it, right?**

A. **That's correct.**

Q. **Okay. And none of Avadel's experts that we've seen in this case, none of them were involved in the prosecution, right?**

A. **Not that I'm aware of.**

Q. **Okay. The examiner didn't have access to expert**

testimony, right?
A. I don't believe so.
Q. But you reviewed the patent history. Did Avadel's expert participate?
A. I don't remember all the names of people that were involved, but I don't remember any Avadel person being involved in the prosecution at all.
Q. Okay. Is your testimony it's possible that one of Avadel's experts participated in a proceeding that Avadel didn't know about?
A. My testimony is that I don't know the people involved and there are lots of names involved, so I don't know.
Q. Okay. Patent examiners don't have access to laboratory facilities?
A. That's accurate.
Q. Okay. You wrote that in your expert report?
A. I believe I did. My -- I think I quoted from the MPEP for that.
Q. Now, you testified when you spoke to Mr. Nimrod on direct that copying is okay under some circumstances, right?
A. As long as you have written description and enablement.
Q. You knew right where I was going.
You still have to comply with all the statutory requirements, right?

A. **That is correct.**

Q. **You don't comply with the statutory requirements, you don't get to copy?**

A. **That, well, you get a rejection and you may figure it out later on, but you -- you would not probably go through right away.**

Q. **Okay. You don't get a patent?**

A. **Not until you convince the examiner you're right.**

Q. **Okay. And you shouldn't get a patent, right?**

A. **Not if you're not meeting the statutory requirements.**

Q. **Okay. The patent system works because inventors are required to describe their inventions in clear and specific terms; is that right?**

A. **That's 112 second, or B, yes, that's a requirement.**

Q. **Okay. Clear and specific terms?**

A. **Yes.**

Q. **Okay. So the jury has heard a lot of about this, but just to be clear, you understand one of the issues in this case is whether Jazz copied Avadel's patent claims into its own patent applications, right?**

A. **I understand that's an issue, yes.**

Q. **Okay. As part of your work in this case, you reviewed the claims of both Jazz's '782 patent and Avadel's '866 patent, right?**

A. **Yes.**

Q. **That's some of -- that's some of what you talked about with Mr. Nimrod, right, the '866 patent and whether it was disclosed?**

A. **Yes.**

MR. ZUBICK: Okay. Can we please put up demonstrative DDX-RS-.001, Mr. Jarrett?

BY MR. ZUBICK:

Q. **And just to orient you, Mr. Stoll, on the left, we have Avadel's '866 patent claims; on the right, we have the application that led to Jazz's '782 patent. These are -- these are claims you reviewed, and what I've done is I've put some color-coding just to match them up. Make sense?**

A. **Yes.**

Q. **Okay. Now, you used the term during direct when you spoke to Mr. Nimrod "alleged copying," right?**

A. **I did.**

Q. **Okay. As part of your work in this case, you concluded that there were extremely similar claims, right?**

A. **That's true.**

Q. **Okay. Extremely similar, but you didn't conclude that Avadel copied -- sorry, that Jazz copied Avadel's claims, right?**

A. **I didn't because I didn't see that anybody said that they copied the claims.**

Q. **Okay. And, in fact, you testified at your deposition**

that you haven't seen anything that makes you convinced that there was, in fact, copying, right?

A. I did not see anybody from Jazz saying, We copied the claims. I think that they're very similar. I think I said that in my deposition.

Q. You did. But you also said at your deposition under oath that you haven't seen anything that makes you convinced that there was, in fact, copying. That's what you said, right?

A. And what I meant was I hadn't seen any admission that there was copying.

Q. Okay. And you can talk to Mr. Nimrod on redirect. I'm going to ask you again.

Your testimony was, "I haven't seen anything that makes me convinced that there was, in fact, copying." Is that what you said?

A. I think that's correct.

Q. Okay. Now, you reviewed testimony from Jazz's patent attorney. That's who wrote the claims, right? Mr. Valentine? You saw some testimony from him?

A. I did.

Q. Okay. And Mr. Valentine said that he referred to Avadel's claims when he drafted Jazz's claims, right?

A. I heard that.

Q. Okay. After considering that testimony and reviewing

the claims, you haven't seen anything that convinced you there was copying, right?

A. **Mr. Valentine didn't say he copied the claims.**

Q. **Right. I understand that. He said he referred to the claims.**

I'm asking you, having read that testimony and looked at these claims, your testimony is that you haven't seen anything that convinced you there was copying by Jazz, right?

A. **That's correct.**

Q. **Okay. You'd agree with me that when evaluating the patentability of claims, one of the things examiners primarily rely on is information that's provided to them by individuals having a duty of disclosure and duty to make truthful representations, right?**

A. **Yes.**

Q. **That's a direct quote from your expert report, right?**

A. **That's correct.**

Q. **Okay. And that includes inventors who apply for a patent, right?**

A. **Yes, it does.**

Q. **And that also includes their attorneys who prosecute the patent, right?**

A. **And anybody substantially involved in the drafting or prosecution of the application.**

Q. **Okay. So Mr. Valentine would be included in that list?**

A. **I would think so.**

Q. **Okay. Mr. Allphin would be included in that list?**

A. **I would think so.**

Q. **Okay. As part of your work in this case, you reviewed the prosecution history of Jazz's '782 patent, right?**

A. **I did.**

Q. **You talked to Mr. Nimrod about that on direct?**

A. **I did.**

Q. **Okay. And when you reviewed the prosecution history, you didn't see anything where Jazz told the Patent Office that they copied Avadel's claims, right?**

A. **I did not.**

Q. **Nothing one way or the other, no statement about that?**

A. **I didn't see any words of copying.**

Q. **Okay. And to be clear, it's your testimony Jazz didn't need to tell the Patent Office that, if it was true?**

A. **That -- that is my testimony, yes.**

Q. **Okay. I'm told if I say "MPEP," you won't like it.**

A. **Say what?**

Q. **"MPEP" is not the preferred pronunciation. It's M-P-E-P, right?**

A. **Correct.**

Q. **Okay. And that is -- you spoke to Mr. Nimrod about that. This is the Manual of Patent Examining Procedure, right?**

A. **It is.**

Q. **Okay. And that's -- we're going to look at it in a minute. That's where that section that you and Mr. Matal disagree about. That comes from the MPEP, right?**

A. **Yes, it does.**

Q. **I immediately went back to it.**

It comes from the MPEP, right?

A. **The Manual of Patent Examining Procedure.**

Q. **Okay. The MPEP is binding on patent examiners, right?**

A. **It is binding on patent examiners; it is not binding on applicants unless they're -- with reference to a rule, statute, or case law.**

Q. **It is informative to the attorneys who are prosecuting patents, right?**

A. **It can be.**

Q. **Well, in your expert report, you wrote, "It's informative to patent attorneys," right?**

A. **I think I did, yup.**

MR. ZUBICK: Okay. Can we please put up page 3 of DTX499 in evidence, and let's blow up the 2001.06(d).

BY MR. ZUBICK:

Q. **Mr. Stoll, this again -- you spoke with Mr. Nimrod about this. Mr. Matal spoke about in this. This is the section that talks about telling the Patent Office that you copied, right?**

A. **Yes, and it relates to pre-AIA patents, as I said.**

Q. **You did.**

And your opinion is that because the '782 is not a pre-AIA patent, this section doesn't apply.

A. **Yes.**

Q. **Okay. And I think you just said this. This section only applies to pre-AIA patents.**

A. **Only applies to pre-AIA that are attempting to establish an interference. It doesn't even apply to pre-AIA where the -- the applicant is not trying to establish an interference.**

Q. **Okay. Understood.**

Now, the title says, "2001.06(d) Information Relating to Claims Copied from a Patent," and then there's an "R-08.2017."

Did I read that correctly?

A. **Yes, you did.**

Q. **Okay. Nothing in that title mentioned the AIA one way or the other, right?**

A. **No, that's only from the rule.**

Q. **Okay. Now, you're aware that there are other sections of the MPEP that call out pre-AIA in the title, right?**

A. **Some do; some don't.**

Q. **Okay. But you've seen some that do, right?**

A. **I have.**

Q. **Okay. Can you turn to the tab labeled "MPEP 2132" in your binder, please. It's just going to be in your binder. It's not going to be on the screen.**

A. **Oh. Turn to where?**

Q. **MPEP 2132.**

A. **Okay. I'm there.**

Q. **Now, this is a section on 35 U.S.C. 102(a), right?**

A. **Where are you? Yes, I see --**

Q. **You see it now?**

A. **I see 2132, yes.**

Q. **That's correct. Okay.**

So this is a different section of the MPEP, right?

A. **Yes.**

Q. **Okay. And if you look at it, the title starts "Pre-AIA," right? Those are the first two words?**

A. **Yes.**

Q. **We can quibble if the hyphen makes it one word or two, but the first thing you read on 2132 is "Pre-AIA,"**

right?

A. **Yes.**

Q. **Okay. And if you look below that, there's something that starts "Editor Note." Do you see that?**

A. **I do.**

Q. **Okay. In the editor note, it says, "This MPEP section is not applicable" -- and that's in bold -- "to applications subject to examination under the first inventor to file, FITF, provisions of the AIA..." and then it goes on.**

Did I read that correctly?

A. **You did.**

Q. **Okay. So we have a title, it says "Pre-AIA," and "Editor's Note." It says in bold "not applicable." And it mentions the AIA, correct?**

A. **It does.**

Q. **Okay. Looking back up to the screen, the MPEP section 2001.06(d), that's at issue here, does not mention AIA in the title, right?**

A. **It doesn't.**

Q. **Doesn't mention the AIA in an editor note, right?**

A. **It doesn't.**

Q. **It doesn't have an editor note?**

A. **It doesn't need one.**

Q. **Okay. Now, can you go in your binder to tab labeled**

MPEP 2138. Let me know when you're there.

A. **I am.**

Q. **Okay. And do you see the MPEP section 2138?**

A. **I do.**

Q. **Okay. And this section is titled Pre-AIA. Again, the first word or two words mentions pre-AIA, right?**

A. **It does.**

Q. **Okay. And then it says 35 U.S.C. 102(g), right?**

A. **It does.**

Q. **Okay. Now, pre-AIA 102(g) is the basis for the interference practice we've been talking about, right?**

A. **It is.**

Q. **Okay. So this deals with interferences?**

Correct?

A. **Excuse me.**

Q. **This is relevant to interferences, right?**

A. **Yes.**

Q. **Okay. And below the title that starts Pre-AIA, there's an editor note again.**

Do you see that?

A. **I do.**

Q. **And it says, "This MPEP section has limited applicability" -- that's in bold -- "to applications subject to examination under the first inventor to file, FITF, provisions of the AIA..." and it goes on, correct?**

A. **It does.**

Q. **Okay. That's another section that mentions pre-AIA, both in the title and in the editor note, right?**

A. **It does.**

Q. **And this one deals with interferences?**

A. **It does.**

Q. **It's a statutory basis for interference?**

A. **It is.**

Q. **Okay. MPEP section 2001.06(d) appears as shown on the screen, this is how it looks today in the MPEP, right?**

A. **Yes.**

Q. **Okay. You testified earlier that Jazz disclosed the '866 patent, that's Avadel's patent, to the examiner during the prosecution of Jazz's '782 patent, right?**

A. **I did.**

Q. **You spoke to -- with Mr. Nimrod about that?**

A. **I did.**

Q. **Okay. And you showed that on the screen?**

A. **He showed it on the screen.**

Q. **Fair enough. And you specifically looked at an information disclosure statement, which is called an IDS, right?**

A. **That's correct.**

Q. **And the IDS that Mr. Nimrod showed you had the '866 patent, you highlighted it?**

A. **It did.**

Q. **Okay. I suppose he highlighted it?**

A. **He did.**

Q. **Okay. That IDS that you discussed with Mr. Nimrod was filed on April 27, 2021, does that sound right?**

A. **I -- yeah, it could be right. I know that she signed it in May, but I --**

Q. **Okay. I want to be precise. So why don't you go to your expert report, which is your binder.**

A. **Got it.**

Q. **I think it's called something pithy like Stoll expert report?**

A. **Yes. I'm there.**

Q. **Okay. If you look at paragraph 78 of your expert report, and if you --**

A. **Yes.**

Q. **-- look, first sentence, on April 27, 2021, "Applicant submitted an IDS which identified Avadel's '866 and '986 patents."**

Do you see that?

A. **I do.**

Q. **Okay. April 27th, right?**

A. **Yes.**

Q. **Okay. Now, that was not the first IDS that Jazz submitted, right?**

A. **No.**

Q. **Okay. And, in fact, Jazz submitted an IDS a week after it filed the application for the '782 patent, right?**

A. **I believe you.**

Q. **Okay. Well, do you believe me or do you know?**

A. **I don't remember when --**

Q. **Okay. Again, I'd like to be precise, so let's take a look at your expert report. And if you look at paragraph 74, Jazz filed the application --**

A. **74.**

Q. **Paragraph 74. Jazz filed the application for the '782 patent on March 23, 2021, do you see that?**

A. **It says on March 23, '21, yeah.**

Q. **Okay. Now look at paragraph 77. It says on March 30th, "applicant submitted an IDS," do you see that?**

A. **I do.**

Q. **Okay. There's going to be a little bit of math here, March 23rd to March 30th is a week, right?**

A. **Thank you. Yes.**

Q. **Okay. Now, just to level set here, the allegation is that Jazz copied Avadel's claims. But regardless, whether Mr. Valentine referred to them or copied them, he filed that application, he had the '866, the Avadel patent in his possession. And a week later he filed an IDS, correct?**

A. **Sounds like it, yes.**

Q. **Okay. And the '866 patent, Avadel's patent that Mr. Valentine referred to, that was not disclosed on the first IDS?**

A. **Yeah, that's true.**

Q. **Okay. Now, if you look at your expert report, where you mentioned this first IDS, which is paragraph 78, you don't mention how many references were disclosed on that IDS, correct?**

A. **No.**

Q. **Okay. There were three other IDS's that Jazz submitted to the Patent Office, and for each of those you listed the number of references. Was there a reason you didn't do so for this one?**

A. **No.**

Q. **Coincidence?**

A. **No.**

Q. **Okay. Let's take a look at that IDS.**

MR. ZUBICK: Can you put up, please, Mr. Jarrett, JTX12 in evidence. And let's go to page 64.

BY MR. MR. ZUBICK:

Q. **So, Mr. Stoll, this is the first IDS that Mr. Valentine submitted a week after he referred to Avadel's claims. And you see on the top left there's 21 pages of this IDS, right?**

A. **Yes.**

Q. **Okay. And if you look, there's numbered references, so on this first page there's 30 references, right?**

A. **Yes.**

Q. **Okay. And Mr. Valentine did disclose some Avadel references, you note that in your expert report, just not the '866 patent you referred to, right?**

A. **Yes.**

Q. **Okay.**

MR. ZUBICK: Can we go to the next page, please.

BY MR. ZUBICK:

Q. **So you got another 30 references on this page, right?**

A. **Yes.**

MR. ZUBICK: Next page, please.

BY MR. ZUBICK:

Q. **Another 30 on this page, right?**

A. **These look like the references submitted in the parent application and submitted again here.**

Q. **Okay.**

MR. ZUBICK: Can we go to the next page, please. And the next page, please. Let's go to next page. Again, please. I could keep doing this, but let's go to sheet 21.

Can we get to the last page, Mr. Jarrett, 21 of 21. Looks like a little bit too far. No, not page 21. So we got to do 64 plus 21, let's go 85, please. One back. Okay. Here we go.

BY MR. ZUBICK:

Q. **So this is sheet 21 of 21. This is the last page of the IDS, right?**

A. **Yes.**

Q. **Okay. And there were 332 total references, correct?**

A. **Yes.**

Q. **Okay. Now, you were speaking to -- well, let me first ask you, do you have any idea how many pages total these 332 references make up?**

A. **No.**

Q. **Did you look into that as part of your work on this case?**

A. **No.**

Q. **Okay. Any guess?**

A. **No.**

Q. **A lot?**

A. **I don't know what your definition of a lot is.**

Q. **Fair enough. Do you know the total number of references that Jazz disclosed to the examiner between this IDS and three subsequent IDS's that were filed?**

A. **I know I did at one time but I don't remember the number right now.**

Q. **350 or so sound right?**

A. **It does sound right.**

Q. **I think that's what Mr. Matal testified to yesterday.**

(Reporter asks for clarification.)

MR. ZUBICK: I said 350 or so. I think the number is 374 if I'm being precise.

BY MR. ZUBICK:

Q. **Now, it's your opinion the examiner reviewed and considered all these references, right?**

A. **If the examiner initialled and said that she considered them, it's my opinion and the Office's opinion that she considered the references.**

Q. **Okay. And so that initialling by the examiner, it was electronic initials -- and I don't mean to say there's anything wrong with that -- that's what you're talking about, right?**

A. **Yeah, I used to write it with my own hand but I think now they do that.**

Q. **Okay. Examiners don't always spend the same amount of time reviewing every reference, right?**

A. **They consider it to the same degree that they consider the references that they find on their own.**

Q. **And sometimes an examiner may look at the title of a reference, decide it's not relevant, initial it and move on, right?**

A. **It can happen.**

Q. **And, in fact, the examiner's initials don't tell you to what degree the examiner considered the reference, right?**

A. **I think that's true, it doesn't tell you how in-depth she went into it.**

Q. **And you've testified to that effect before, right?**

A. **I probably have.**

Q. **Do you remember if you've testified to that effect before?**

A. **Not specifically, but I believe that, so it's very possible that I testified to that before.**

Q. **Okay. Now, during your direct, you mentioned that the notice of allowance -- strike that.**

In your expert report, you mentioned the notice of allowance for the '079 patent, right?

A. **I don't --**

Q. **You don't remember --**

A. **-- I was only focusing on this one.**

MR. ZUBICK: Can we put up JTX12, pages 230 to 231.

BY MR. ZUBICK:

Q. **This is the reasons for allowance for the '782 patent, right?**

A. **Yes, there is a reason for allowance section here.**

Q. **There's no mention of any Avadel patent on the reasons for allowance, right?**

A. **It's rare to mention. It happens, but they don't need to --**

Q. **Okay.**

A. **-- explain the reasoning for allowing the application.**

Q. **Right. There is mention, though, of an Allphin patent, you see that?**

A. **I do.**

Q. **No mention of an Avadel patent, right?**

A. **I don't see any.**

Q. **Okay.**

MR. ZUBICK: Pass the witness, thank you, Mr. Stoll.

THE COURT: Okay. Redirect.

MR. NIMROD: Can you please put up the first demonstrative you used. Thank you. Thank you very much.

REDIRECT EXAMINATION

BY MR. NIMROD:

Q. **Do you recall you were asked about these claims?**

A. **Yes.**

Q. **And the claims that are highlighted here with similarities are Claims 1, 2, and 3 on the right for Jazz's?**

A. **Yes.**

Q. **Okay. And do you recall --**

MR. NIMROD: You can take that down, please, thank you. Mr. Lewis, can we please put up JTX6. If we go to the last page, it's 0.19, thank you.

The first three claims, if you can just bring those up for a second.

BY MR. NIMROD:

Q. **Those are the claims that were on the slide you were shown?**

A. **Yes.**

Q. **Okay. Do you understand that the claim at issue here --**

MR. NIMROD: If we can go down to Claim 24, Mr. Lewis. Thank you, call that out, please, Claim 24.

BY MR. NIMROD:

Q. **Claim 24 is a claim at issue before the jury, right?**

A. **I believe so.**

Q. **Okay. And did Mr. Matal give any opinions as to whether there were copying the effective Claim 24?**

A. **I didn't hear you.**

Q. **Did Mr. Matal provide any opinions as to whether there was copying for Claim 24?**

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

MR. NIMROD: Thank you, no further questions.

THE COURT: All right.

All right. Mr. Stoll, you may step down.

All right. Jazz, you may call your next witness.

MR. CALVOSA: Your Honor, at this time Jazz

calls Dr. R. Christian Moreton.

Richard Christian Moreton, having been called on the part and behalf of the State as a witness, having first affirmed to tell the truth, testified as follows:

THE COURT: Dr. Moreton, you may take the stand.

MR. CERRITO: Your Honor, may I approach?

THE COURT: Yes.

DIRECT EXAMINATION

BY MR. CALVOSA:

Q. **Good morning, Dr. Moreton. Can you please introduce yourself to the jury.**

A. **Yes, my name is Richard Christian Moreton.**

Q. **And can you please tell a little bit about your educational background.**

A. **Yes, I have a degree in pharmacy -- an undergraduate degree in pharmacy, a master's in pharmaceutical analysis and a PhD in pharmaceuticals.**

Q. **How many years have you worked in the pharmaceutical field?**

A. **About 45, maybe 46 years.**

Q. **And what type of work have you done?**

A. **I have worked mostly as a formulation scientist, so taking the medicine -- the active drugs and making it into medicine so a patient can take them.**

Q. **And what type of dosage forms have you worked on?**

A. **I have worked on tablets, hard capsules, soft capsules, suppositories, creams, ointments, oral suspensions, oral solutions and parenteral solutions.**

Q. **Have you held any roles in any professional organizations in your field?**

A. **Yes, I held roles in the American Association of Pharmaceutical Sciences and also at the United States Pharmacopeia.**

Q. **Is that called the "USP" for short?**

A. **Yes.**

Q. **Have you won any awards at the USP?**

A. **Yes. In 2018, I was awarded the Jacob Bigelow Award, which is awarded annually to an expert volunteer who makes what they call a substantial contribution to the standards-setting process.**

Q. **Has any of your work in your field related to the sustained release and the enteric polymers that we have been talking about?**

A. **Yes, I have experience working in that field.**

Q. **Do you have any publications or speaking engagements related to your work?**

A. **Yes, I have, I authored or co-authored book chapters on modified release which includes controlled-release and enteric release.**

I have given presentations on enteric release

and controlled-release and I have worked with different colleagues on training courses, mainly covering excipient sound, immediate release and other kinds of modified-release formulations.

MR. CALVOSA: Your Honor, at this time Plaintiffs move to call Dr. R. Christian Moreton as an expert witness in the field of pharmaceutical sciences including drug formulation and drug delivery and technologies.

MR. BRAUSA: No objection.

THE COURT: All right. Dr. Moreton may testify in those areas.

BY MR. CALVOSA:

Q. Dr. Moreton, why are you here today?

A. I'm here to give opinions on the validity of the Claim 7 and 11 of the '488 patent.

Q. And is there anyone in particular that you're responding to?

A. Yes, Dr. Charman.

Q. Were you here in court to hear Dr. Charman's opinions yesterday on written description, enablement and improper inventorship/derivation?

A. Yes, I was.

Q. Do you agree with Dr. Charman's opinions?

A. No, I do not.

Q. **Let's start with written description, and I want to start with Dr. Charman's opinion that the '488 patent specification lacks any description of a sustained-release formulation possessing a functional coating containing that MAMM polymer.**

And I think we heard someone say "no MAMM" yesterday, which we all were waiting for, but do you agree with that opinion?

A. **No, I do not.**

Q. **Why not?**

A. **The '488 patent clearly describes to a POSA, in my opinion, that the MAMM co-polymers can be used as pore formers in a controlled-release -- a sustained-release formulation and the patent goes on to describe how you use them and what kind of results you can expect.**

MR. CALVOSA: And Mr. Lewis, can you please pull up JTX003 at page 25, column 18, lines 53 through 67, which is already in evidence.

BY MR. CALVOSA:

Q. **And, Dr. Moreton, can you please explain to the jury what the patent is talking about here.**

A. **Excuse me, let me put my glasses on.**

This is the excerpt of the patent that explains how you can have a controlled-release formulation which exhibits start-up time and that the sustained release starts

after the delivery of the drug from the immediate-release component.

And they say where a start-up lag time is desired, an enteric coating may be applied over the controlled release coating or a start-up lag time can be -- hold on. I'm forgetting the word. A start-up lag time can be achieved by use of enteric pore formers.

Q. And does the '488 patent provide any guidance to a person of ordinary skill in the art about which pore formers to use?

A. Yes, it does. You can apply soluble pore formers or enteric pore formers --

(Reporter clarification.)

-- and/ or enteric pore formers.

BY MR. CALVOSA:

Q. And does the '488 patent provide any guidance to a person of ordinary skill in the art regarding what percentage of those enteric pore formers to use in a standard formulation?

A. Yes, it does.

Q. And what percentage were those?

A. Those mentioned --

(Reporter clarification.)

Cellulose acetate phthalate and methacrylic acid-methyl methacrylate copolymers, the MAMM copolymers

that have been referred to and also poly -- polyvinyl acetate phthalate, as said, folate.

Q. Does the '488 patent provide any guidance to a person of ordinary skill in the art regarding what percentage of those enteric pore formers to use in the sustained-release formulations?

A. Yes, it does.

Q. And what percentage is that?

A. The percentage that's in the patent specification is 20 to 50 percent of the controlled-release coating.

MR. CALVOSA: And, Mr. Lewis, if you can please pull up JTX003 page 23, column 13:26-41, lines 26 through 41, please, Mr. Lewis.

BY MR. CALVOSA:

Q. Is this the portion of the specification that you're referring to with the enteric pore formers and the percentage?

A. Yes, it is.

Q. I want to focus on a portion that Dr. Charman mentioned yesterday. The last sentence in the first paragraph there about "incorporating enteric components in the film may result in delivery characteristics that exhibit some level of sensitivity to gastric and intestinal transit times."

Do you see that?

A. **Yes, I do.**

Q. **And did you hear Dr. Charman say that that would cause some concern for a POSA?**

A. **Yes, I did.**

Q. **Do you agree with that?**

A. **No, I do not.**

Q. **Why not?**

A. **The enteric pore form -- enteric polymers have been known for many, many years. They -- it's well understood that the properties of these pore formers are certainly pH dependent in certain circumstances, and a POSA, a person of skill in the art, would understand that and use that to their advantage. That's why they use them.**

Q. **And we keep referencing the person of ordinary skill. Which person of ordinary skill did you use in your analysis?**

A. **I think there's an agreed definition that Dr. Charman mentioned, and I don't have any problem with that, using that definition as well.**

Q. **So the same definition as Dr. Charman?**

A. **Yes.**

Q. **Now, the -- Dr. Charman also testified that the '488 patent specification does not show that the inventors were in possession of that MAMM pore former formulation with the claimed deionized water dissolution profile. Did you hear him say that?**

A. **Yes, I did.**

Q. **And do you agree with that?**

A. **No, I do not.**

Q. **Why not?**

A. **Well, the MAMM copolymers are specifically mentioned, called out in the patent specification, and the patent specification clearly describes that if you want a lag time, this is one way to do it, and that if you have a lag time, you can expect that the release, the controlled-release portion of the medication would not start to release immediately, but there would be a delay of maybe one to two hours before the sustained release starts, and then you would get a conventional, what we call an S-shaped curve for the shape of the dissolution profile after the lag time.**

Q. **Now, Dr. Moreton, does the '488 patent specification include examples of using that MAMM pore former in a dissolution profile?**

A. **The examples do not use MAMM in the -- in the patent.**

Q. **Did you prepare a demonstrative showing the difference between the enteric pore formers and the nonenteric pore formers that you just discussed with the jury?**

A. **Yes, I did.**

MR. CALVOSA: Mr. Lewis, can you please pull up PDX7.7. And could we go to 7.8 perhaps. There we go.

BY MR. CALVOSA:

Q. **The figure 1 on the left, which pore former is being used in figure 1 of the '488 patent?**

A. **The one on the left or the one on the right?**

Q. **The one on the right.**

A. **The pore former used in the figure on the right, figure 1, is hydroxypropyl cellulose, which is a nonenteric pore former.**

Q. **And if we move that figure over onto the one from the left, the one from the left is using which pore former?**

A. **The one on the left is using the MAMM copolymer pore former.**

Q. **And as we look at it now -- and that's from Mr. Allphin's laboratory notebook that he used earlier this week?**

A. **Yes, the blue line is the deionized water or purified water dissolution medium. The other one is a more complex medium that is sometimes used.**

Q. **And we see that those two dissolution profiles don't match up?**

A. **They don't match up specifically, but they're very similar in shape. They both would be S-shaped curves. The one in -- the curve from figure 1, they didn't analyze the earlier time points before one hour. If they did that, we would see an S-shaped curve.**

Q. **Now, if you move that over one hour for the lag time, what do we see here?**

A. **What we see here is that if we had -- if this is -- if we had used the MAMM copolymers in that experiment, we would have shifted the start of the controlled-release portion by about one hour. That's the lag time. And -- but then after the lag time, the release occurs in a conventional manner, and you have this S-shaped curve that we talked about.**

Q. **And those match up pretty good, don't they?**

A. **They match up pretty close, yeah.**

Q. **Now, the testing that was done in figure 1 of the '488 patent, what USP apparatus did that use?**

A. **That used USP 2 apparatus.**

Q. **And which USP apparatus did Mr. Allphin use?**

A. **He -- in the --**

Q. **In the figure we're looking at.**

A. **In the other figure? That was USP 7.**

Q. **And how did those USP 2 and USP 7 apparatuses match up?**

A. **So as you can see, there is a very close comparison, very similar dissolution profile between the two dissolution apparatuses.**

MR. CALVOSA: And, Mr. Lewis, can we go to JTX003, page 20, lines -- column 7, line 64, through column

8, line 4. 7, line 64, through column 8:4.

BY MR. CALVOSA:

Q. Can you tell the jury what we're seeing here in the '488 patent?

A. Yes, this is describing the very -- the standard USP type of dissolution conditions, and it says you can use USP Type 2 or USP Type 7 dissolution apparatus set at 37 degrees C, which is normal dissolution temperature, it reflects body temperature, and then it provides for a different media. One of the media is purified water, which is the same as deionized water, and that's the one that Mr. Allphin used in his experiments.

Q. You've mentioned that "lag time" phrase before when discussing the graphs. Does the '488 patent provide a reason that a person of ordinary skill in the art would want a lag time?

A. The '488 patent only says that if you want a lag time, this is the way to do it. The person of skill in the art would rely on other members of their team, the clinical people and the pharmacokineticists, to determine that -- if a lag time is needed, and then the formulation scientists would understand how to develop that lag time.

Q. And would there be anything advantageous about using a lag time?

A. It could be. I mean, it would depend on the

pharmacokinetics of the particular drug and the dosage form, but there could be advantages in avoiding super high blood levels and side effects. That could be a -- it could be a means of extending the dosing interval, which would be beneficial to patients too.

Q. **And that formulator relying on the pharmacokineticists or other pharmaco development team, is that consistent with Mr. Allphin's testimony about him relying on his co-inventor to set the profile for his formulation?**

A. **Yes, it is.**

Q. **Okay. I'd like to move on now to Dr. Charman's testimony about whether the inventors of the '488 patent were in possession of microparticles or just tablets. Did you hear that?**

A. **Yes, I did.**

Q. **Did you agree with him that the inventors were not in possession of microparticles?**

A. **I do not agree with him.**

Q. **Why not?**

A. **Because. Excuse me. I need to put some gloves on my hand again.**

Q. **Sure, take your time.**

A. **There's a passage in the patent specification which refers to a specific coating process, and that coating**

process is used mainly, in my experience, for coating microparticles.

Q. And what is that coating process called?

A. It's called a Wurster film coating process.

MR. CALVOSA: And, Mr. Lewis, if you could pull up page 23 of JTX003 at column 14, line 63-65.

BY MR. CALVOSA:

Q. Is this the portion of the '488 patent you were referring to?

A. Yes, it is.

Q. Have you seen in other documents you reviewed in this case that Wurster fluid bed coating process being used?

A. Yes, I have.

Q. And where have you seen that?

A. It's actually in the Avadel NDA application where they describe their process for manufacturing their -- their product.

Q. Did you rely on Avadel's NDA, though, to form your written description opinions?

A. No, I just used it as an example of a coating of microparticles using a Wurster fluid bed coating process.

Q. Were you in court yesterday when Dr. Charman was testifying about whether powders are microparticles?

A. Yes, I was.

MR. CALVOSA: And can we pull up that portion of

the specification, please Mr. Lewis. It's page 18 of JTX003, column 4, lines 10-23.

BY MR. CALVOSA:

Q. **Do you agree with Dr. Charman that powders are not microparticles?**

A. **Powders can be microparticles, so I disagree with him.**

Q. **And were you here yesterday when we saw the example of Lumryz being a powder?**

A. **Yes, I was.**

Q. **And is Lumryz a microparticle?**

A. **Yes, it is.**

Q. **Now, here it says that the IR component can be in a powder formulation. How does that relate to the other sustained-release or controlled-release component being in a powder formulation?**

A. **See, if you administer them separately, they don't have to be, but that's not a very convenient way for a patient to take their medicine. And so if you have -- want to have what they call an integrated dosage form, you have to match up the immediate-release and the controlled-release components to be able to allow the patient to take them at the same time, and it simplifies their dosing regimen and it's less confusing, particularly for certain people, for certain patients.**

Q. **Did you hear Dr. Charman testify that tablet formulations are not easily transferable to microparticle formulations?**

A. **Yes, I did.**

Q. **Do you agree with that?**

A. **No I do not.**

Q. **Why not?**

A. **We have known how to make tablets. We have known how to make microparticles for decades, and if we have a controlled-release target specification, we can use the standard technologies, the standard ways of making these particles, the standard testing that we do on these such formulations to develop either a microparticle or a tablet formulation and achieve the same in vitro dissolution.**

Q. **Are there calculations that a POSA could do to transfer different sizes and shapes of dosage forms?**

A. **Yes, there are.**

Q. **And did you prepare a demonstrative for the jury showing that?**

A. **Yes, I did.**

MR. CALVOSA: And, Mr. Lewis, can you please pull up PDX 7.5.

BY MR. CALVOSA:

Q. **Can you explain to the jury what we're seeing here on this slide?**

A. **This is just a very schematic representation, so we have a 1-inch cube. So each surface of the cube -- there are 6 surfaces -- each surface of the cube is 1 square inch, and so the total surface of that cube is 6 square inches, and that's what you have to coat.**

Now, if we split that cube -- that's the coating, by the way. If we split that cube into eight regular, you know, equal-sized portions so we have eight cubes now, and each of them would have --

Could we move on to the next slide, please. Yeah, thank you.

Each would have -- each side is -- half an inch, and so each side has a surface area of a quarter square inch. But there's 6 faces to the cube, so the total surface area of those smaller cubes would be 1.5 square inches. And now we have 8 of them, so we have 12 square inches in total. So by splitting it in 8, we have doubled the amount of surface that we need to coat and we would need to compensate the amount of paint in this case, which would be double that required to coat the other -- the larger particle.

And there are similar equations that we can use for coating other shapes like particles that are spherical and other shapes as well. And this is something that we've known about for a long, long time. This is very straightforward geometry and arithmetic.

Q. **Have you, yourself, done work that relates to coating different shapes and sizes of dosage forms?**

A. **Yes, I have.**

Q. **I'd like to move on now to Dr. Charman's inventorship opinions. Besides from Dr. Charman's testimony, were you in the courtroom earlier this week for Clark Allphin's testimony?**

A. **Yes, I was.**

Q. **Did you hear his testimony regarding his work on sustained-release oxybate formulations with MAMM pore formers?**

A. **Yes, I did.**

Q. **And did you see his deionized water dissolution testing?**

A. **Yes, I did.**

Q. **And as part of your work in this case before we came to court this week, did you review the documents that Mr. Allphin talked about here?**

A. **Yes, I did.**

Q. **And what conclusions, if any, did you draw from your review of those documents and listening to Mr. Allphin's testimony?**

A. **Well, Mr. Allphin and Mr. Pfeiffer, obviously they spent -- they had an extensive amount of work on the project. They really nailed down the technology. They**

understood how to modify the delay of the lag time. They really had a good, good understanding of the technology and were able to use it to develop formulations which met the specifications and claims in the patent.

Q. And then what's your conclusion with respect to Dr. Charman's allegation that the '488 patent Claims 7 and 11 are invalid for improper inventorship and derivation?

A. I disagree. I believe in my opinion Mr. Allphin and Mr. Pfeiffer properly invented the -- the claim -- the claims of the '488 patent.

Q. Okay. Last topic, enablement.

MR. CALVOSA: And we can pull up Dr. Charman's slide from yesterday, please, DDX90.

BY MR. CALVOSA:

Q. And he went through these quickly yesterday largely repeating the written description analysis, but let's go through them together. Can you tell me what these factors on the slides are?

A. These are *Wands* factors, which are some of the factors that are used in evaluation of enablement. This is a legal term. I'm not a lawyer. This is what I have been told over the years. And so these are five of the *Wands* factors that Dr. Charman mentioned yesterday.

Q. And remember Dr. Charman yesterday said the class of potential dosage form was so large and the scope of the

claims was so big. Do you agree with that?

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

Q. **Why not?**

A. **We have to remember that this is -- this technology is essentially about coating technology. And coating technology can be applied to tablets, capsules, microparticles. What it is applied to is irrelevant. What you have to achieve is the dissolution characteristics of -- that are cited in the patent.**

Q. **And does the '488 patent tell a person of ordinary skill in the art that any particular excipient or inactive ingredient that Dr. Charman lists on the slide is incompatible with the GHB formulations?**

A. **No, it doesn't.**

Q. **And did you hear Dr. Charman testify that any ingredient would be incompatible?**

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

Q. **Now, the next one, the nature of the invention. Do you agree that using GHB in the dosage form would add to the unpredictability?**

A. **No, I do not.**

Q. **Why not?**

A. **GHB is just another drug in the formulation, a formulator's understanding. This is -- formulation scientists will take any drug, and they will formulate it.**

If they don't have the information on the properties, they will investigate it, they will use that information in combination with their knowledge of excipient materials and processing in order to develop the right formulation. This is something that is done many, many times and has been done many, many times over the years. I have done it myself. Every drug -- new drug is different, but this one, it's, in many respects, just another drug.

Q. **And what about the next factor, the level of skill in the art and the state of the art, do you agree with Dr. Charman that the challenges of working with GHB would cause a person of ordinary skill in the art to question whether the '488 patent discloses how to make and use the claim formulations?**

A. **I do not agree.**

Q. **Why not?**

A. **The '488 patent describes how the inventors developed their formulations, how they overcame the properties of the drug which could be challenging, that they were able to make the formulations that gave the dissolution profiles that they needed, and this is something that I would have expected a POSA to do dealing with any drug.**

Q. **And the next one, the teachings in the patent, would your opinions be the same?**

A. **Yes, they would.**

Q. **And lastly, the quantity of experimentation. Dr. Charman used the word "extensive experimentation." Do you agree with Dr. Charman that a person of ordinary skill in the art would not be able to make and use the claimed inventions of Claims 7 and 11 of the '488 patent without extensive experimentation?**

A. **No, I do not. There would be some experimentation. That is what we do. Sometimes you hit it straight off, but very often you have to do a certain amount of experimentation, but it's not extensive. This is normally done. This is the normal way that formulation science works, and this is done many times all over the globe.**

Q. **And so I get the correct legal standard, would your opinion be the same if it was "undue experimentation" instead of "extensive experimentation" in my question?**

A. **It's not undue experimentation.**

Q. **No, I asked a different question this time.**

And then just one last question. Is dissolution test itself routine experimentation?

A. **Dissolution testing is routine experimentation. It's required -- in terms of soluble dosage forms, the FDA and other regulatory authorities around the world expect and demand that the formulation is tested, and dissolution is one of those mandatory tests.**

MR. CALVOSA: Okay. Pass the witness.

THE COURT: All right. Cross-examination.

MR. BRAUSA: Permission to approach with binders, Your Honor.

THE COURT: Yes.

CROSS-EXAMINATION

BY MR. BRAUSA:

Q. **Good morning, Dr. Moreton. I don't think we've met before. My name's Adam Brausa. I'm one of the attorneys representing Avadel.**

A. **Good morning.**

Q. **If I heard your testimony correctly, it's your view that every new drug has some challenges, but GHB, sodium oxybate, it's just another drug?**

A. **Correct.**

Q. **Now, sodium oxybate's not a new drug, to be clear, right?**

A. **That's my understanding, yes.**

Q. **You've never actually worked with sodium oxybate in your career?**

A. **No, I have not.**

Q. **You don't know how hard it is to formulate controlled-release sodium oxybate, correct?**

A. **From the teachings of the '488 patent, the formulation of sodium oxybate is not unduly difficult.**

Q. **You don't know how hard it is to actually develop a**

controlled-release form of sodium oxybate; you've never done it, have you, Dr. Moreton?

A. **I have not done it personally, no.**

Q. **And when you formed your opinions in this case, you didn't do anything to check out the properties of sodium oxybate beyond reading the patent, right?**

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

Q. **It's highly soluble?**

A. **Yes.**

Q. **It requires a high dosage?**

A. **Yes.**

Q. **It deliquesces?**

A. **Yes.**

Q. **It's hygroscopic?**

A. **Yes.**

Q. **These are all challenges associated with formulating sodium oxybate, right?**

A. **Yes, but there are other --**

Q. **Dr. Moreton, I've got limited time.**

These are all challenges associated with formulating sodium oxybate, right?

A. **These are all challenges associated with many drugs.**

Q. **And in your long career, you've never developed a formula with sodium oxybate in it, correct?**

A. **Correct.**

Q. **We talked a bit about microparticles just now, and in your entire career, you've only been involved in developing controlled-release microparticle formulation once, right?**

A. **Once, yeah -- it was more than that, but some of the others didn't go very far, so it didn't get to the full development.**

Q. **Okay. And when we took your deposition in this case, you only referred to one time in your career that you were involved in developing a controlled-release microparticle formulation, right?**

A. **Yes.**

Q. **And that wasn't for sodium oxybate, right?**

A. **No, it wasn't.**

Q. **It was many years ago?**

A. **A good few, yes.**

Q. **And you were an adviser on that project, right?**

A. **I believe so, yes.**

Q. **You just made suggestions about what ingredients should be included, what shouldn't?**

A. **A little bit more than that.**

Q. **Okay. You don't recall the drug that was being formulated, do you?**

A. **I don't recall the number. I don't think it had been given a name yet.**

Q. **Okay. And you don't remember at the time -- or you**

didn't remember at the time of your deposition whether that drug was soluble in water?

A. That, I don't recall.

Q. You don't recall whether it was hygroscopic?

A. I don't recall.

Q. And you don't recall whether it required a high dosage, do you?

A. I think it was medium dosage, but it wasn't low dose.

Q. Okay. So not a high dosage like sodium oxybate?

A. I don't believe so.

Q. Okay. And you don't know whether that project was ultimately even successful, correct?

A. No, I don't.

Q. Other than that one-off consultation, at the time of your deposition, you weren't able to identify any other time in your control -- in your career that you were involved in working with controlled-release drugs as microparticles, correct?

A. If that's what I said at deposition, that would be true.

Q. Okay. And most of your work these days is with drugs that don't easily dissolve in water, meaning they're water-insoluble, right?

A. That appears to be the trend these days, yes.

Q. Okay. And your work actually focuses on making them

immediate-release drugs, right?

A. **My work focuses on early stage, and in early-stage work, we're looking to get therapeutic levels or at least blood levels in human patients ultimately. And so I am looking to immediate release.**

Q. **And that's a different technology, correct?**

A. **It can be, yes.**

Q. **Well, at your deposition, you said that was a different technology, correct?**

A. **Yes, okay.**

Q. **And you've not worked on any projects where the goal of the project was to take a drug tablet and reformulate it as microparticles, correct?**

A. **I don't believe so.**

Q. **I want to talk to you a little bit about some portions of the patents, and some will look familiar because we talked about them during your questioning by Jazz's counsel. But I want to focus on slightly different portions that weren't highlighted, and I'm going to try and take this fairly slow.**

MR. BRAUSA: And I'll note for the jury, if you want to follow along, this is in your binder. It's JTX003, and I'll try and call out the page numbers, the column numbers, and the line numbers as we go.

BY MR. BRAUSA:

Q. **So I want to start out with JTX003, the '488 patent, at page 26. And here, Dr. Moreton, is where the examples of the patent that we've heard so much about start out, right? We see example 1 on page 26, column 19, right?**

A. **Yes.**

Q. **Okay. And the columns are at the top of the patent, 19 and 20, and then the line numbers go right down the middle, correct?**

A. **Yes.**

Q. **Okay. And these examples, they start on page 26, but there are 13 of them, and they go through page 27, 28, 29, and all the way to 30 before we get to the claims of the patent, right?**

A. **Yes.**

Q. **And all 13 of these examples describe tablet formulations, right?**

A. **I believe so, yes.**

Q. **The patent doesn't identify any problems with these tablet formulations, does it?**

A. **Not as far as I recall.**

Q. **And just to be clear, none of these examples involve microparticle formulations, right?**

A. **Correct.**

Q. **None of these examples explain how you make microparticle formulations, do they?**

A. **No, they don't, but that's what a POSA would understand --**

Q. **Dr. Moreton, again, I've got limited time.**

None of these examples describe microparticle formulations or how to make them, correct?

A. **Well, while they don't explain that, that's what a POSA would bring to the table.**

Q. **Right. They don't need to look at Jazz's patent to know that. That's your opinion?**

A. **They would understand how to make particles.**

Q. **Without looking at Jazz's patents?**

A. **That technology has been known for years.**

Q. **Okay. I think you testified that that the patent references a powder and that that can be a microparticle, right?**

A. **Yes.**

Q. **So it can be something else, right?**

A. **It can be a powder as well.**

Q. **Right?**

A. **A simple powder or it can be a complex powder.**

Q. **So microparticles is one type of powder; it's not the only?**

A. **Correct.**

Q. **And the portion of the patent that you were talking about is at page 18, column 4:10-22 and I have highlighted a**

portion at lines 14 to 17, you see that?

A. **Yes.**

Q. **And this portion of the patent where powder is referenced is talking about the immediate-release component, right?**

A. **Yes.**

Q. **And just because it lists forms that the immediate-release component can take there sentence in the patent doesn't tell you anything about how the controlled release formulation can be formulated, it's separate, right?**

A. **That's what it say, yes.**

Q. **For example, liquid is listed as a form the IR component can take, but that doesn't mean you can have a controlled release liquid, does it?**

A. **There are controlled-release liquid suspension.**

Q. **Your testimony is you can have a controlled-release liquid?**

A. **My testimony is that you can have a controlled release liquid suspension.**

Q. **Okay. Dr. Moreton, we talked at your deposition. You were deposed in this case, right?**

A. **Yes.**

Q. **At line -- or at page, rather, 23, lines 20-25, at your deposition, you were asked, "Why is it that a controlled-release formulation could not be a solution?"**

And you answered, "Because the controlled-release formulation, everything has to be soluble in a solution, and how would you get a controlled release?"

I read that correctly, right?

MR. CALVOSA: Objection, Your Honor. That's not improper -- that's improper impeachment. His previous question referred to liquid; now he's changing it to a solution. Those are two different things.

THE COURT: Well, Dr. Moreton can answer the question. You can explain.

THE WITNESS: He just referred to solutions. I referred to suspensions.

BY MR. BRAUSA:

Q. **Okay. So let me clear it up. Let me clear it up.**

Liquid solution is listed as an immediate-release component, right?

A. **Yes.**

Q. **And just because liquid solution is listed as an immediate-release component does not mean that the controlled-release component can be a liquid solution, correct?**

A. **That's what I said at deposition.**

Q. **Because you can't have a controlled-release liquid solution, correct?**

A. **Correct.**

Q. **Now, the patent doesn't actually include any description of a controlled-release component that is a powder, right?**

A. **In the specification, no.**

Q. **Right. But I think on direct exam, you said that you read this next sentence of the patent to mean that if the IR component's a powder, the CR component, the controlled-release component, would also be a powder. Did I understand your testimony correctly?**

A. **What I said was if you wanted to integrate the two, you would combine them as both as forms of powder.**

Q. **Okay. And in this portion of the patent, it doesn't say integrate a powdered IR component, or immediate-release component, with a powdered controlled-release component, does it?**

A. **Not in this part of the patent.**

Q. **Okay.**

A. **But if you look --**

Q. **And, in fact, in the next sentence is --**

THE COURT: Let him -- he wasn't finished with his answer.

MR. BRAUSA: Oh, excuse me. Go ahead.

THE WITNESS: Not in this part of this patent, but it does mention an integrated dosage form in another part of the patent.

BY MR. BRAUSA:

Q. **Okay. And in that other part of the patent, it doesn't refer to a powdered immediate-release component and a powdered controlled-release component, does it?**

A. **I'd have to look at the other part of the patent.**

Q. **Okay. You don't know, sitting here right now?**

A. **I can't recall.**

Q. **In the next sentence after the section that Jazz counsel pointed you to, it says: In such an embodiment, the formulation is provided in the form of a coated tablet or capsule, right?**

A. **It says the pharmaceutical formulation may be provided in the form of a coated tablet or capsule.**

Q. **Right. And your emphasis on "may," I want to get back to in just a moment.**

But I want to confirm what the words in the patent actually are, and it doesn't refer to a microparticle, does it?

A. **No, it does not.**

Q. **It doesn't refer to a sachet?**

A. **No, it does not.**

Q. **But you put the emphasis on "may" in this sentence because it's your opinion that it could be in any form, right?**

A. **It could be in many forms.**

Q. **Okay. And so we should just cross out "tablet or capsule" and say "many forms," right?**

A. **The whole point is that these controlled-release technologies can be used in many types of different formulation.**

Q. **Okay. But that's not what the patent says, correct?**

A. **That's not what this sentence says, yes.**

Q. **Okay. Now, the sustained-release portion that we've been talking about, it has to include a core, and then that core has a functional coating wrapped around it, right?**

A. **Yes.**

Q. **Okay. Let's talk a little bit about what the patent says about the core. Just in terms of getting my wording correctly, the patent talks about a "CR core" at times.**

A. **Yes.**

Q. **And that stands for controlled-release core?**

A. **Yes.**

Q. **It's actually the core of the controlled-release table, though, correct?**

A. **Controlled-release core can be the core of a controlled-release tablet. It can be the core of a controlled-release microparticle.**

Q. **Okay. But what the patent actually is talking about, they call it the controlled-release core, but it's actually the core of the controlled-release tablet, correct?**

A. **Yes.**

Q. **And that makes sense because when we see the section at page 21, column 9, lines 45-50, talking about the controlled-release component, it starts off and talks about these formulations and it refers explicitly to a coated tablet, right?**

A. **Yes it does.**

Q. **Okay. And then it again says that these tablets can be made using known techniques. That's at page 22, line 11 -- I'm sorry, column 11, lines 45-52. And again, when it's talking about these manufacturing techniques that are known, it's talking tablets, right?**

A. **Yes.**

Q. **Okay. And you agree that these techniques were known at the time?**

A. **Oh, yes.**

Q. **Okay. A person of ordinary skill wouldn't need Jazz's patent?**

A. **Those techniques, those types of processing have been known for many years.**

Q. **Okay. Now, in the claims of the patent, if we look at page 30, column 27, and this is -- highlighted portion is at line 38, this is from Claim 1, but you understand that's part of Claims 7 and 11 that you considered. It refers to a range of drug in the core -- a range of drug, rather, in the**

sustained-release portion of about 500 milligrams to 12 grams of the pharmaceutically active ingredient, right?

A. Yes.

Q. And this is the amount of sodium oxybate in the formula?

A. Yes.

Q. Okay. I want to go back to what the patent says about these numbers, which we see on page 21, column 9, and it's at lines 59 and 60. And here you see it referring to sodium oxybate in that same range, right, 500 milligrams to 12 grams?

A. Yes, that's correct.

Q. And when it does so, it's talking tablets, right?

A. Yes.

Q. This is the only part of the patent, the only other portion of the patent outside of the claims that refers to 500 milligrams to 12 grams of drug, right?

A. I think so, yes.

Q. Okay. Now, we've been talking about the core, but there's also a separate section of the patent that talks about the functional coating composition for the sustained-release portion, right?

A. Yes.

Q. And, again, there's a separate section, it's Roman Numeral II, "Functional Coating." This is at page 22,

column 11, lines 54-56. And when it describes the "Functional Coating Composition," we're still talking tablets, right, Dr. Moreton?

A. **Yes, that's what it says.**

Q. **But, again, your opinion is that we should just cross out "tablet" because it can be any coated composition in your view?**

A. **What I said was that this coating technology can be applied to tablets, capsules, microparticles.**

Q. **That's not what they said here, is it, Dr. Moreton?**

A. **That's what they're claiming.**

Q. **I understand, but you understand that written description looks at the specification of the patent and what is said in the specification of the patent, right?**

A. **Yes.**

Q. **And what they say in the specification of the patent under this heading of "Functional Coating Composition" refers to coated tablets, correct?**

A. **That's what it says, yes.**

Q. **It doesn't mention microparticles here.**

A. **It doesn't mention microparticles.**

Q. **Now, the patent also talks about the amount of functional -- or amount of functional coating that you can use to coat the drug substance, right?**

A. **Yes.**

Q. **And that's in the next page at page 23, column 14, and I have highlighted lines 8-10 and 12-15. And here we see that the functional coating can be applied at a weight of about 10 to about 100 milligrams, and then in the next section, it provides more specific ranges for the amount of functional coating you can put on the drug substance, right?**

A. **Yes.**

Q. **Now, a scientist would know without anything more that these ranges wouldn't be applicable to microparticles, right?**

A. **That's correct.**

Q. **This is way too much coating for a microparticle, right?**

A. **That's correct.**

Q. **But a scientist wouldn't need to wonder, because if we go to the next portion right after those range, it says these are useful for tablets of a certain size, and then gives alternative for tablets of different sizes and tells you how much functional coating you want for tablets like that, correct?**

A. **Yes, and that can be extrapolated.**

Q. **Right, we'll get to that. But this is the paintbrush cartoon you're referring to?**

A. **Yes.**

Q. **Okay. The patent, though, it doesn't tell you how to**

take any of these numbers and scale them for microparticle formulations, though, right?

A. **The patent says that you have to go -- you need to change the weight of the coating depending on -- essentially on the size of the tablet, so you change the weight of the coating depending on the surface area of the tablet, and if you understand what the weight of the batch is, you can make the calculations.**

Q. **Right. And just to be clear, though, the patent tells you how to adjust the weights of the coating for tablets of different sizes, correct?**

A. **Yes.**

Q. **It doesn't include any instructions how to change the weight of the coating for a completely different form of drug substance, does it?**

A. **That is something that the POSA brings to the equation.**

Q. **Right. And, again, I want to make sure I understand, though, that is not in the specification of Jazz's patents, correct?**

A. **Correct.**

Q. **Now, in the patent it also talks about the techniques you can use to apply this functional coating to coat the stuff, right?**

A. **Yes.**

Q. **And, again, it says, at column 14 on page 23, that conventional coating methods and techniques are used; is that fair?**

A. **Correct.**

Q. **And I think I heard you refer to one in your discussion with Jazz counsel called a Wurster coating bed, right?**

A. **Yes.**

Q. **And we see that referenced right here. This is the Wurster fluid bed film coating process that you were asked about?**

A. **Yes.**

Q. **And that's named for its inventor, Mr. Wurster, right?**

A. **It's Professor Wurster.**

Q. **Professor Wurster. Excuse me.**

And it was a known technique when Jazz filed its patents, right?

A. **Yes.**

Q. **It's been around for many years?**

A. **Correct.**

Q. **And you can use a Wurster bed film coating process to coat tablets, right?**

A. **Generally it isn't used to coat tablets because it's a very, what do I say, it adds -- it generates a lot of**

agitation and particularly large tablets very often get damaged in the Wurster process. So for tablets, we tend to use -- in my experience, we tend to use a pan coater, which is a much more gentle action. Wurster coating is used for, in my experience, for coating microparticles, not for coating large tablets.

Q. Okay. And just to be clear, you've never worked with any microparticles of sodium oxybate, right?

A. That's correct.

Q. Okay. And my question was actually: Wurster fluid bed can be used to coat tablets, right?

A. It has been, but as I said, it causes a lot of damage to particularly large tablets --

Q. Okay.

A. -- because of the agitation in the fluid bed.

Q. Understood. So it's your opinion it's not preferred, right, for tablets?

A. Correct.

Q. The specification in Jazz's patents doesn't say don't use a Wurster bed apparatus with tablets, does it?

A. Well, the specification doesn't tell it, but a POSA would know.

Q. Okay. And, in fact, in the specification, when it talks about the Wurster fluid bed, that's in the same column, column 14 on page 23, just after we heard about the

tablet coating weights that can be applied, right?
A. Sorry, I can't read this. It's very blurred. What column --
Q. Sure, we're at JTX003.23 at column 14.
A. Okay, thank you.
Q. And it's the three passages we just walked through.
A. Okay, sorry. Repeat your question, please, sir.
Q. Sure, I just wanted to confirm, when the patent talks about the Wurster fluid bed, it does so just after giving weights that applicable only for tablets, right?
A. Yes, it's down in different paragraphs, but yes.
Q. Okay. And nothing in this column that we see here refers to coating microparticles, does it?
A. Only the Wurster coating process at the bottom.
Q. And the cartoon you referenced where there was a cube and then it split in part and the paintbrush was painting different surface areas, those types of calculations aren't set forth anywhere in the specification of Jazz's patent, are they?
A. They don't need to be. This is simple geometry and arithmetic.
Q. Okay. It's your testimony that it's simple geometry and arithmetic to scale a tablet formulation down to a microparticle formulation?
A. That wasn't what I said. Calculating the surface

area required is simple geometry and arithmetic.

Q. Okay. And the actual process of taking a tablet formulation and converting it into a microparticle formulation, that's not something you've ever done, correct?

A. That's not something I have ever done, but it's reported in the literature.

Q. Okay. But you've never done it in your career, correct, Dr. Moreton?

A. I have never done it, right.

Q. And tablets and microparticles, you would agree, they have different characteristics, right?

A. Different sizes, yes.

Q. And they have different characteristics in other regards, too?

A. Probably, yes.

Q. Okay. The same ratio of ingredients formulated as a tablet and formulated as a microparticles might lead to different dissolution curves like the one you showed with Jazz counsel, correct?

A. Which -- sorry. Say that again, please.

Q. Well, let me just back up. The same ratio of ingredients formulated as a tablet and formulated as a microparticle might lead to different dissolution profiles, right?

A. The same ratio of ingredients -- which ingredients?

Q. **The ingredients in the formulation.**

A. **If we take the whole of all of the ingredients, possibly, but if you focus on the core or the coating, it's much more, what do I say, much more straightforward.**

Q. **Okay. Well, I want to focus on the overall formulation. The same ratio of ingredients formulated as a tablet and formulated as a microparticle might lead to different dissolution profiles, fair?**

A. **Possibly.**

Q. **Now, when you initially offered your opinion in this case, you said that the patent itself teaches a POSA how to adjust the weight of coating of a tablet and scale it down to a microparticle size, right?**

A. **Yes.**

Q. **But that wasn't correct, right?**

A. **It gives an indication and we looked at that in -- in the top of this -- whatever, is called out. It gives an indication that you have to change the weight of the coating on an individual particle, tablet to reflect the changed surface area. And what I have said is that if you know the surface area you have to coat, you can calculate how much coating to apply on a batch basis. I mean, we don't talk about coating individual tablets or individual microparticles; we talk about coating batches. And for a given weight of tablets or a given weight of microparticles,**

we can do the necessary calculations.

Q. Dr. Moreton, my question is a little different. I just want to make sure I confirm.

When you initially offered your opinions in this case, it was your opinion that the specification provides information teaching a POSA how to adjust coating composition and amounts to account for any differences in surface area between a tablet and microparticle, right?

A. Yes.

Q. That was incorrect, right? The patent doesn't teach that.

A. The patent teaches that you have to take the size of the tablet and therefore the surface area into account.

Q. Okay. But the patent doesn't actually teach how to do it?

A. Well, the patent doesn't teach how to do it. That's something a POSA would know.

Q. Okay. At your deposition, you were asked to point to anything that taught you how to adjust coating composition and amounts to account for differences between tablets and microparticles, and you couldn't do it, correct?

A. It's not in the patent, no.

Q. Okay. Now, we heard some testimony from your -- from you on examination by Jazz's counsel about your review of some of Mr. Allphin's work.

A. **Yes.**

Q. **Okay. How did you obtain materials about Mr. Allphin's work? Was that provided to you by counsel?**

A. **Yes, it was.**

Q. **Do you know whether you received a complete set of documents from counsel about Mr. Allphin's work?**

A. **I received what I received.**

Q. **Okay. And did you ask for anything more about Mr. Allphin's work?**

A. **I didn't need to.**

Q. **Why is that?**

A. **I felt that what I saw was good, showed good, extensive review of the technology.**

Q. **Okay. Can you turn in your binder to DTX1321?**

A. **Yes.**

Q. **Was this document provided to you by counsel?**

A. **I don't recall the exact document.**

Q. **Okay. And this is a technical memo, correct?**

A. **That's what it says, yes.**

Q. **And --**

MR. CALVOSA: Excuse me, Your Honor, I don't believe I have the second binder.

MR. BRAUSA: I think it should be in your binder. It's DTX1321.

MR. CALVOSA: Oh, that's why.

(Discussion held between counsel off the record.)

BY MR. BRAUSA:

Q. **All right. So you weren't aware that this was a 2016 technical memo from Clark Allphin's files?**

A. **It's dated 2016, but...**

Q. **But you don't know where it came from?**

A. **It came -- it says it came from Jazz. That's all I know.**

Q. **Okay. Can you turn to 1321.10, and it's in the lower right-hand corner.**

A. **Yes, okay.**

Q. **And there's a section on that page called nonenteric approach?**

A. **Correct.**

Q. **And so you weren't aware that in Jazz's technical memo there was a reference to nonenteric means for achieving delayed release in tablets?**

A. **Like I said, I'm not sure I reviewed this. I think I did, but...**

Q. **Okay. You think you did review this?**

A. **I'm not sure.**

Q. **Okay. Well, in the second sentence, it refers to applying these techniques to pellets, right?**

A. **Yes.**

Q. **And it says applying the techniques for tablets to pellets is considerably more challenging, right?**

A. **Yes.**

Q. **Were you aware of that statement when you formed your opinions in this case, Dr. Moreton?**

A. **I may have been.**

Q. **Okay.**

MR. BRAUSA: Your Honor, we move to admit DTX1321 into evidence.

MR. CALVOSA: No objection, Your Honor.

THE COURT: DTX1321 is admitted.

(Exhibit admitted.)

MR. BRAUSA: Okay. And, Mr. Jarrett, if we can pull DTX1321.10 onto the screen. DTX, Mr. Jarrett. There we go. And if we can turn to the tenth page, .10.

BY MR. BRAUSA:

Q. **So here we see at the top, Dr. Moreton the, portion of the document I was referring to under the "Nonenteric Approach" heading?**

A. **Yes.**

Q. **And it's that second sentence where Jazz says, "applying these techniques to pellets is considerably more challenging" in a technical memo from 2016, right?**

A. **Yes.**

MR. BRAUSA: Can we pull up the second paragraph

under the graph on this page. The text under the graph, please, Mr. Jarrett.

BY MR. BRAUSA:

Q. And we see in the first sentence of this paragraph that Jazz says, "Although the behavior with tablets looks promising, the required film formulation for use in a pellet will be substantially different," correct, Dr. Moreton?

A. Yes.

Q. Did you consider this statement when you rendered your opinion in this case?

A. Yeah, if I read it, I did. If I didn't read it, I didn't.

Q. Okay. And the patent, turning back to Jazz's specification, it doesn't tell a scientist what parts of the formulation need to be changed to move from a tablet to a microparticle, does it?

A. That's correct.

Q. Okay. Were you aware that as of February 2015, Mr. Allphin reported that his attempts to make even immediate-release beads were unsuccessful?

A. I may have been aware of that.

Q. Okay. Can you turn to PTX1167 in evidence.

MR. BRAUSA: Mr. Jarrett, if we can go back to 21.

BY MR. BRAUSA:

Q. **So this is an e-mail from Mr. Allphin dated February of 2015 where he says his work has been focused on making IR beads in his lab; unfortunately, all attempts were unsuccessful, correct?**

A. **Yes that's what it says.**

Q. **You didn't conduct any investigation into why Mr. Allphin's attempts were unsuccessful?**

A. **Not that I recall.**

Q. **Okay. I want to turn a little bit to your discussion with Jazz's counsel about MAMM, this copolymer that we've heard so much about over the past few days.**

None of the functional coating -- excuse me. The claims of the patent required MAMM to be in the functional coating in amount of 20-50 percent by weight, right?

A. **Yes.**

Q. **Beyond that, the claims of Jazz's patent don't require any specific ingredients to be in the functional coating, right?**

A. **They are not specified, no.**

Q. **Right. So if I have a functional coating with 20 percent MAMM, the other 80 percent can be any of the ingredients listed in Jazz's patents, right?**

A. **Not any of them.**

Q. **Okay.**

A. **Only the ones that's listed in the coating polymers sure.**

Q. **Sure. And so in that section we saw for the functional coating component, it lists various ingredients, right?**

A. **Yes.**

Q. **And Jazz's patent doesn't state any preference for those ingredients one over the other, correct?**

A. **No, it does not.**

Q. **And different combinations of those ingredients would result in a functional coating with different properties, right?**

A. **I'll have to refresh my memory on what's listed there.**

Q. **Okay. We may do that another time.**

But as we saw -- and we can turn back to some of this and we'll go through some of this, but it's a lengthy section. If we go to page 22, this is the section you were referring to, right, Dr. Moreton?

A. **"Functional Coating Composition," yes.**

Q. **Right. And it's the ingredients in this section from column 11 to column 13 that provide those ingredients?**

A. **Yes, I believe so.**

Q. **And the ingredients that are listed here and the ways they can be used, these were all known before Jazz filed its**

patents, right?

A. Yes, the ingredients that are listed, yeah.

Q. And how the functional coating works, if it works, will depend on the contents of the functional coating, right?

A. Yes.

Q. The patent says the coating can "include one or more base polymers and at least one pore former," right? This is at page 22, column 12, lines 40-42.

A. Yes, that's correct.

Q. And here we, again, see the word "may," right?

A. Yes.

Q. So these are both optional ingredients in the functional coating as it's described in the specification?

A. It says, "may include one or more," but I believe it means at least one.

Q. Okay. So your testimony is that that means -- "may include" here requires one base polymer and requires one pore former?

A. That's my reading of the -- of the wording.

Q. Okay. Polymers can be water-soluble or water-insoluble, agreed?

A. Correct.

Q. Water-soluble polymers function differently than water-insoluble polymers?

A. **Correct.**

Q. **There are more than a dozen different polymers you can use, right?**

A. **Which type?**

Q. **Both.**

A. **There are many. There are many water-soluble and water -- there are many polymers, some of which are water-soluble, some of which are water-insoluble.**

Q. **When you say "many," how many is that, Dr. Moreton?**

A. **Let's think. So water-soluble, there's probably between 12 and 20 if we include the natural polymers.**

Q. **Okay.**

A. **For water-insoluble polymers, maybe 5 or 6.**

Q. **So my estimate was a little more. It's more like 20 different water-soluble polymers you can use.**

A. **You could use 20 different polymers, but you only want to use 2 insoluble polymers.**

Q. **Okay. Now, the patent doesn't express any preference for any particular polymer or combo of polymer, does it?**

A. **No, I don't believe so.**

Q. **And we see here pore formers are another functional ingredient you can put in the polymers?**

A. **That's correct.**

Q. **And the patent describes the inclusion of pore former in the functional coating as an optional ingredient?**

A. **Well, this refers to the base polymer -- the pore formers, that's a different part of the specification.**

Q. **At line 41 and 42, it refers to the pore former, right, Dr. Moreton?**

A. **Oh, sorry. It does, yes, apologize.**

Q. **And so these are another optional ingredient that you can use in the functional coating?**

A. **Yes, they would -- they would include at least one --**

Q. **Okay.**

A. **-- I believe.**

Q. **Your testimony is that the specification requires the functional coating to include one pore former?**

A. **If you don't have the pore former, you may not get the functional coating.**

Q. **I'm just asking what the specification says.**

A. **The specification says "may," but a POSA reading it would understand that you would need at least one pore former.**

Q. **Okay. So the POSA would just cross out that "may" and understand that it's required; that's your testimony?**

A. **POSA would understand that in order to get the functional coating, you would need something that allows you get the functional coating.**

Q. **Well, you could have a base polymer, correct?**

A. **Some base polymers may, but many may not.**

Q. **Okay. Now, there are different types of functional -- or different types of pore formers referred to, correct?**

A. **Yes.**

Q. **And we see you can have polymeric pore formers at column 12, you can have small-molecule pore formers on page 22 and 23, you can have pore formers that comprise a polymer that expands in the presence of a drug, right?**

A. **Yes.**

Q. **And then the patent says it's possible to use an enteric component as all or part of one of the pore formers in the coating, right?**

A. **Correct.**

Q. **It doesn't say it's a good idea?**

A. **It doesn't say it's a bad idea either.**

Q. **Okay. Right.**

And after it introduces this concept of enteric pore formers, it says, "However, incorporating enteric components in the film may result in" certain delivery characteristics, right?

A. **Yes.**

Q. **When counsel showed you this section, he didn't highlight the word "however," correct?**

A. **I can't recall.**

Q. **Okay. "However" would suggest that there's something**

dis- -- there's a disadvantage to using an enteric pore former?

A. **No, it does not.**

Q. **Okay. You don't take anything from the word "however" in this sentence?**

A. **It's reminding the reader of the patent that enteric pore formers have certain properties --**

Q. **Okay.**

A. **-- and that they should remain aware of them.**

Q. **Okay. And in the middle of this paragraph, we see the reference to MAMM, right?**

A. **Correct.**

Q. **It's one of three different examples of an enteric pore former listed in the patent?**

A. **Correct.**

Q. **And nothing in this section provides guidance that MAMM specifically should be used, right?**

A. **It doesn't make a distinction.**

Q. **Okay. MAMM is what's a type of compound called a polymethacrylate, right?**

A. **It's polymethacrylic acid-polymethyl methacrylate copolymer.**

Q. **And that's a member of a broader class of polymers commonly referred to as polymethacrylates?**

A. **Correct.**

Q. **There are other polymethacrylates that are nonenteric, right?**

A. **Yes.**

Q. **And, in fact, Plexiglass is a type of polymethacrylate, right?**

A. **Plexiglass is a type of acrylate. It may be even a methacrylate, but it's not a copolymer.**

Q. **Okay. Now, we can agree, I think, that MAMM, because it's enteric, it's a pH-dependent polymer, correct?**

A. **It has a pH-dependent solubility, yes.**

Q. **Okay. And there are also polymers and ingredients you can use in the functional coating that are nonpH dependent, right?**

A. **That's the nonenteric pore formers, yes.**

Q. **And you testified on your direct examination that if you wanted a lag time, you'd use an enteric pore former, correct?**

A. **That's what I testified to, yes.**

Q. **Okay, but in the specification of the patent, it doesn't give you any reason that you'd want a lag time?**

A. **Like I said on direct examination, the lag time or lack -- or if they wanted a lag time, that would be decided in consultation with the clinical and pharmacokinetics members of the team. The formulation scientists would take their advice as to whether lag time was needed.**

Q. **So just to be clear, Jazz's patent doesn't give you any reason you'd want a lag time, correct?**

A. **Well, it doesn't give you any reason why you'd want a lag time. It says if you do want a lag time, this is a way to do it.**

Q. **Okay. And there are other ways to get a lag time besides using an enteric pore former, correct?**

A. **Yes.**

Q. **And in general terms, a formula that includes a pH-independent polymer will not behave the same way as a formula with a pH-dependent polymer, right?**

A. **Sorry. Would you say that again, please.**

Q. **Sure. A formula with an enteric pore former will not be expected to perform in the same way as a formulation with a nonenteric pore former?**

A. **That would be a difference, yes.**

Q. **Okay. And pore formers can interact with other components in the functional coating, right?**

A. **Possibly.**

Q. **And you don't actually know whether all pore formers work in the same way at the same concentration?**

A. **No, I do not.**

Q. **Jazz's patent doesn't refer to vegetable oil as a potential ingredient in the functional coating in that section of the patent, does it?**

A. **It refers to the fact that you can have fillers in the coating and those are fatty hydrophobic materials.**

Q. **Okay. But it never uses the words "hydrogenated vegetable oil" in the section of the patent describing the functional coating?**

A. **Correct.**

Q. **In the cartoon that you put up with the curves, one from the patent, one from Mr. Allphin's notebook -- do you recall that?**

A. **Yes.**

Q. **The data from Mr. Allphin's notebook, that's not in the patent, right?**

A. **That's correct.**

Q. **Do you know why Mr. Allphin didn't provide that data to the Patent Office?**

A. **I have no -- I have no idea. You'd have to ask Mr. Allphin.**

Q. **Thank you.**

THE COURT: All right. I'm going to give the jury the morning break at this time.

All right. Let's come back at noon.

Dr. Moreton, you're still under oath. You can't talk to counsel.

THE WITNESS: Thank you, Your Honor.

(Break taken.)

THE COURT: All right. You may be seated until the jury comes.

MR. CALVOSA: May I proceed, Your Honor.

THE COURT: Yes.

BY MR. CALVOSA:

Q. **Dr. Moreton, I just have a couple follow-up questions for you.**

The first is, do you remember Avadel's counsel asked you about a document that talked about a nonenteric approach?

A. **Yes.**

Q. **Is MAMM a nonenteric polymer?**

A. **No, it is not.**

Q. **Do you remember counsel for Avadel asked you about why Dr. Allphin's IR beads were unsuccessful, and then you said you'd have to ask Dr. Allphin?**

A. **Yes.**

Q. **I didn't hear it, did you hear Avadel's counsel ask Mr. Allphin about that e-mail?**

A. **I didn't hear it, no.**

Q. **Okay. And it could have been for a reason unrelated to the technology in this '488 patent, correct?**

A. **Correct.**

Q. **We just don't know?**

A. **No, we...**

Q. **You mentioned, sir, knowledge of a POSA. Does a POSA, in your opinion, just walk up to a patent with none of their prior knowledge?**

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

Q. **They --**

A. **They wouldn't be a POSA if they didn't have prior knowledge.**

Q. **And Avadel's counsel kept insinuating that Jazz's patent wasn't adding anything because certain information was already known in the art, did you hear that?**

A. **Yes.**

Q. **Avadel's put a bunch of experts on the stand this week. Did you hear any experts saying that combining the enteric pore formers that are disclosed in Jazz's patents, such as MAMM, with gamma-hydroxybutyrate, was known in the art?**

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

Q. **You had mentioned that a POSA would know how to go from tablets to microparticles based on the literature that existed before the '488 patent?**

A. **Yes.**

Q. **Can you turn to JTX101 in your binder?**

A. **Yes, okay.**

Q. **Do you recognize JTX101?**

A. **Yes, I do.**

Q. **What is it?**

A. **This is a U.S. Patent Number 6,514,531, it's dated February the 4th, 2003, and the inventors are Gérard Alaux, Gareth Lewis, and Frédéric Andre.**

MR. CALVOSA: Your Honor, at this time we move for admission of JTX101 into evidence.

MR. BRAUSA: No objection.

THE COURT: JTX101 is admitted.

(Exhibit admitted.)

BY MR. CALVOSA:

Q. **And I'm just going to call it JTX101, because I can't pronounce Alaux as well as you.**

Can you turn to page 15 of JTX101, column 6, lines 4-10. And it's up on the screen in front of you as well.

A. **Okay.**

Q. **Can you explain to the jury what's being taught by this patent?**

A. **This is the -- this patent is explaining that prolonged-release pellets are prepared by coating immediate-release pellets in the same way as described for tablets. And the coating may be carried out, for example, in coating. And the amount and composition of the coating is adjusted for that use in tablet manufacturing of coating to reduce permeability of the coating in order to take into**

account the far greater surface area for diffusion of the pellets.

Q. And how does that relate to your opinions regarding transferring from tablets to microparticles?

A. This is explaining how these inventors transitioned from the tablet to microparticles and how they adjusted the surface -- or the coating composition to take into account the change.

Q. So would this be something a POSA would have been aware of as of the '488's March 24, 2011, priority date?

A. Yes, they should have been. Yes.

Q. Let's go back to the '488 patent, JTX003.23, and I want to look at column 4, lines 10-22. And I want to focus on the last sentence that opposing counsel focused on.

That capsule there, how would a POSA go about formulating a controlled-release capsule?

A. In my experience working both in formulation and as a practicing pharmacist, formally, sustained-release capsules have, in my experience, the ones I have encountered, all contain coated microparticles.

Q. I'd like to go to page 23, beginning column 13, line 59, and continuing on to column 14, line 4. You had mentioned during opposing counsel's questions about certain fillers and anti-tack agents in the '488 patent when he asked you about hydrogenated vegetable oil.

How did that inform your opinion regarding hydrogenated vegetable oil being used in the functional coating?

A. **Well, it listed here two, what they call anti-tack agents, glyceryl monostearate and -- magnesium stearate, as I mentioned earlier. These are hydrophobic materials which can be used as -- also as fillers, and that's explained in the -- further down, the fatty hydrophobic materials, which can be used, and hydrogenated vegetable oil type 1 is a fatty hydrophobic material that can be used in the same way, has very similar properties to glyceryl monostearate.**

MR. CALVOSA: You can take this down, Mr. Lewis.

BY MR. CALVOSA:

Q. **A couple of questions, I promise. Opposing counsel asked you about your experience with GHB, the molecule at issue here?**

A. **Yes.**

Q. **And while you testified you have no experience with GHB, you testified you have experience with compounds related to GHB, right?**

A. **What?**

Q. **I'm sorry?**

A. **Sorry. I have experience with compounds that -- not chemically related to GHB, but have been used in what you might call neurological conditions and things like that.**

Q. **So similar properties?**

A. **Some property, maybe, yes.**

Q. **Did you hear Dr. Charman testify that in Claim 24 he has no experience with GHB?**

A. **Yes, he did.**

Q. **And Dr. Charman didn't testify that he had experience with any compounds either related or similar to GHB?**

A. **That's correct.**

Q. **And did you hear Dr. Charman testify yesterday that the level of proof for invalidity is that clear and convincing evidence standard all the way up here?**

A. **Yes.**

Q. **Who has the burden on for the clear and convincing evidence standard, is it on --**

MR. BRAUSA: Objection.

THE COURT: Sustained.

BY MR. CALVOSA:

Q. **Dr. Moreton, based on the '488 patent disclosures, if a POSA wanted to use lag time, which type of pore former would they use?**

A. **They'd use an enteric pore former.**

Q. **And how many enteric pore formers does the '488 patent disclose?**

A. **Three.**

MR. CALVOSA: No further questions.

THE COURT: All right. Dr. Moreton, you may step down, thank you, sir.

THE COURT: Thank you, Your Honor.

MR. CERRITO: Plaintiffs call Dr. Steven Little.

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

(Dr. Steven Little, having been previously sworn, testified as follows:)

THE COURT: Dr. Little, you're still under oath.

THE WITNESS: Yes, sir.

DIRECT EXAMINATION

BY MR. CERRITO:

Q. **Welcome back, Dr. Little.**

Would you reintroduce yourself to the jury?

A. **Sure, nice to see you all again, my name is Steve Little. If any of you have a space heater you can lend me, that would be great.**

Q. **I did walk by the stenographer's desk, there seems to be heat coming from there.**

Why are you back to testify today?

A. **Yeah, so Defendants offered testimony on the '782 patent, which is one of the patents that you heard Dr. Charman talk about. There were arguments. I was asked to evaluate any arguments and offer opinions in that response.**

Q. **Can you remind me what Claim 24 requires?**

MR. CERRITO: Can I have JTX6.19, please.

THE WITNESS: Okay. So what's being shown here is Claim 24, it depends on Claim 14, which is right above it. And you can see this is the one here that's got the viscosity-enhancing agent and acids and the viscosity-enhancing agents and acid are separate from the GHB-containing pieces, the particles.

And then there's also the addition that the unit dose is in a agent.

BY MR. CERRITO:

Q. **I assume you were in the courtroom for Dr. Charman's testimony?**

A. **I was.**

Q. **Do you agree with Dr. Charman's invalidity opinions?**

A. **There are opinions he gave I disagree with.**

Q. **Why don't we go over what these are.**

MR. CERRITO: Charman's slide DDX60, please.

Thank you.

BY MR. CERRITO:

Q. **Let me ask you, what was your approach for responding to these issues with Dr. Charman?**

A. **Sure, the issues that are on the screen here that I'm going to be replying to here today, these involve the '782 patent, Dr. Charman talked about a couple of different patents. I'm going to be talking about these different**

critiques on the '782, and these are what's called written description.

So there is a legal standard that I was asked to use, I'm not going to go through that, I understand the judge is going to instruct you on what the legal standard is and how to apply that. I'm just going to try to describe that in the simplest way I can.

So I'm responding to Dr. Charman on these issues, and what my understanding is he needs to provide evidence that is clear and convincing evidence that is '782 patent claim, 24, that we just saw, and claim 14, which it depends from, is not described in the specification of the application for the '782 patent, which was in 2016.

So what I was asked to do is step into the shoes of the person of ordinary skill here, which, again, is the person that the specification here was written to so that they could understand.

And if you remember -- I'm not going to go through it again, you've seen it a lot. But if you remember that individual had a number of different degrees and a number of different years of hands-on experience. So if you add them up, it's somewhere around approaching 15 years of education and experience being a formulator.

So I'm stepping into that individual's shoes, with that amount of education, with that amount of hands-on

experience. And through their eyes, I'm looking at the 2016 application for the '782 patent and I'm saying, can that individual see description of these things that are listed here?

And I did that, and I did find description, and I'm going to show you where that description is. In addition to that, the examiner looked at it and the examiner found description for it, and I'll show you that.

So in my opinion, Dr. Charman has not provided any standard let alone clear that this does not have description.

Q. **Why did you analyze the written description from the perspective of a POSA in 2016?**

A. **That was when the application for the particular patent was given and when the examiner found written description for these individual pieces.**

Q. **And just so we can talk about the application, what is the application?**

A. **It is the '586 application, I believe were the last three numbers, and it was in 2016, that's the priority date to the '782 application.**

A. **Yes.**

Q. **Let's go to Dr. Charman's example in the '782 patent. Does it describe nonresinate microparticles?**

A. **Absolutely not. There is description that I found in**

and both the examiner found for that claim element.

Q. Did you hear Dr. Charman say whether or not the Patent Office examiner did a written description analysis during the prosecution of the '782 patent?

A. What I heard was he did not see or was not aware that the examiner did that.

Q. Do you know whether the examiner looked to see whether the modified-release particle limiation of Jazz's '782 patent claims had written description support in the '586 patent application?

A. Yes, I found the examiner did do that analysis and did find description.

MR. CERRITO: Mr. Lewis, could we pull up JTX12 at 0.123.

BY MR. CERRITO:

Q. And, Dr. Little, can you explain what this is?

A. Sure, this is the portion of the back-and-forth where the examiner found description for the element that Dr. Charman says missing. It says here in highlights there's immediate-release, and then you see modified-release portion.

And then it says "comprising gamma-hydroxybutyrate," and then it lists the location where the examiner found the description for it.

Q. So, Dr. Little, do you agree with the examiner that

the '586 application discloses nonresinate particles?

A. I do. It's here and also it's in a number of places that I'll show you now.

MR. CERRITO: Mr. Lewis, can you now go to PTX700.11.

BY MR. CERRITO:

Q. Dr. Little, what does that paragraph show?

A. This, again, is '586, paragraph 10. It says, "One embodiment of the invention is a GHB formulation comprising polymeric beads and pharmaceuticals, it's pharmaceutically acceptable excipients."

So polymeric beads are what we have been talking about in the different patents, those do not need to be resinate, that's a more general term.

Q. So in your opinion, it supports your view it's not limited to resinates?

A. It does, yes.

MR. CERRITO: Mr. Lewis, PTX700.10, please.

BY MR. CERRITO:

Q. Dr. Little, what is the jury seeing here?

A. Yeah, this is in the summary of inventions. This is paragraph 4. It says, "One embodiment of the invention is a GHB formulation comprising polymeric beads and pharmaceutically acceptable excipients."

This is another example of it being general.

Q. **Any other disclosures that we already went over that supports an opinion of the POSA understanding the '782 specification is not limited to resinates?**

A. **Yes, there's also the specification of the '488 patent, which is incorporated by reference into the '782 patent specification.**

Q. **How does the '488 support your opinion?**

A. **Well, the '488 is only about nonresinate formulations, so it's going through the technology that we've been hearing about, it's not resinates. I think Dr. Charman called them conventional formulations, right. And there's descriptions that refer to those formulations in the '488.**

Q. **You mentioned "incorporation by reference," we've heard that all, incorporation by reference a number of times, can you just remind the jury what that means?**

A. **When we write patents, one of the things I understand we're allowed to do is incorporate by reference, and one of the ways we can keep the specifications manageable and short so you can -- it's like referring to another document but this is such -- you're saying, I am referring to this other document such that its specification is actually in my specification.**

Q. **Thank you. Were you in the courtroom when Dr. Charman testified that the powder formulations disclosed**

in the '488 patent would not include microparticles?

A. I was.

Q. Do you agree?

A. I don't.

Q. Why not?

A. Well, first of all, microparticles are certainly powders, we make microparticles all the time and we call them powders. It's one of the subset that we call powders. In addition to that, this patent -- patents that we're talking about here refer to them as powders, and even Avadel's patent, the '062, refers to particles they are talking about as powder.

Q. Did you hear Mr. Charman testify about the '782 patent specification criticizing conventional approaches for modified release saying they were difficult to use with oxybate, do you have an opinion on whether a POSA would agree with Dr. Charman?

A. I did hear that, and I -- I've reviewed the portion of the specification that he's referring to, it's just I don't read it in the same way that Dr. Charman does.

Q. Okay. Let's look at the section of the specification Dr. Charman relies on.

MR. CERRITO: Mr. Lewis, could you please pull up DDX61, please.

BY MR. CERRITO:

Q. **Dr. Little, what's your opinion how a POSA would understand this section of the '782 patent?**

A. **Okay. This is the portion that Dr. Charman says disparages conventional formulations, it's part of a greater section. You can see up at the top, it's kind of grayed-out, it says, "Unusually mobile in solution" -- that's referring to the drug and leads into what we're going to be talking about.**

Dr. Charman used an analogy -- and he's from Australia, so maybe that's a good analogy. I instead will use the analogy of a bird.

If you have a very small bird, that would be something that would be highly soluble and mobile in solution. So what you're trying to do is -- how you can keep it from flying out of the cage too fast, okay.

So I'll just read this. It says, "These factors complicated, and, in many case, limit conventional approaches." It doesn't say it's going to eliminate all conventional approaches, it says limit.

Then it says for modified release, such as core-shell, or matrix formulation, as the high solubility and mobility of GHB -- again, a small bird -- would tend to significantly reduce the number of viable approaches, so they are reduced but they are not eliminated. It's not like there are zero approaches using such conventional soluble

and diffusivity control technologies that I would refer to in a simple analogy as a bird cage.

Q. Doctor, how would a POSA hold that small bird in a cage, as you described it?

A. Yeah, in the case of a bird cage, we can come up with some things that we might do to keep it in, if you think about it for a second. So one thing we could do would be to use maybe thicker bars, that would help to keep the bird in. Another thing, if you think for a second what we could do, is maybe add more bars. So you can use the same bar but you would put more of them in.

So in the context of the '782 patent specification and the '488 patent, that's incorporated by reference, it talks about things like pore formers which are the spaces between cages, or the thickness of coating is another example of this. And those are analogous to the thickness of the bars or the spacing of the bars for the pores.

And if you do those things, although you wouldn't be able to use perhaps what you would call standard potential, like a bird cage, you could come up with a bird cage design that fits this criteria. Solve the problem with GHB. Yes.

Q. With a POSA eye and experience and education, they could -- Dr. Charman said a POSA would need to see data

demonstrating the nonimmediate release of oxybate from the particles in order to show written description, do you agree with that?

A. I don't in this instance, no.

Q. Why not?

A. Well, so, first of all, let me just establish that I look at a lot of patents, I write my own, and you do not have examples for every single permutation of something that you would have an embodiment for a particular invention.

MR. SCHULER: Objection, Your Honor, Rule 26.

THE COURT: Okay. Let's come to sidebar.

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

MR. SCHULER: I don't --

MR. CERRITO: This is the deposition transcript of 11/16 at 189 to 190.

MR. SCHULER: He appears to be testifying and seems to implying what the legal standards are for a patent.

MR. CERRITO: I'm asking what a POSA would need to see and he's testifying as a POSA, does he need to see data, no a POSA needs to see it.

MR. SCHULER: They are admitting something not in his report.

MR. CERRITO: I have given a citation, he testified about it, Your Honor. They know it, it's no

surprise.

THE COURT: What a POSA needs to see, so... what's...

MR. SCHULER: I don't see it in his report.

MR. CERRITO: Again, you asked him questions at his deposition.

THE COURT: Okay. So you're saying it's not in his report, you're saying he answered these questions at deposition.

MR. CERRITO: They were put on notice, it's not a surprise.

MR. SCHULER: I don't have the transcript, I can check, but...

MR. CERRITO: It's one question. I'm not going to spend a ton of time. I want to make sure I'm not telling you false -- you can't see my questions. I'm sorry. I apologize.

(Whereupon, the discussion held at sidebar concluded.)

BY MR. CERRITO:

Q. So let's regroup real quick, Doctor. Dr. Charman testified that a POSA would need to see data, you remember we talked about that, and you said you didn't agree, correct?

A. Yes.

Q. **And I asked you why, why wouldn't you agree?**

A. **Well, so the first thing I was going to just establish is that I have seen a lot of patents, I write them myself -- I work with lawyers to write them myself, probably more involved than they'd like me to do, but I enjoy it. And when we do that, we have to look at all these other ones to compare it to as well.**

In the pharmaceutical formulation patent world, if you put an example of every permutation, the patent would be so big you wouldn't be able to use it. So what I think you have to understand is a person of ordinary skill in the art comes to the table with a specific set of experience, expertise, education.

And what they do, they see the teachings and they think back to all the teachings that they have, so any particular example of something, depending on the circumstances, may allow you to apply it across things in order to get specific release profiles, for instance.

Q. **So let me see if I can just clarify that a bit. Why wouldn't a POSA need to see data for the actual formulation that the inventors claimed?**

MR. SCHULER: Objection, asked and answered.

MR. CERRITO: I think I asked a slightly different question.

THE COURT: You can ask it one last time, go

ahead.

THE WITNESS: I'll give an example here. In this particular case, you have in the '488 patent a demonstration that you can actually get the bird to stay in the cage, okay. So now that a person of ordinary skill in the art sees that, and they know of the kind of formulations and the techniques that can be used, you can actually use things to tune those so you -- again, you could use different sized bars, you can space the bars differently, you can do a number of other things that a person of ordinary skill in the art has in their tool box that they bring to the table.

So what that would mean is you wouldn't need to see release profile after release profile for every single permutation. As you can imagine, it wouldn't need to be taught to you that way because you have already had that teaching.

BY MR. CERRITO:

Q. **Is there any data disclosed in the '782 patent showing examples of modified release?**

A. **There -- there is, there is example in the '488 patent.**

Q. **Where is that data in the '488 patent?**

A. **It's in the examples and then it's described. And I think that --**

MR. SCHULER: Objection.

BY MR. CERRITO:

Q. **I meant the '488 patent, sorry, Steve.**

A. **Right, it's incorporated by reference into the '782. So in the '488 you have the figure that shows the data that you can keep the bird in the cage.**

MR. CERRITO: Can we get back to Charman slides DDX60, please. And let's turn to the second part.

BY MR. CERRITO:

Q. **Dr. Little, it's Dr. Charman's slide here. That the claims do not describe modified resinate particles. What do you understand Dr. Charman's opinion to be there?**

A. **My understanding of Dr. Charman's opinion here is that the patent specification talks about loading the resinate, there's examples of loading it. But loading it doesn't mean that it can lead to a modified release.**

Again, in this case, immediate release is quick, right, and modified release is not that. So what Dr. Charman's opinion is that because you load doesn't mean that you wouldn't always get immediate release. It doesn't say that you could get modified release.

Q. **Unlike Dr. Charman, do you have any actual hands-on experience in this area?**

A. **I do, we use resinate-based formulations and the mechanisms all the time to release things.**

Q. **And do you agree with Dr. Charman that resinate formulations disclosed in the '782 patent would not control the release of GHB?**

A. **I disagree with that strongly.**

Q. **Do you remember when -- Dr. Charman's graphics when he put up how a resinate particle works, it was that pink ball, squares came in, do you recall that?**

A. **It looked like a big porous ball.**

Q. **Yeah.**

MR. CERRITO: Mr. Lewis, Charman demonstrative WC 66 and 67, please.

THE WITNESS: These it.

BY MR. CERRITO:

Q. **Is that it? Yup, that's the one.**

Dr. Little, how is this -- how do resinates work, does it all release as quickly as shown in what Dr. Charman showed?

A. **Here's what I'll say. I think the mechanism that he discussed is right, I agree with that particular characterization of how it works. There is a charge on these beads and the drug has the opposite charge, so they are sticky in that way and it makes these stick.**

The issue was, and I think my feeling is that, you know, if you blink, that's all gone, that's not the way it works.

So what would be more accurate is that those blue guys that just all flew in made everything dissolve immediately, that's not how that is. Those are sort of everywhere.

And what happens is one of those blue guys will come in and you'll see, like, an exchange happen, and that exchange takes a period of time. And then once that happens, this guy can go away. But then the other one over here, it doesn't just go away like that, there's a period of time where this exchange occurs, it's not immediate like this.

In my personal experience, we actually have a harder time getting them to release sooner than we do getting them to release longer.

Q. **Does the patent specification, the '586 patent application specification talk -- address this issue?**

A. **It does. In fact, it says specifically for this instance a person of ordinary skill in the art would understand it teaches you it would have the opposite problem. It potentially always be modified release, according to the way the patent talks about it.**

MR. CERRITO: Mr. Lewis, could we get paragraph 62, that's PTX700.31, please.

BY MR. CERRITO:

Q. **Dr. Little, what is the jury seeing here?**

A. **Yeah, this is in paragraph 62 of the '586 application. And what it says is because of the circumstance here with the drug, you have an unusually large molar amount. What that means is there's lots and lots and lots of these molecules that are taking up these sites.**

In order to exchange for that site, you need a lot of counterions. So what it says here is that, for example, when the resinate beads are retained in the stomach, the release of GHB from the resinate beads provided by ion exchange with gastric ions, so that's like a chloride ion in your gastric conditions in your stomach, that can be limited by rate of stomach acid secretion. So it isn't like it flies off, it's like there's not enough of those ions to be able to make the exchange.

If you keep reading, it actually says as the resinate beads transition to -- that funny word is the duodenum, that's the stomach and small intestine. So now we're talking about hours after you take it, not right away, where there is still the chance of this secreting.

If you see -- just right underneath of it, local and ion capacity, what the specification, you're going to have too long of a limit not too short of a release so you're not going to be concerned about having release for these.

Q. **Dr. Little, let's turn to third basis of**

Dr. Charman's opinion, DDX60.

What did you understand Dr. Charman's opinion on cross-examination to be?

A. **Okay. So this has to do with the viscosity enhancing and the acid being separate. What I understand his opinion is the patent doesn't explicitly tell you to keep them separate. But then asked on cross-examination, what I heard in the deposition, he said it would be trying to remember the word for it, it was -- it was rare or something like that. That's probably not correct. But it was not the case that you would expect it to be inside of the particles very often. And that's absolutely not the case here.**

I can't think of a reason why in this case you would want to put it inside. It would overcomplicate things and things wouldn't be readily available right away in order to do the jobs that the specification says they need to do.

Q. **Doctor --**

MR. CERRITO: Mr. Lewis, can you pull up PTX700 at paragraph 54, that's 700.29, please.

BY MR. CERRITO:

Q. **Dr. Little, what are we seeing here?**

A. **This is paragraph 54 of the '586, and this is the portion of the specification that talks about adding things to the suspensions. And if you go down on this list, one is a thickener which is, again, the viscosity-enhancing agent.**

And then you have a particular list of some examples of viscosity-enhancing agent.

Q. **Let's move on to the other, the second component, the acid. What's your opinion regarding what the '782 patent teaches a POSA about using an acid?**

A. **So what's discussed in regard to using an acid, I think we might have seen this already, if I remember, but you're talking about having components in this dosage form that respond when things get too basic. So if it's designed to function in an acidic condition and things get too basic, you're messing up the function. So there's a portion of the specification that talks about that.**

Q. **Okay.**

MR. CERRITO: Excuse me, could we get Dr. Charman's slide back up, please. Sorry, sorry, Mr. Lewis, can you turn -- let's go to -- pull up the '586 application, paragraph 21, that's PTX700 at 16.

BY MR. CERRITO:

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

A. **Yup, there is the portion of the specification that discusses this and what's needed. So it says here, "Due to the buffering effect of oxybate," and then there's a phrase there that has to do with how the drug is going to impact the pH of the solution, it's called a PKA. It says, "The immediate-release portion of the dose would cause the**

gastric pH to increase."

So you are at a pH where everything is functioning the way you want, but then you have the immediate release of the GHB, that GHB then is going to take the pH and it's going to shift it, right. But it's going to get close to that 6 where something is not going to work. So more basic is bad for the components, more acidic puts it back into the range of what you want it to for these components.

So it says the concomitant rise of gastric pH could result in at least partial dissolution of the enteric coating, which is what I was talking about earlier.

Q. **Based on the teaching of the '782 patent and the prior application, would a POSA have an understanding where viscosity-enhancing agent and an acid are in the formulation?**

A. **Yeah, for them to do these jobs, you would just put them outside of the immediate-release and the modified-release particles, they would be readily available to dissolve and then serve these functions.**

MR. CERRITO: Mr. Lewis, could we call up Dr. Charman's 90, DDX90, please.

BY MR. CERRITO:

Q. **Did you address the Wand factors and whether Claim 24 was enabled as part of your analysis in this case?**

A. **Yes, I did.**

Q. **And first, what did you understand your task to be with respect to assessing enablement?**

A. **So like written description, there's a legal framework that I was asked to do this. And, again, the Judge is going to instruct you on that.**

Very briefly, the idea, again, is to put yourself in the shoes of a person of ordinary skill through their eyes, their hands-on experimentation, their amount of education. And what you're doing is looking at the specification and saying, with those things that are here, can I make that and can I use it?

And I'm responding to Dr. Charman's critiques on these because I understand he has to demonstrate by clear and convincing evidence that a person of ordinary skill in the art couldn't do that. I used that standard, I looked, and I believe that a person of ordinary skill in the art can make and use it. And the examiner looked at it and believed that a person of ordinary skill in the art can make and use it.

Q. **Can make and use it without undue experimentation?**

A. **That's correct.**

Q. **In your opinion, would undue experimentation be required to practice Claim 24 in view of the disclosures in the specification?**

A. **No, absolutely not.**

Q. **Okay. Dr. Charman mentioned, I think he used the word "extensive experimentation," that was his testimony he didn't say undue, he said "extensive." Is it -- is that different in your understanding from undue experimentation?**

A. **Yes, it is. So I would say that what we do in the art is usually extensive. In fact, right now my students are working in the lab, I'd be pretty surprised if they are not doing extensive experimentation. I might hear about it later. They are doing extensive experimentation, that's what's required to do this.**

What we're talking about when we're talking about undue, you're just overwhelmed by the amount of experience, you don't even know which direction to go. So extensive experience is completely different and very normal in the art, undue is something completely different.

Q. **In your opinion, are there any general qualities running through the formulation that fall within the scope of Claim 24 that allow those formulations to modify the release of GHB?**

A. **Yes, there is, there is the more conventional formulations, coatings, and pore formers that are described in the '488 as particulates in the context of the '782. And then in the '782 there's also the resinate particulate formulation.**

Q. **Could -- did you hear Dr. Charman testify the resinate formulations encompassd in the '782 patent are inoperable based upon some formulation work done by a company called Tris Pharma, we saw some documents?**

A. **I did hear that, yes.**

Q. **Did you -- did Dr. Charman offer any opinion that the Tris formulations actually fell within the scope of the '782 patent?**

A. **Not that I heard, no.**

Q. **Did he tell you what the formulation was at all?**

A. **I don't know, he didn't describe the formulation.**

Q. **No, he didn't.**

Did Dr. Charman offer any opinion that the Tris Pharma formulations made any use of the formulation that had an acid separate from the microparticles?

A. **No.**

Q. **Did you hear Dr. Charman testify that if Claim 24 of the '782 patent was adequately described then he had no inventorship opinion?**

A. **Yes.**

Q. **So if it's adequately described, he walks away from inventorship, right?**

A. **Well, I don't know what you mean by "walks away" but --**

Q. **Fair enough.**

A. **-- I think that his inventorship opinion is contingent upon the written description.**

Q. **Have you been in the courtroom this whole trial?**

A. **Sometimes stepping out from time to time, but for most of it, yes.**

Q. **Did you hear Mr. Allphin testify?**

A. **I did.**

Q. **Did you hear Dr. Guillard testify?**

A. **Yes.**

Q. **Did you hear Dr. Mégret testify?**

A. **I did.**

Q. **Did you hear when Mr. Allphin filed this patent application for the '782 patent?**

A. **Yeah, it was February 2016.**

Q. **And when did Dr. Guillard and Mégret file their application?**

A. **It was July later that year, 2016.**

Q. **Five months later?**

A. **Yes.**

MR. CERRITO: Pass the witness.

THE COURT: All right. Cross-examination.

MR. SCHULER: Yeah, may we approach the witness on the bench?

THE COURT: Yes.

MR. SCHULER: May I proceed, Your Honor?

THE COURT: Yes.

CROSS-EXAMINATION

BY MR. SCHULER:

Q. **Good afternoon, Dr. Little. If you need to rub your hands together for a break, let me know, I'm --**

A. **It looks like you put a space heater in here.**

Q. **I at least move around a little bit. I apologize for you.**

Now, Doctor, one of the factors that you analyzed with regard to enablement is the nature of the invention and the predictability of the art, correct?

A. **Yes.**

Q. **And here, the field is formulation science, right?**

A. **Yes.**

Q. **And we can agree that formulation science is complex?**

A. **I'd say that's fair, yeah.**

Q. **And in addition, we can agree that formulation science is often unpredictable?**

A. **I think it can be, yes.**

Q. **And the difficulties of working with oxybate only increase the complexities associated with formulating oxybate into a finished dosage form, true?**

A. **Yes, as I described.**

Q. **And formulation science can also be unpredictable because a formulator often has to -- I'm sorry, let me**

rephrase.

Formulation science can also be unpredictable because ingredients can interact with the active ingredient in unexpected ways, correct?

A. **Yeah, that's possible.**

Q. **Now, the claim at issue provides a particular design constraint called modified release, right?**

A. **Yes.**

Q. **And that constraint itself increases the complexity of the formulation work?**

A. **It would, yes.**

Q. **And Claim 24 recites a unit dose, correct?**

A. **It does.**

Q. **Now, we can agree that the various challenges that are associated with formulating GHB are magnified in the context of formulating a unit dosage form providing controlled release of GHB?**

A. **Yeah. But, again, that's what I described to the jury. That section is -- is what you just summarized, yes.**

Q. **Right. So we can agree that the challenges we just talked about are magnified because now we're trying to make a unit dose of a controlled-release formulation?**

A. **I don't know what you mean, I'm sorry, could you please --**

Q. **Let's look at -- you recall the Allphin 2012**

reference that you mentioned several times?
A. Sure, yeah.
Q. If we put that up at 892.13. And the very first sentence says, "Formulating GHB into a unit dosage form presents various challenges," right; you agree with that?
A. Okay. Sure.
Q. And then "such challenges are magnified in the context of formulating a unit dosage form providing controlled release of GHB," correct?
A. Again, that's what I was describing a little bit earlier to the jury.
Q. Okay. Now, I want to talk about the subject matter that falls within the scope of Claim 24.
MR. SCHULER: So if we can put that up, it's JTX6 at Claim 24 -- not at 24, Claim 24.
All right. So the last claim on the next page. Okay.
BY MR. SCHULER:
Q. Claim 24 is the unit dose of Claim 14 wherein the unit dose is a sachet, correct?
A. Yes.
Q. And what is the purpose of a unit dose?
A. The purpose of a unit dose is that, you know, for -- let's say a sachet has a particular amount of drug that you want to administer to a patient, that's a unit, right.

That's got to be all packaged together such that whenever -- whenever you have it, the patient can be able to, you know, open the package, pour it out, and take it.

Q. So it's for administration to a patient, right?

A. A unit dose is designed for administration to a patient, yes.

Q. Okay. And were you -- you were here for Mr. Allphin's testimony, right?

A. I was.

Q. And did you hear him refer to this invention as one involving improved administrability of a formulation?

A. I did hear that, yes.

Q. Okay. And in your expert report, you also said that you see this patent as involving improved administrability of a GHB formulation, correct?

A. Yes.

Q. Now, compared -- more administrable compared to what?

A. Yeah, so the way that I would describe this is this -- and if you recall, we were talking -- this was, what, two days ago when I testified, about how if you have a tablet, it's big and it's hard to swallow.

So if you go to particles, you could swallow that, but what happens is that it now makes it so that you have several other design challenges, because if you've got a lot of particles, for instance, you have to keep them from

settling to the bottom of the glass. So you have got to build in something to do that.

If you have a lot of particles, you have a lot of surface area. So under that circumstance, you know, you might have a situation where you have lots of this drug that's released, like we were just describing, it could influence the pH. And now all of a sudden you have got to build something else in too.

So to make that thing administrable and functional, there's additional challenges that are described in the '782.

Q. Okay. Now, what patient population was taking tablets containing oxybate as of 2016?

A. Patient population?

Q. Yeah. You said we were talking about problems with tablets; who was taking tablets in 2016 with oxybate?

A. I don't know.

Q. Okay. The formulation that was taken by patients at the time of that was called Xyrem, right?

A. Sure.

Q. And Xyrem is an immediate-release oral solution, right?

A. Sure, yes.

Q. And there's no discussion in the specification of the '782 patent stating that the Xyrem immediate-release product

was a problem from administrability perspective, correct?
A. Well, no, the -- what I'm trying to describe is if you're going to turn it into a controlled-release dosage form, then you have got to have, you know, excipients in there, you've got to make it -- portions of it has got to be nonsoluble, it can't all be dissolved in order for it to be a modified-release system. So it's a different system.
Q. Okay.
MR. SCHULER: So if we could put up JTX6 at the bottom of column 5. No. Actually, go in and bring out the bottom of column 5.
BY MR. SCHULER:
Q. All right. The specification says, "While extended-release oxybate dosage forms are known, such extended-release dosage forms are provided as solids, as tablets. Because the required dose of oxybate is high, such tablets can be quite large and/or require the administration of multiple tablets."
Do you see that?
A. Yes.
Q. And you don't know what that's referring to, is that your testimony?
A. No, no, that's not my testimony at all.
Q. Okay.
A. I'm just saying that if you were going to do an

extended-release system, now you've got to take into account a number of other things, like we were discussing.

Q. **And this one says that the -- the ones that are known are in the form of tablets. Do you know what prior art reference taught tablets?**

A. **I'm sorry, I don't understand your question.**

Q. **It says that release -- extended-release oxybate dosage forms are known in the art, right?**

A. **Sure.**

Q. **Which prior art taught tablets of GHB?**

A. **Well, it's at least -- it's in the discussion we were talking about with the '488 patent.**

Q. **Oh, okay, so the '488 patent involves tablets?**

A. **It does. The technology was originally demonstrated in the '488 as tablets, but the '488 talks about other things as well.**

Q. **Okay.**

A. **But here's the different, the difference is --**

Q. **I --**

A. **-- if you were going to --**

Q. **All I need is --**

THE COURT: It's cross-examination. Your counsel will give you a chance to explain.

MR. SCHULER: So let's put up PTX423.

BY MR. SCHULER:

Q. **And this is an e-mail from Mr. Allphin to colleagues in August of 2014, do you see that?**

A. **Yes.**

Q. **And the second paragraph says U.S. 20120076865 is the US application we filed for sustained-release film-coated tablets, do you see that?**

A. **I see it there, yes.**

Q. **So that's the Allphin 2012 reference, correct?**

A. **'865. It -- I'd have to check the number, it might be. I don't remember the number.**

Q. **Okay. Look in your binder at DTX892.**

A. **'865 is the number, yes.**

Q. **Okay. So the problem that's defined and identified by the '782 patent is a problem that was created by the Allphin 2012 patent, correct?**

A. **That's not an accurate characterization. If you'd like me to finish, I can explain, if you'd like, or would you like me to wait until direct examination?**

Q. **I'll go step-by-step.**

The reference in the '782 patent to an extended-release formulations that are in the form of a tablet is a reference to the Allphin 2012 application, correct?

A. **That part is correct, yes.**

Q. **Okay. That problem was created then by the Allphin**

2012 application, correct?

A. That's the part that's a mischaracterization.

Q. All right. Now, sir, the '782 patent specification includes a description of the difficulties of formulating GHB?

A. Yes.

Q. Okay.

MR. SCHULER: And let's put that up at JTX6.9.

BY MR. SCHULER:

Q. And it says, "Those skilled in the art will appreciate that these factors complicate and in many cases limit conventional approaches for modified release, such as core-shell or matrix formulations, as the high solubility and mobility of GHB would tend to significantly reduce the number of viable approaches using such conventional solubility and diffusivity control technologies," correct?

A. Yes.

Q. Now, I thought I heard you said on direct that, well, that just means that you'd have to change some things around, put some more bars on; is that right?

A. I did say you would have to use one of the number of approaches that's described here that would be more limited so that it wouldn't be your standard bird cage.

Q. Okay. But in reality, sir, in the context of the sentence we are looking at, the reference to significantly

reduced tells a person of skill that one would not be able to use every formulation strategy, correct?

A. Mm. It depends on what you mean by "formulation strategy," because you're still utilizing this formulation strategy, you just have to be able to adapt for the size of the bird.

Q. All right. You had your deposition taken in this case, correct?

A. Yes.

Q. And if you -- your deposition transcript is in your binder, your second binder, and you can follow along.

MR. SCHULER: But if we could play the video, page 71, 17-21.

MR. CERRITO: We wouldn't go to the video, I mean, this is improper impeachment, and before he publishes it.

MR. SCHULER: I --

THE COURT: Tell me what you're establishing.

MR. SCHULER: He just gave an inconsistent answer.

THE COURT: Okay. He's saying he gave an inconsistent answer. He can play it.

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

Q. In the context of the sentence that we just read,

what does significantly reduce mean to you as a person of skill in this context?

A. That it would not allow you to use every formulation strategy.

(End of video deposition.)

MR. CERRITO: That's not inconsistent with his answer, Your Honor.

MR. SCHULER: It's -- I'm not going to argue.

BY MR. SCHULER:

Q. The specification, sir, of the '782 patent does not identify which conventional solubility and diffusivity technologies do not work with GHB, agreed?

A. I don't think there's an explicit reference to it but I don't think a person of ordinary skill in the art would need every explicit reference for that.

Q. My simple question is: There's no description in the '782 specification telling a person of skill which of the conventional solubility and diffusivity technologies do not work with GHB?

A. That's right, but I --

Q. Okay.

A. I --

MR. SCHULER: Your Honor, can I just get a yes or no.

THE WITNESS: -- everything that doesn't work.

THE COURT: Dr. Little, you're on cross-examination. If he asks you a yes-or-no answer, please just answer his question yes or no. Again, your attorney will get a chance to redirect, you'll have an opportunity to explain.

BY MR. SCHULER:

Q. **Okay. So just so the record is clear, the specification of the '782 patent does not identify which conventional solubility and diffusivity techniques do not work with GHB, right?**

A. **They don't go through every one that doesn't work, no.**

Q. **Okay. Now, let's turn to DTX892.13. And were you here during Dr. -- it sounds like you were here during Dr. Charman's testimony yesterday --**

A. **Yes.**

Q. **-- cross-examination?**

Do you recall Mr. Calvosa pointing to the last sentence here stating, "Despite the challenges noted, formulations and unit dosage forms providing controlled release of GHB are described herein, correct?

A. **Yes.**

Q. **Now, let's look at the last sentence of paragraph 29, right above. Paragraph 29. The last sentence there says, "Even further, high water solubility increases drug mobility**

and may preclude the use of some approaches utilized to achieved a controlled-release dosage form."

Now, GHB is such a compound with drug mobility issues, right?

A. I don't know if I'd call it drug mobility issues but it's one of the physiochemical characteristics that you need to consider when you're using GHB.

Q. Okay. And it has high water solubility, correct?

A. It does.

Q. All right. And Allphin 2012 doesn't describe which approaches may be precluded, correct?

A. Again, no, it doesn't go through everything that wouldn't work.

Q. Now, I think you said you were in court for Mr. Allphin's testimony, right?

A. Yes.

Q. And do you recall that he said that the technique used for the '488 patent is called a core-shell?

A. Okay, yes, I think I remember hearing him say that.

Q. Okay. And in this submission, this patent submission, Jazz characterized core-shell as allegedly providing controlled release of GHB, correct?

A. Could you repeat your question again, I'm sorry.

Q. Yeah. If we go down to paragraph 30, the sentence that counsel read during Dr. Charman's cross-examination,

this Jazz reference -- patent represents that despite the challenges noted, formulations and unit dosage forms providing controlled release of GHB are described using a core-shell technology, right?

A. Yes.

Q. Okay. Now, five years later, the '782 patent makes another comment about core-shell technique, doesn't it?

A. It makes a comment about some types of core-shell techniques, yes.

Q. Let's look at that together.

MR. SCHULER: Let's put up JTX6 at column 5, starting at line 55.

BY MR. SCHULER:

Q. And it says, "Those skilled in the art will appreciate the fact these factors complicate, and in many cases limit, conventional approaches for modified release, such as core-shell," right?

A. That's what we read before, yes.

Q. Okay. In fact, Mr. Allphin himself characterized the tablet project utilizing the core-shell technique as unsuccessful, do you recall that?

A. There might have been a portion where he said that one of the attempts that he made was unsuccessful, yes.

Q. Okay. Let's look at DTX692, this is in evidence. This is an e-mail from Mr. Allphin to colleagues on

December 23, 2014, right?

A. Okay.

Q. And that's three years after the filing date you identified for the '488 patent, correct?

A. Three years after the filing date?

Q. You were discussing on direct examination that the '488 patent was filed in 2011, do you recall that testimony?

A. I don't remember saying that. 2016 was the reference point that I was talking about.

Q. All right. It's talking about background materials on a PLE-2 legacy program for oxybate sustained release, do you see that?

A. Okay.

Q. And then in the second sentence, Mr. Allphin says, "You requested some background on our previous unsuccessful attempt at oxybate sustained release," did I read those words correctly?

A. It sounds like in 2014, yes.

Q. And then he provides a Live Link folder for PLE-2 program.

Do you see that?

A. Yes.

Q. Now, turning to page 2, there's a few bullet points at the top of the page. And the second one says, "Drug overcoating sodium oxybate onto a sodium oxybate tablet is

very difficult."

Do you see that, sir?

A. **Okay, yes.**

Q. **All right. Now, let's turn to another subject. As I understand it, your view of the specification of the '782 patent is that it encompasses various techniques for modified release, right?**

A. **The whole patent? It does discuss various techniques, yes.**

Q. **Okay. And it includes modified release by resinate technology?**

A. **Yes.**

Q. **It includes modified release by enteric coatings?**

A. **Yes.**

Q. **And it includes modified release by nonenteric coatings?**

A. **Yes.**

Q. **All right. And in your view, I think I understood you to say this, that Allphin 2012 teaches a multiparticulate formulation for modifying release; isn't that your testimony?**

A. **It does.**

Q. **All right. But we can agree that using a modified-release technique with pellets is considerably more challenging when it's applied to tablets, right?**

A. **It can be more challenging, yes.**

Q. **And can we agree that the Jazz scientists concluded that a nonenteric delayed approach was almost impossible for pellets?**

A. **I don't remember that. It's possible.**

Q. **Okay. You were --**

A. **I don't remember.**

Q. **You were not made aware of that in the course of your review of the materials?**

A. **Maybe. It's just I don't remember, yeah, sitting here.**

Q. **Okay.**

MR. SCHULER: Let's put up DTX262.2.

BY MR. SCHULER:

Q. **And do you see that this is a assessment of delayed release option for once-nightly oxybate?**

A. **Okay.**

Q. **And on the bottom right, you see it was printed on March 18, 2016?**

A. **Yes.**

Q. **Okay. And so that's right about the time the '782 patent was filed for?**

A. **A little bit after, yes.**

Q. **Okay. And if we go to DTX262.11, there's something called nonenteric approach in the top paragraph, do you see**

that?

A. Yes.

Q. And the first couple of sentences say, "There are nonenteric means of achieving delayed pulse tile release in tablets; however, applying these techniques to pellets is considerably more challenging. The high water solubility of oxybate salts combined with the high dose almost precludes the use of non-pH-triggered dissolvable delay layers."

Did I read that correctly?

A. Yes.

Q. Now, how did you go about determining which documents involving the Jazz scientific work that you were going to evaluate for purposes of your validity opinions?

A. Oh, wow. I mean, I -- I reviewed so many documents. I mean, I just remember, you know, when I went through the patent, there were all the references to the documents that were in here, there was the prosecution history. I followed trails that way. I had discussions with counsel about seeing things, that was my process.

Q. So I assume that you requested some materials, you got some materials?

A. Yes.

Q. Okay. And were you provided with DTX262?

A. Again, sitting right here, I can't remember whether -- whether I have seen this or not, but this is

similar to what the specification says, so...

Q. Okay. Now, Doctor, we can agree that because formulation science is complex, it's not something that can be determined theoretically, right?

A. Agreed.

Q. And put another way, formulation science is empirical?

A. It is.

Q. And you agree with Dr. Charman that, as a general matter, experimentation is necessary to develop a pharmaceutical dosage form?

A. Experimentation is necessary, yes.

Q. And you specifically agree that formulation work is required to develop a pharmaceutical dosage form?

A. I don't understand the difference between your last question, but I still agree, correct.

Q. And, Doctor, in your view, the specification -- we just talk about this -- of the '782 patent encompasses modified release using enteric coatings?

A. Yes.

Q. Empirically, Jazz scientists found that sodium oxybate presents unique challenges for enteric coatings; you agree with that, right?

A. You're going to have to repeat your question again, I didn't hear it.

Q. **Empirically, the Jazz scientists encountered difficulties trying to formulate sodium oxybate using enteric approaches?**

A. **I mean, I think -- I think you could characterize, you know, the formulation process as encountering difficulties, yes.**

Q. **And so let's look at JTX -- well, in your binder, if you would look at JTX253. In your binder.**

A. **I'm sorry, what?**

Q. **You need to look in your binder.**

A. **For what?**

Q. **JTX253.**

A. **Okay.**

Q. **And do you see that it's a presentation entitled "Oxybate SR/DR?"**

A. **Yes.**

MR. SCHULER: Your Honor, we'd move for admission of JTX253.

MR. CERRITO: No objection.

THE COURT: JTX253 is admitted.

MR. SCHULER: All right. Let's publish that.

BY MR. SCHULER:

Q. **You see there's a technical review from May of 2015?**

A. **Yes.**

MR. SCHULER: And if we could turn to slide 44.

BY MR. SCHULER:

Q. **The second bullet point says, high soluble, high --**

(Reporter clarification.)

-- high solubility, high hygroscopicity, basic properties of sodium oxybate are challenges for enteric coatings?

Do you see that?

A. **Yes.**

Q. **And several companies affiliated with Jazz tried to obtain bead formulations of sodium oxybate over the years, do you recall that?**

A. **I do.**

Q. **And the first one that did so was called Orphan, and that was the company that actually brought Xyrem to the market, correct?**

A. **I think the name is right, yes.**

Q. **Okay.**

MR. SCHULER: And if we can put up DTX1367.

BY MR. SCHULER:

Q. **This is an e-mail from Mr. Allphin to his colleagues on July 2, 2015, right?**

A. **It appears to be, yes.**

MR. SCHULER: And if we put up slide 1 of the PowerPoint.

BY MR. SCHULER:

Q. **This was an oxybate LCM backgrounder, do you see that?**

A. **I see it.**

Q. **And if we could turn to DTX1367.7. It says, "Orphan considered beads and a sachet, ultimately chose liquid form. Hard to make beads with sodium oxybate deliquescent."**

What does deliquescent mean?

A. **Yeah, deliquescence is the concept of a chemical compound liquifying. So typically what you're doing -- most often what you're talking about is when you have a solid and there's water in the air, it can get in. And then what happens is, is that it forms this structure so that, although the thing didn't melt, it looks like it melted, so it liquifies.**

Q. **And so you can't process it to make a dosage form effectively?**

A. **It depends on what you're trying to do.**

Q. **Okay. Now, Doctor, during your direct examination, I think you testified that you heard Dr. Charman use the word "extensive"?**

A. **I did.**

Q. **Okay. Let's look at the trial transcript from yesterday at page 816.**

We'll come back to that in a second.

THE COURT: Mr. Schuler, do you have more than

five minutes?

MR. SCHULER: Yeah, I do, Your Honor.

THE COURT: All right. Let's break for the lunch break.

All right.

(Whereupon, the jury exited the room.)

THE COURT: All right. Dr. Little, you're still under oath, you can't talk to counsel. Come back at 2 o'clock.

(Break taken.)

THE COURT: All right. We can continue. You may be seated. Get the jury.

(Whereupon, the jury entered the room.)

MR. SCHULER: Mr. Jarrett, if we would bring up the trial transcript from yesterday at page 816, lines 10-16.

BY MR. SCHULER:

Q. Now, Dr. Little, during Dr. Charman's examination, I asked, "What did you conclude about the quantity of experimentation that would be required to practice the full scope of the claims?"

His answer was, "It would be excessive. There's a lot of experimentation that would have to be done in an attempt to formulate a material such that it might meet that is -- as is described in the claims."

Now, when you were answering questions from your counsel, I believe you answered questions about whether extensive experimentation would be required.

A. **Mm-hmm.**

Q. **Is that true?**

A. **Yes.**

Q. **Okay. Now, I think I heard you say that you would consider the type of formulation work at issue to be routine?**

A. **With the disclosures that you have in order to, for instance, you know, do the things we were talking about, I think once you have that, it would be routine, yes.**

Q. **Okay. And the scientists at Jazz who conduct such work called it "laborious," isn't that true?**

A. **Yeah, they did.**

Q. **Let's look at that together, it's DTX1707. This is an e-mail from Mr. Allphin to colleagues in 2016. This is after he had filed for the patent at issue, correct?**

A. **Yes.**

Q. **And this is preliminary results of enteric assessment for "JZP 324." Do you see that? That's the subject line?**

A. **Yes.**

Q. **And Mr. Allphin says he only tested 100 tablets by way of dissolution testing.**

Do you see that?

A. **Yes.**

Q. **And he did six sets representing different combinations of subcoat weight and enteric film weight in that order, correct?**

A. **Yes.**

Q. **All right. And if we go to the next, Mr. Allphin said, "The main limitation was dissolution testing, which turned out to be far more laborious than I estimated."**

Did I read that correctly?

A. **Yes.**

Q. **Doctor, did you do any experimentation yourself to see if a person of skill could take the specification at issue and succeed without undue experimentation to achieve various embodiments of the claim?**

A. **If you're asking me if I did physical experiments on this, no, I did not.**

Q. **Now, I think I understand, but I want to make sure I understand. My understanding of Claim 24, in light of Claim 14, is that there's a sachet from Claim 24, right?**

A. **Yes.**

Q. **You have the separate acid and separate viscosity-enhancing agent, right?**

A. **Yes.**

Q. **And particulates?**

A. **Yes.**

Q. **And is it my understanding that your view and -- your view that that is a more administrable, an improved administrable formulation of extended or modified-release formulation?**

A. **Yeah. So it's administrable because the technology allows it to be because of the various challenges of that particular one, yes.**

Q. **Okay. And for a sachet, I assume we're talking about a suspension of the particles?**

A. **Yes, the intent is that it would be poured into a glass, it's like a sugar packet so you're pouring it into a glass to suspend it.**

Q. **Okay. And for a suspension formulation, people evaluating administrability look to the mouth feel of the dosage form after it's been suspended, correct?**

A. **They might.**

Q. **And undue acidity could be another aspect of administrability, correct?**

A. **It's possible.**

Q. **And whether a formulation is too basic or too chalky, also might be an aspect of administrability, correct?**

A. **It could be.**

Q. **And swallowability certainly is an aspect of administrability?**

A. **Yeah. It could be, yeah.**

Q. **And taste as well, correct?**

A. **Yes.**

Q. **Doctor, there's no data in the specification that addresses the taste associated with the particular formulations that are described when given as a suspension; agreed?**

A. **No, those weren't the problems it was solving.**

Q. **And can we agree that there was no data from any administrability experiment in the specification?**

A. **I'm sorry. Can you say that again?**

Q. **Can we agree there is no data from any -- of any experiment directed to administrability in the specification?**

A. **Data? There's -- the things you're talking about aren't quantified if that's what you're asking.**

Q. **Okay. Now, in fact, Doctor, the Jazz scientists concluded that a liquid multiparticulate formulation was a nondesirable dosage form in terms of administrability; isn't that right?**

A. **You said "liquid is nondesirable"?**

Q. **A liquid multiparticulate formulation is -- they concluded it was a nondesirable formulation?**

A. **You'd -- I don't remember that, you'd have to show me.**

Q. **Okay. Let's look at JTX219. This is a PLE Tech**

transfer document dated September 16, 2009, correct?

A. Yes.

Q. And the authors are the two inventors of the '488 patent, right?

A. 2009, okay.

Q. Mr. Mr. Allphin and Mr. Pfeiffer?

A. Okay.

Q. And if we turn to dot 14, there is a -- beads or pellets in a sachet and it says, "Less preferred for volume of liquid needed. Physical conveyance from cup, chasing down stray particles in mouth, possibly dealing with aftertaste from IR components."

Did I read those words correctly?

A. Yes.

Q. And then it says, "Huge penalty on drug loading."

Do you see that?

A. Yes, I see it.

Q. What does that mean?

A. Well, it -- well, I could say what it could mean. It could mean that when you have -- I presume that that means protective layers down here at the bottom.

So a protective layer, if you were to implement one, would add additional excipient.

Q. So you'd have less --

A. Let me explain what that is.

Q. **Oh.**

A. **Excipient is other materials that you put into a formulation to help it with something, some property, some quality, some -- it could be flow, it could be modified release.**

And if you have to add more of that, then now your -- your mass load increases. So at some point, if you kept doing it, let's say you did it more and more and more, then there wouldn't be any room left for the drug because it's all excipient.

Q. **And "excipient," you could also use the word "ingredient"?**

A. **An excipient can be an ingredient, yes.**

Q. **Now if we look at JTX690.**

This is "Oxybate QD Approaches Part 2" from January 2015. Do you see that?

A. **Yes.**

Q. **And to put that in perspective, that's a few weeks before the original provisional application was filed for the '782 patent, correct?**

A. **Yes.**

Q. **Okay. And if we turn to page 690.7, under "Multiparticulates," it says -- second bullet, "Less convenient to administer, high product mass, ingestion of more liquid or gel, mouth feel, particles are large enough**

to be noticed/felt."

Did I read that correctly, doctor?

A. **Huh, yeah, I see it.**

Q. **And then Claim 24 is to a unit dose of a sachet, correct?**

A. **It is, yes.**

Q. **And down below, the unit doses that were being considered by Jazz at the time were tablet, soft capsule, hard capsule, correct?**

A. **It says "more options" there.**

Q. **Yeah, more options, unit doses, tablet, soft capsule, hard capsule, correct?**

A. **Yes.**

Q. **All right. Now, I think I heard your testimony on direct that a person of skill would recognize them, when you have an acid of the type that you discern from the specification, that would be separate from the GHB -- let me rephrase.**

I think I understood your testimony to be that the person of skill, the formulator would want to put the acid in separately from the oxybate-containing particles?

A. **In this instance, yes, that would be apparent.**

Q. **And I think I heard you say, absolutely, it would be outside or something along those lines?**

A. **Yeah.**

Q. **Okay. But Mr. Allphin concluded that having a separate acid was unacceptable; isn't that right?**

A. **I'd have to see the context of that.**

Q. **Okay. Let's put up PTX906.**

And this is an e-mail from Mr. Allphin to a colleague or a couple of colleagues, January 22, 2016?

A. **Okay.**

Q. **And that's just a few weeks before the next application was filed in this family, correct?**

A. **I think so, yes.**

Q. **All right. If we turn to the next page, Option 4, "Acidify the stomach by including a solid acid, probably citric acid, with the beads. Can't do it as a loose powder in a sachet -- in a sachet because it would be unpalatable, I did some taste tests."**

Did I read those words correctly, Doctor?

A. **I see that, yes.**

MR. SCHULER: I pass the witness.

THE COURT: All right. Redirect?

REDIRECT EXAMINATION

BY MR. CERRITO:

Q. **Doctor, just a few questions. It's a prime example, there was a bunch of Jazz documents just shown to you, right?**

A. **Yes.**

Q. **You were here for Mr. Allphin?**

A. **Yes.**

Q. **Did they show them to him?**

A. **No, they didn't.**

Q. **He couldn't explain them, right, he wasn't given the opportunity?**

A. **That's right.**

Q. **So he couldn't tell you what context any of those statements were made in, correct?**

A. **Well, yeah, he wasn't shown the documents, that's all --**

Q. **They decided to show you instead?**

MR. SCHULER: Your Honor, I object, sidebar.

MR. CERRITO: Withdraw the last question.

THE COURT: Withdrawn.

Please disregard the question and answer.

BY MR. CERRITO:

Q. **In your opinion, Doctor, are the disclosures of the '488 patent specification or Allphin 2012 limited to tablet formulations?**

A. **No.**

Q. **Okay. And Mr. Schuler suggested the problem that Mr. Allphin attempted to solve in his '782 patent was created by, I think he said his own work and he cut you off and you were trying to explain.**

Can you finish your answer, please?

A. **Yeah, so I think the implication that I was hearing, he said it twice, so I think the implication was, is that in the '782, you have particles now that can control the release and that's the discussion; whereas, in the '488 patent, it's tablets.**

I understand that that may be something -- that's somebody's opinion. It's not mine as I described to you.

What I'm -- what happens in the '782 is that if you take the dosage form of '488 and one of them, let's say, is a particle, you start to realize if you're going to turn those into a dosage form, now you have -- you have other problems. So you've got a lot of surface area. You've got one of them that dissolves and changes the pH. Because of the particles you have to use, they'll settle down to the bottom, so what the '488 is saying, okay, let's look at what has to happen if we do pick a particle solution in this particular instance, what are the issues and how do we solve it?

So it's not like the '488 created some problem; it's that the '782 solved the problem with one of the dosage forms that's in the '488.

Q. **Thank you, Doctor.**

I think in my question I probably asked, it was

my fault, I said, Dr. Charman talked about extensive or excessive experimentation, are those words different to you in your mind?

A. Well, no, I mean, I guess, he -- he said "excessive" and then he said "a lot."

Here's the way I think about this: Undue is like, you don't have a point of reference, okay, so you're -- you don't know which way to go. If you have excess of something, so excess or extensive, that's more than normal. Normal is a lot, is what I'm trying to describe to you.

So sometimes you realize that you have a lot that you would need to do, but you still get there.

I think there was an example of that in Dr. Charman's testimony where he was talking about how, you know, it was very difficult to coat the pellets, but then they were able to do it, that could be considered as excessive, but you still get there.

"Undue" is like you don't have a point of reference, that's different in my mind.

Q. Thank you.

So are those words interchangeable even though --

A. I don't think so, no.

Q. Thank you.

When looking at the '782 patent, would a POSA have access to all these internal Jazz documents that they didn't ask Mr. Allphin about?

A. **No.**

Q. **Thank you.**

MR. CERRITO: No more questions.

THE COURT: All right. Dr. Little, you may step down, thank you, sir.

THE WITNESS: Thank you.

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

MR. CERRITO: With that, Your Honor, plaintiff rests.

THE COURT: All right. Ladies and gentlemen of the jury, that completes the presentation of the evidence.

So what I'm going to do for the rest of the afternoon is let you leave early because there is some matters that the Court needs to handle outside of your presence and that's going to take a couple of hours, instead of having you wait around and just getting an hour or less of the closings done today, we'll start fresh tomorrow morning so that you can hear the closings back to back and then the Court will give you the instructions on the law and then you will begin your jury deliberations.

What I would ask is instead of starting at 9:30

tomorrow, could we start at 9:00 a.m., which would mean you would have to get here between 8:45 and 8:50. Is that a problem for anyone? All right.

So let's plan on that, starting at 9:00 a.m., meaning you'll be here between 8:45 and 8:50. And I'll remind you all of the same instructions that I have given you: Don't do any independent research on your own, don't communicate with anyone about the case, don't start talking about the case among yourselves, keep an open mind and don't review any news or radio or other types of stories about the case, if there should be any.

And leave your jury notebooks in the jury room until you come back tomorrow.

We will see you in the morning.

(Whereupon, the jury entered the room.)

THE COURT: All right. Counsel, let's plan to meet at 3:30 to -- for the charge conference.

MR. SILVER: Your Honor, before we conclude this session, we have a motion to make.

THE COURT: Okay. And Ms. Sawyer, Audra Sawyer is going to make that motion for Avadel.

Okay.

MS. SAWYER: Avadel renews it's prior JMOL motion on infringement and damages. No reasonable jury could find for Jazz on either issue. Jazz offered no

further evidence on damages in its rebuttal case, so Avadel moves on the same grounds as previously.

Jazz offered no evidence on infringement in its rebuttal case so Avadel moves on the same grounds as previously.

Avadel also moves for JMOL on invalidity because no reasonable jury could find against Avadel on invalidity given the evidence Avadel offered on invalidity and the evidence that Jazz offered in response.

On noninfringement, Jazz has not shown that the accused Lumryz product directly infringes any of the asserted claims. Lumryz does not infringe the asserted claims, for example, because it lacks a core comprising at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate as required by the asserted Claims 7 and 11 of the '488 patent.

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

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

On damages, Jazz has not shown that the royalty rate it has requested is reliable or based on credible evidence. Jazz's damage's expert did not limit the royalty to the incremental value provided by the asserted patents.

Jazz's damages expert also failed to properly apportion damages between the patents-in-suit and unrelated Jazz patents and between the patents-in-suit and Avadel's contribution.

Jazz's judgment as a matter of law should be denied because Avadel has offered evidence from which a reasonable jury could find in Avadel's favor on the issue of invalidity of the asserted patents, the patents and their prosecution history alone, are clear and convincing evidence that the asserted patents are invalid for lack of written description and enablement.

The documents and testimony confirm that Jazz was aware of and referred to Avadel's work and patent application in filing the asserted patents which is clear and convincing evidence of improper inventorship, derivation and copying.

The '488 patent lacks written description support for Claims 7 and 11 because the specification, as drafted in 2011, lists many potential ingredients which can be combined in many ways to make a large number of potential formulations, but the specification lacks any blaze marks

that would point to the narrow species ultimately claimed.

The '488 patent also lacks written description support for the asserted claims because those claims encompass microparticles, methacrylic acid-methyl methacrylate copolymers and dissolution testing under specific testing conditions yet none of the disclosures in the patent encompass these claimed features.

This is further supported by Ms. Gray's testimony that dissolution testing will be different depending on the testing conditions and Dr. Charman's testimony, that the specification of the '488 patent lacked an indication that the dissolution testing was conducted under the claim testing conditions and with the claimed amount of methacrylic acid-methyl methacrylate.

The '488 patent also lacks written description support because the asserted claims require a certain release profile for gamma-hydroxybutyrate under certain testing, but the specification does not disclose a representative number of species within the claimed subgenus of formulations that provide the desired release profile, nor does it disclose structural features commended of the claimed subgenus formulations.

The '782 patent also lacks written description support, for example, because the claims encompass nonresinate dosage forms and the evidence at trial establish

conclusively that the specifications disclosure is limited only to resinates, Mr. Allphin and Dr. Charman testified about the lack of data or examples showing nonresinate modified-release particles.

And even years later, Jazz was, itself, only able to achieve immediate release with its resinate technology, not the controlled release claimed.

Mr. Allphin, the purported inventor, remained skeptical that resinate technology would work long after the filing date of the patent application.

The '782 patent also lacks written description because it fails to describe an acid or a viscosity-enhancing agent that is separate from the microparticles.

The specification of the '488 patent does not enable a person of ordinary skill in the art to make and use the full scope of Claim 7 and 11 of the '488 patent because it does not enable a POSA to create microparticles meeting the claim limitations. Jazz, itself, was not able to do so, despite years of effort.

Avadel's expert, Dr. Charman, testified, among other things to the unpredictability of orally administered controlled drug release formulations and the lack of guidance as to how to practice the asserted patents.

The specification of the '782 patent does not

enable a person of skill in the art to make and use the full scope of Claim 24, which is directed to formulations that provide modified release of oxybate.

Jazz, itself, was unable to create such a formulation despite years of effort and development both in-house and with partners.

Written description is not a predicate for improper -- for inventorship, let me rephrase.

Written description is not a predicate for inventorship because inventorship focuses on whether the true and correct inventors are named on the patent; while written description focuses on disclosure.

The facts presented at trial conclusively show that Drs. Hervé Guillard and/or Claire Mégret are the proper inventors of the '488 and '782 patents because they first conceived of the idea behind the patent's claims.

Jazz and its purported inventors did not conceive of the claimed invention and instead, copied Flamel's ideas once they became public via Avadel's patent publications.

Avadel's Patent Office expert, Mr. Matal, opines that claim copying calls into questioning the true inventors of the patent, particularly where the inventors did not inform the Patent Office of the copying.

Avadel moves for judgment as a matter of law,

that Jazz and its purported inventors derived the invention claimed in the '488 patent from Drs. Guillard and Mégret.

As just discussed, the evidence presented at trial conclusively establishes that Drs. Guillard and Mégret first conceived of the idea behind Jazz's '488 patent claims and that this idea was communicated to Jazz's purported inventors.

Thank you.

THE COURT: All right. Jazz?

MR. THOMPSON: Your Honor, Jazz opposes Avadel's Rule 50(a) motion.

If I may borrow a phrase from the trial, I'd like to incorporate by reference, Mr. Cerrito's arguments from yesterday on Jazz's Rule 50(a) motion, I'm happy to go through them today but if I may just incorporate them because as you know, Jazz moved after Avadel had presented its invalidity case.

So if that's okay with Your Honor, I'll just note that in Jazz's rebuttal case, the Court, and the jury heard testimony today from Mr. Stoll that there is support for Section 112 and inventorship, that claim copying is permissible under Patent Office rules and that the examiner made a specific finding that there was full Section 112 support as of February 18th, 2016, prior to the date of Avadel's patent.

We heard Dr. Moreton testify at length that there's full written description and enablement for the '488 patent as of March 24th, 2011.

And we heard Dr. Little testify that there's written description and enablement support for the '782 back to February 18, 2016, provided the testimony that Jazz was the true inventor of the subject matter of Claim 24 of the '782 patent.

This testimony provides further support, in addition to the evidence that Mr. Cerrito described yesterday for opposing Avadel's motion for judgment as a matter of law.

In addition, Jazz would renew its Rule 50(a) motion based not only on what Mr. Cerrito described yesterday, but why the Court should grant judgment as a matter of law in favor of Jazz on infringement, invalidity and damages, but, also, now on the testimony that the Court heard today from Mr. Stoll, Dr. Moreton and Dr. Little.

For that reason, judgment as a matter of law should be granted in favor of Jazz and it should not be granted in favor of Avadel, especially given that Avadel has the higher burden of proof of clear and convincing evidence, no reasonable juror could conclude that Avadel had met that burden.

So unless Your Honor would like me to go through

the points that Mr. Cerrito made yesterday, judgment as a matter of law should be granted in favor of Jazz and Avadel's motion should be denied.

THE COURT: All right. Are you done?

MR. THOMPSON: Yes, thank you, Your Honor.

THE COURT: All right.

MR. SILVER: Your Honor, very briefly, we will oppose Jazz's renewed JMOL motion for the reasons stated by Ms. Durie yesterday and I think, very clearly, stated by Your Honor this morning.

I don't think the defendant's presentation of the rebuttal case can remove the issues Your Honor identified this morning in denying Jazz's motion in terms of there being disputed factual issues that have to go to the jury.

So unless Your Honor has any specific questions, we'll note that opposition and we can take a break if that's what Your Honor prefers.

THE COURT: All right.

MR. SILVER: Thank you.

THE COURT: All right. So the Court having heard Avadel's motions for judgment as a matter of law under Rule 50 on infringement/noninfringement, the Court finds that there continues to be material issues of fact for the jury to decide on those issues.

Viewing the evidence in the light most favorable to Jazz as the nonmoving party with respect to infringement and Avadel as the nonmoving party on the other side of noninfringement, the Court denies both Jazz's -- Avadel's judgment -- motion for judgment as a matter of law and Jazz's motion for judgment as a matter of law on the infringement/noninfringement issue finding that there is sufficient evidence of record to support a jury verdict in favor of Jazz with respect to infringement and Avadel with respect to noninfringement.

With respect to Avadel's motion for judgment as a matter over law on damages, the Court, again, finds that the issue of what is a reasonable royalty rate if the jury finds infringement is an issue for the jury to determine. There is sufficient evidence of record to support a reasonable royalty award if that's what the jury concludes.

For those reasons, Avadel's motion for judgment as a matter of law on damages is denied. The issue will go to the jury.

With respect to Avadel's motion for judgment as a matter of law under Rule 50 on invalidity, including lack of written description, enablement, inventorship and derivation, for all the reasons stated by the Court earlier, that motion is denied.

There remain continuing issues of material fact

for the jury to decide on those issues and there's sufficient legal basis on the record for the jury to find in favor of Jazz on those issues to support a jury verdict if that's what the jury so finds.

With respect to Jazz's renewal of its Rule 50 motion on infringement, invalidity and damages, that motion is denied for the same reasons that the Court denied it earlier.

There remain genuine issues of material fact for the jury to decide. There is sufficient evidence of record to support a jury verdict in favor of Avadel on those issues.

Viewing in the light most favorable to Avadel as the nonmoving parties and giving Avadel the benefit of all reasonable inferences, there's sufficient evidence of record to support a jury verdict in Avadel's favor, thus, that motion is denied.

So all the issues remain live except the one JMOL motion granted this morning on the issue that the parties stipulated to. The other issues will go to the jury to decide.

All right. That deals with the JMOL motions, I will meet with counsel for the parties at 3:40 p.m. to deal with the final jury instructions and the verdict form.

(Recess taken.)

THE COURT: All right. You may be seated.

All right. So we handed out redlined versions of the proposed jury instructions and the verdict form.

So let's go through it. Starting with the preliminary jury instructions -- with the final jury instructions.

The first dispute was 1.6, that FDA approval instruction, I agree with Jazz that this instruction would be confusing in that the jury is not being asked to decide any issue related to FDA approval or FDA law.

Moving on. 1.15, burdens of proof. There's a dispute concerning the instruction for what clear and convincing evidence means, and that sentence that Avadel proposes is the sentence that I have used in several other cases.

MR. SILVER: Your Honor, I apologize for interrupting, just as a matter of procedure, I think we're obligated to lodge objections on the record to instructions.

THE COURT: After I finish, you can lodge your objections.

MR. SILVER: Thank you, Your Honor.

THE COURT: 2.2 is the next. In that second paragraph, the first sentence, Jazz proposes to include the phrase, which parties have referred to as the "core and deionized water limitations" to inform what the two

limitations at issue of the '488 patent are, and the Court doesn't believe that that -- will include it, it believes it's helpful and doesn't believe it hurts Avadel in any way.

Instruction 3.3, constructions of the law, that, after the chart containing the claim constructions of the Court, Jazz has proposed to include an additional two sentences instructing about what the asserted claims -- what the Court is determining the asserted claims do not require.

The Court doesn't believe that that's necessary or helpful under the circumstances and agrees with Avadel on this one, and is not going to include those two sentences.

Next is 4.2, direct infringement. So the dispute is on page 32, so they're here, I didn't go with either parties proposed language. The Court drafted a hybrid to attempt to satisfy both parties' concerns without -- in a more balanced fashion, thus, that last paragraph will read:

"The existence of Avadel's patents is not relevant to whether Avadel infringes Jazz's patent. The patent grants only the right to exclude others. A patent confers no right on its holder to make, use or sell a product that infringes someone else's patent. The existence of Avadel's patent is relevant to Avadel's defenses and its theories of written description, enablement, improper inventorship and derivation."

In 5.1, invalidity, Jazz proposes additional sentences in that second paragraph and the Court will include those sentences.

On page 35, that addition proposed by Avadel on balance, the Court thinks that could be misleading in this case and I think it's addressed elsewhere in the instructions.

Next is 5.3, written description. And the dispute is on page 40, that paragraph that begins with, "the hallmark of written description is disclosure," at the end of that paragraph, Avadel proposes a sentence which the Court will include.

All the remaining proposed insertions by both sides in that instruction will not be included.

Enablement, 5.4, Avadel's list of the factors, the Court is going to include, those are -- the Court has previously used those factors in other cases with enablement issues and supported by W.R. Grace -- well, W.R. Grace and Company was an example where I adopted those factors.

On page 45, that paragraph that Jazz proposes to include, the Court is going to accept, that comes from the *United States vs. Gilead Scientific*. So in considering Jazz's proposal and Avadel's proposal on that point, the Court finds that Jazz's proposal is more balanced and reasonable and was used by Judge Noreika in that *Gilead*

case.

Going to 5.5, inventorship. The proposal Avadel seeks at the end of paragraph 4, the Court is not going to include. And the proposal that Jazz proposes to include as paragraph 6, the Court is not going to include.

Moving to 5.6, derivation, that last sentence in the first paragraph, that's a factual truth and the Court will include it.

The third paragraph that Jazz proposes, the Court is not going to include.

And those six paragraph proposals by Avadel and Jazz neither is going to be included.

Moving to 6.1, damages. Avadel's proposal in the first paragraph will be included.

Jazz's proposal in that second paragraph will be included with the modification that it will read, "there's no requirement that Jazz make, use or sell its patented invention for damages to occur. If you find Avadel infringed, the damages you award..." pick up with the language that's there. Insert it if you find Avadel infringed, comma.

On page 56, Avadel's proposal to include "if any" in that second paragraph will be included.

Moving to 6.3, reasonable royalty, generally. Avadel's proposal in that second paragraph will be included.

6.5, the Court's going to go with Jazz's proposal for that first dispute, so absence will be the language included and Jazz's second proposal in that instruction will not be included.

6.6, Avadel's proposal was most similar to the Court's prior instructions on this issue. Thus, it is what the Court will go with.

That's it.

All right. So both sides can lodge whatever objections you want to lodge.

MR. SILVER: Thank you, Your Honor. Do you want to go instruction by instruction or should one side or go and then the other?

THE COURT: You should do them all. You should go and do them all for the record.

MR. SILVER: Okay.

THE COURT: All right. So let's go with Jazz first and then we'll go with Avadel.

MR. LoCASTRO: Thank you, Your Honor. Nicholas LoCastro for Jazz.

If Your Honor will indulge me, I'd like to start out of order, because there's one instruction here that I feel has the potential to confuse the jury and working off the redline, I'm on page 32 of section 4.2.

And the instruction that the Court wrote here

is, "The existence of Avadel's patents is not relevant to whether Avadel infringes Jazz's patents."

And my concern with that, Your Honor, is if you'll recall, a good chunk of the evidence that Jazz put forward for its infringement case was actually based on what was put forth in Avadel's '062 patent.

The way that we'd initially put forth the proposal is that the existence of an accused infringer's own patent doesn't constitute a defense to infringement. So by rewriting this to say, "the existence of the patent isn't relevant to infringement," I have a real concern that the jury might think the Court's instructing it not to look at the evidence that was presented of what's in Avadel's patent and which they do admit that does correspond to Lumryz.

So I would really strongly object to that instruction, just because I really don't want the jury to get the wrong impression as to how they should look at the evidence of Avadel's patent.

THE COURT: Okay. That's a valid point. I see your point. I can -- the Court will change that first sentence back to, "the existence of --" we'll use your first sentence, "the existence of an infringer's -- the existence of an accused infringer's own patent does not constitute a defense to infringement of someone else's patent." And then pick up from there with the language the Court wrote.

And I think the last sentence explains what the relevance of Avadel's patent is, the existence of Avadel's patent is relevant to Avadel's defenses and its theories of written description, enablement, improper inventorship and derivation.

MR. LoCASTRO: Thank you very much, Your Honor, for making that change.

If I -- okay. If I -- I guess then, Your Honor, if we're -- if the first sentence of this particular passage on 32 is no longer using the language of, "the existence of Avadel's patents is not irrelevant, I would, then, I guess, object to the final sentence there, because we're not talking about relevance and relevance any more and given that we're in the infringement section, we would still object to the last sentence talking about relevance --

THE COURT: Your objection is noted but that sentence is going to stay.

MR. LoCASTRO: Okay.

I'm going to turn back now to section 3.3. And we would object to the Court, respectfully, of course, object to the Court striking Jazz's proposal on page 27 in the redline with regards to the Court's determination with respect to the asserted claims and what they don't require.

If the Court will recall, Avadel previously attempted to argue invalidity on the theory that the

asserted claims lacked written description and enablement support because they didn't have safety and efficacy requirements.

Now, I don't think we've heard safety and efficacy being touted as claim limitations in this case, but the jury has heard a lot about pharmacokinetics, they have heard a lot about properties of finished drug products, and, you know, if Avadel and its lawyers were in a position earlier in the case where they legitimately thought that these claims had safety and efficacy limitations, you know, it's our position that in view of a lot of the pharmacokinetics evidence that came in, you know, especially through Dr. Mégret's testimony, the jurors might be wondering, too, do these claims have safety and efficacy limitations?

And --

THE COURT: The Court has ruled on those. The Court isn't saying Jazz, you can't in your closing, you know, point out that these claims don't have safety and efficacy requirements. The Court is just saying, it's not going to include it in its instruction.

MR. LoCASTRO: I understand that, Your Honor, the basis of the objection is that, though, in Jazz's view, the Court's determination as to what the claims don't require was essentially an extension of its previous *Markman*

opinion.

The Court issued its *Markman* about what sustained-release portion meant and then the parties continued to fight about it and then it culminated in the pretrial rulings and essentially, the Court clarified its claim construction opinion and said, "definitively, these claims do not require suitability for once-a-day dosing and they don't require a separate limitation that helps a patient stay asleep throughout the night."

So, you know, the way we see it is, on the first page of 3.3, the Court is explaining what its *Markman* decision was and our proposal was essentially that the Court also tell the jury, not in these words, but, essentially, and this is an extension of the *Markman* ruling.

THE COURT: The Court is not going to do that.

MR. LoCASTRO: Okay. Moving to section 5.5, page 49 of the redline.

Jazz would respectfully object to the deletion of the final sentence or two of this instruction.

Specifically, in Jazz's view, the jury should be instructed that the '488 patent and the '782 patent, you know, they're being adjudicated under two different laws, the '488 is a pre-AIA patent, the '782 is a post-AIA patent. I understood the basis of Avadel's objection to the instruction to be, you know, Jazz can't seek an instruction

that's telling the jury you can't have inventorship for a post-AIA patent, but that wasn't what the instructions sought, what the instructions sought was the inclusion of the language that a post-AIA patent cannot be -- you can't argue that a post-AIA patent is invalid for improper inventorship on the basis of a later-filed patent application.

So that instruction that we saw is grounded in law and we feel, respectfully, that it should be given.

THE COURT: All right. The Court's ruling on that doesn't change.

What's next?

MR. LoCASTRO: Section 5.6, Your Honor. Jazz would respectfully object to the deletion of both of the Jazz proposals in this section.

First, Jazz proposed that the Court give an instruction that very closely, if not verbatim, tracks the holding of the Federal Circuit in the *Kingsdown* case.

During the pretrial conference, Your Honor gave an instruction to the parties that if there were unique circumstances in this case that would warrant, you know, an instruction, the Court would be inclined to consider it. And I feel as though that this is quite a unique case where the jury is hearing, you know, a lot of -- they are not ordinary written description arguments being based on these

allegations of claim copying, and for the jury to be instructed, under the law, there is nothing improper, illegal or unequitable in filing a patent application for the purpose of obtaining a right to exclude a known product, nor it is improper to amend or insert claims intended to cover a competitor's product.

You know, that's the Federal Circuit saying that, that is the law of the land and we feel that an instruction telling the jury that is appropriate under the circumstances in this case.

And because the instruction has a clear basis in law, we respectfully submit that, that it should be given.

With respect to the deletion of the second Jazz proposal in this same section, Your Honor, Avadel's derivation claim, again, it's sort of a rather unique legal theory. When derivation typically comes up, it's because there has been prior conception and prior communication.

You know, we looked, Your Honor, and we weren't able to find any case where the prior communication was based on a public patent filing. These kinds of cases just don't happen that often which is why we thought that this instruction was warranted in the unique circumstances in this case.

And what that instruction is trying to convey, is that if the jury finds that Jazz's '488 patent had the

earlier priority date, then Avadel's public patent filing in 2016 can't, as a matter of law, be the prior communication that's necessary under the derivation test that the parties have agreed upon and that the Court is going to give.

So the second Jazz proposal that was struck is essentially telling the jury, this really is the question for this specific legal issue.

THE COURT: Okay. The Court's ruling is going to stand.

MR. LoCASTRO: I have two more, Your Honor, if you'll indulge me.

Section 6.5, Jazz respectfully objects to the deletion of the last sentence. Avadel has admitted here that there are no noninfringing alternatives. They've said that in their interrogatory responses and we actually cited a letter in the footnote where Avadel didn't let Jazz take discovery on this issue based on the representation that Avadel does not contend there is a noninfringing alternative. I'm paraphrasing but that's the gist of what they told us.

The interrogatory, a direct quote is, "Avadel is unaware of any alternative once-nightly oxybate products for the treatment of narcolepsy, whether covered by claims of the patents-in-suit or not."

So Avadel has admitted this and therefore, we

feel the instruction should be given.

THE COURT: Okay. I mean, Jazz can advise the jury of Avadel's admission, you know, in its closing. I mean, the Court is not -- you know, it's not the Court's role to emphasize some evidence over the other. That's not my -- that's not the Court's job, so that's why I'm not including that.

MR. LoCASTRO: I understand, Your Honor.

The last one is 6.6. And with respect -- and I assume Your Honor is going to have the same reaction but I'll make the objection just to preserve it.

The Jazz proposal and the Avadel proposal on the 6.6 are fairly similar. The difference is, Avadel's proposal asked the jury to consider license agreements entered into the parties shortly after the date of the hypothetical negotiation.

There aren't any license agreements the parties entered into shortly after the date of the hypothetical negotiation, so it sort of invites the jury to consider something that didn't happen, and so we would object on that ground.

THE COURT: Okay. The Court's ruling is going to stand.

MR. LoCASTRO: Thank you, Your Honor.

MR. DAVIS: Good afternoon, Your Honor. May I

proceed?

THE COURT: Yes.

MS. DAVIS: Kira Davis for Avadel.

As I believe Mr. Silver may have previewed with the Court, Avadel has a number of attorneys here to argue, including several attorneys who will be making their first argument. So we will be going through in order and with the Court's indulgence, there will be some back and forth of attorneys.

THE COURT: Okay.

MS. DAVIS: So to begin with, the first instruction that Avadel will be presenting argument on is instruction 1.6 and that will be Ms. Weires' argument.

MS. WEIRES: Good afternoon. Rebecca Weires for Avadel.

The jury heard several times this week about Avadel's use of the 505(b)(2) pathway for FDA approval of its drug. That came up in Jazz's questioning of three different witnesses this week.

THE COURT: Is the jury being asked to decide anything with respect to FDA? Is there any questions with respect to FDA?

There's no questions with respect to the FDA, even in the proposed verdict forms that the parties submitted, right?

MS. WEIRES: We agree that it's not and the concern is more that because this issue has come up in the testimony of several witnesses, that that could be confusing and prejudicial without appropriate context of, you know, what the law has to say about that.

The implication of certain testimony being that Avadel was, you know, exploiting some loophole by using the 505(b)(2) pathway, or that there would be a prejudicial implication that they ought to have used the 505(b)(1) pathway. And we believe that our proposed instruction would be helpful to the jury to cure that prejudice by explaining that the pathway Avadel took is an available, lawful route that Avadel used as Congress intended. And so it should not draw any negative implication against Avadel for its use of that pathway.

THE COURT: Okay. Again, the Court's ruling stands.

MR. SILVER: Your Honor, on that one, do I understand -- just real quick, do I understand you intend to charge the jury after closing statements?

THE COURT: Yes.

MR. SILVER: Okay. So if they raise the issue of Avadel using the 505(b)(2) pathway and relying on Jazz's data in that context, we may raise -- re-request the insertion of that instruction for the reason Ms. Weires

stated.

THE COURT: As I said, the Court's ruling stands. All right.

MR. SILVER: Thank you, Your Honor.

MS. DAVIS: On the next instruction where Avadel will be presenting its objection, Ms. Sawyer will be arguing. This is 4.2.

THE COURT: Ms. Sawyer?

MS. SAWYER: Your Honor, on section 4.2, just on the sentence that was added back in, I think the way that sentence is framed is a bit confusing because invalidity is a defense to infringement and Avadel's patent is a part of our invalidity defense, so we would just propose a slight modification to that sentence.

THE COURT: What's the modification you propose?

MS. SAWYER: The modification -- I'll just read the full sentence: "Further, the existence of an accused infringer's own patent on its own does not constitute a defense."

THE COURT: It's redundant. The existence of an accused infringer's own patent, on its own, that seems redundant, right?

MS. SAWYER: I think, Your Honor, it just clears up that the patent, just on its own, is not a defense, but the existence of the patent in light of other arguments in

this case could be a defense, that's the confusion that we're trying to defend against.

THE COURT: Jazz, you have any objection to the insertion of, "on its own..."

MR. LoCASTRO: I would agree with Your Honor's inclination that that's a bit confusing. If Your Honor would indulge me to propose another sentence, maybe it could alleviate everyone's concern.

What if we said something along the lines of: "The fact that an accused infringer has its own patent on the accused product, does not, on its own, constitute a defense to infringement of someone else's patent."

MS. SAWYER: I think we're okay with that, Your Honor.

THE COURT: Okay. So read that to us again, please.

MR. LoCASTRO: Your Honor, I hope that the court reporter got it, because it was here and I said it and now it's gone.

THE COURT: We have it.

MR. LoCASTRO: I hope it's there. Okay. Great.

THE COURT: All right. Hold on.

All right. Move on.

MS. WANG: Thank you, Your Honor. Good afternoon, Sarah Wang for Defendant Avadel.

So I will be discussing page 34 and 35 of the redline version. And I will start with Jazz's proposal, which Your Honor accepted, on invalidity generally. And there are two reasons we object to the language that Jazz proposed.

First, it does not provide necessary context; and, two, it is confusing and misleading to the jury.

On the first point, it's true that the Patent Office determinations are given weight, however, that weight is tempered when the Patent Office does not have material facts before it. And this context is important, for example, to inventorship and whether, for example, copying was disclosed as being material to inventorship.

And then the second reason is that the instruction is confusing. On the last sentence of Jazz's proposed instruction beginning with, "however, the fact that a patent application is rejected or amended has no bearing on its ultimate validity," suggests that the prosecution has no bearing on validity and we think that that would be confusing to the jury because in this case, inventorship is at issue and in inventorship, the prosecution is important and relevant, so telling the jury the opposite would be confusing for them.

THE COURT: All right. The Court understands those concerns. In order to attempt to balance this

instruction out more evenly, the Court will include the Avadel proposal on page 35, the sentence where the USPTO did not previously have all the material facts before it, Avadel's burden to prove invalidity by clear and convincing evidence may be easier to sustain.

MS. WANG: Thank you, Your Honor.

MR. LoCASTRO: Your Honor, may I be heard on that briefly?

THE COURT: Yes.

MR. LoCASTRO: Your Honor, if the Court is inclined to put that instruction back in, then I would have to object to it. I think -- and the reason why is because it's frankly confusing to the jury. Easier how? It doesn't really give them guidance as to what they should be looking for, which is the reason why, you know, this instruction is not commonly included in previous DDEL jury instructions.

THE COURT: I have included it before and Judge Noreika has included it before. But, go ahead.

MR. LoCASTRO: Yeah, I mean, as the Federal Circuit has said in the *Sciele Pharma vs. Lupin* case, 684 F.3d 1253, the ultimate burden of proof doesn't change. And, again, the burden of proof is clear and convincing evidence. So, telling the jury that it may be easier to sustain suggests that the burden does somehow drop, that it is no longer a clear and convincing evidence standard, and

so we would, we would object on that basis.

THE COURT: Okay.

MS. WANG: May I briefly respond, Your Honor?

THE COURT: Yes.

MS. WANG: So the *Sciele Pharma* case actually has the language in here that if the PTO did not have all material facts before it, its considered judgment may lose significant force, and the burden to persuade the finder of fact by clear and convincing evidence may therefore be easier to sustain.

THE COURT: All right. So as I said before, I'm going to include Avadel's proposed language on page 35 to more balance out the instruction, so I understand that both sides may not be 100 percent happy with the instruction, but that's what your objections are for.

The Court believes that as modified it's fair and that's what it's going to -- that's the Court's ruling. You can -- if you got a further comment, you can state it for the record.

MR. LoCASTRO: The only further comment, Your Honor, would be just that we would suggest the Court consider, after the word "evidence," saying, "does not change but..." so the sentence would read, "Avadel's burden to prove invalidity by clear and convincing evidence does not change, but maybe easier to sustain."

THE COURT: No, because that language is, quote, taken directly from those cases and I'm not going to change the quote.

MR. LoCASTRO: I understand, thank you.

MS. WANG: Thank you, Your Honor.

MS. DAVIS: I will be addressing written description instruction 5.3 and some other instructions following it.

With respect to instruction 5.3, across pages 39 to 40 of the submitted proposed instructions, Avadel had requested an instruction on genus claims and then had requested a blaze marks instruction.

And Avadel submits that on the facts of this case, those two instructions are appropriate.

The blaze marks, in particular, we are aware that we do not have a proposed model instruction to cite from for the blaze mark's instruction, but we believe the law in the blaze mark's has been developing recently, which is perhaps one of the reason that there are fewer instructions being given on it, and then on the facts of this case, the concept of explaining to the jury the forest and trees concept, what the blaze mark's test is doing, would be useful and would assist the jury in navigating some of these concepts that may not be particularly easy to understand.

And the new design case, in particular, that we cited in our proposed instructions, identifies one issue that arises in the absence of a clear instruction on blaze marks, which is that, we know, as a matter of law, it is inappropriate to work backwards from the knowledge of the claims, which is hindsight, the written description test requires looking at the specification and seeing if there are blaze marks to work forward. And so that issue in this case is a particularly acute one and we would suggest that the blaze marks instruction would get at that legal issue.

THE COURT: Okay. So what if I included Jazz's proposal?

MS. DAVIS: We do not agree with Jazz's proposal from the *Idenix* jury instructions, that case the jury returned a verdict in favor of the patentee; and on appeal, it was reversed and that patent was held to be insufficiently described as a matter of law. And it was not a jury instruction issue, to be clear, but in our view, the *Idenix* instruction is likely to be -- seems like it's confusing in that it suggests that the blaze marks -- that the figures and words in the patent are necessarily blaze marks when, in fact, they may not be. So we would object to Jazz's blaze mark instruction.

THE COURT: Okay. So the Court's ruling is going to stand. If the parties want to agree upon some

language for blaze mark instruction, if it's agreed to by the parties, the Court will include it, but unless there's an agreement, it's not going to be included.

MS. DAVIS: Understood, Your Honor, the parties will confer.

Within written description, we also had -- I'm on page 42 of the redline, and it was page 41 of the nonredline, Avadel had requested the sentence, "inventors testimony cannot establish written description support --"

(Reporter clarification.)

MS. DAVIS: Avadel had requested the sentence, "inventors testimony cannot establish written description support where non exists in the four corners of the specification."

And that sentence, we would maintain our request that it be included in this case. Based on the facts of this case, Mr. Allphin, the named inventor who testified in this case, testified regarding the work that he did, that very specifically, was not included in the patent, which may be confusing for the jury.

The instruction is supported in the case law, it is a correct statement of law. And, therefore, on the facts of this case, we believe that it would be helpful to assist the jury in understanding that the work that Jazz chose not to include in the patent cannot fill a hole in the

specification.

THE COURT: All right. The Court's ruling is going to stand.

MS. DAVIS: Turning then to enablement, instruction 5.4. Regarding the language added with respect to -- it was 45 of the redline, it was page 42 of our original proposed submission.

THE COURT: The Jazz proposal?

MS. DAVIS: Yes, the Jazz proposal, and in particular, the language at the end that, "in addition, the patent disclosure need not enable persons of ordinary skill to make a commercially viable product or to otherwise meet the standards for success in the commercial marketplace."

Avadel continues to maintain its objection to that and to request its instruction on the same concept. And here, the law that Jazz is relying on concerns a situation in which an inventor succeeds, but the success does not rise to the level of a commercially viable product. In that situation, courts have said that you should not consider that to be a failure. It is not a lack of enablement. And that concept was also included in Avadel's proposed instruction, we acknowledge that there is no requirement to get to the level of commercial success.

The concept that is in Avadel's, that was missing from Jazz's, is that there is very clear law that,

in the case where the inventor does try, they don't have to try, but where they do try to make a commercial embodiment and they fail, that is highly probative of enablement. And in particular, I would direct the Court's attention to the *Ormco* case and that case reads:

"If an inventor attempts, but fails to enable his invention in a commercial product that purports to be an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement. Substantial doubt concerning the enablement of the invention was cast by the inventors in this case."

And so we believe our instruction is fully supported by the case law and more closely matches the facts of this case in which the evidence that has been elicited does demonstrate the failure by Jazz as opposed to the situation covered by Jazz's instruction, which is the success that does not go the full distance.

THE COURT: Let me hear from Jazz on that issue.

MR. LoCASTRO: Jazz's instruction, Your Honor, was taken from another court in this district. Avadel's instruction is essentially seeking to equate commercialization with the safety and efficacy limitations that Your Honor found are not actually limitations of any asserted claim.

To emphasize to the jury these instructions

about commercially viable products based upon the *Ormco* case, it would imply to the jury that the fact that Mr. Allphin and his co-inventors didn't arrive at something that was claimed, somehow now becomes part of the enablement inquiry.

And I just -- there's really no basis to give that instruction, especially when Jazz, you know, has already proposed that this aspect of the enablement inquiry to the extent that it is going to be given at all, should track what the instruction that Judge Noreika gave in the *Gilead* case.

THE COURT: Okay. The Court's ruling is going to stand.

MR. LoCASTRO: Thank you, Your Honor.

MR. KOWALSKI: Thank you, Your Honor. David Kowalski Avadel. I'm going to briefly address instruction 6.1 on damages.

THE COURT: Okay.

MR. KOWALSKI: Avadel respectfully objects to the last sentence of the proposed -- of the insert that Jazz proposed and the Court has adopted in its redline. In particular, Avadel objects to the inclusion of the language about Jazz, "in any event, is entitled to no less than a reasonable royalty."

The reason that Avadel objects, Your Honor, is

this is only a reasonable royalty case. Jazz put on a reasonable royalty case, this is not a situation where there's some alternative form of damages such as lost profits that the jury is potentially going to award in this case. The jury is not going to be asked to decide any other form of damages beyond a reasonable royalty.

And, for example, I believe this Court in the *CiRBA* case in the past, which also was a reasonable royalty only case, in instruction 14.0 in the *CiRBA* case, had the language about adequate to compensate the patentee for infringement but then did not include the language about, "no less than a reasonable royalty," so Avadel objects on those grounds.

THE COURT: Let me hear from Jazz on the deletion of -- Jazz's entitled to no less than a reasonable royalty.

MR. LoCASTRO: Your Honor, I'm going to quote from 35 U.S.C. Section 284, which states that:

"Upon a finding for the claimant, the Court shall award the claimant damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer."

So Jazz's instruction is directly quoting from the damages statute and I think Your Honor recognized, in placing this in here, is that to not instruct the jury on

the exact words of the statute, you know, I -- would frankly be error.

MR. KOWALSKI: May I very briefly respond, Your Honor.

We don't dispute that those words appear in the statute, however, this is a reasonable royalty only case and as the Court has done in the past in *CiRBA*, we don't believe -- it's not appropriate to discuss other forms of potential damages to the jury, thank you.

THE COURT: Okay. So the Court is going to -- the Court's ruling is going to stand. It quotes directly from the statute and, you know, Avadel is -- can make the argument in its closing that, you know, the jury should award no reasonable royalty, you know, that's --

MR. KOWALSKI: Thank you, Your Honor.

MS. DAVIS: Finally, Your Honor, for instruction 6.5, Ms. Pasvantis.

MS. PASVANTIS: Good afternoon, Your Honor. Tannyr Pasvantis for Avadel.

I would like to direct your attention to page 64 of the redline and I'd like to speak to the party's competing instructions and the first sentence of the instructions.

Avadel's proposed instruction recites that the jury may consider evidence concerning the availability or

unavailability and cost of acceptable noninfringing alternatives to using the patented invention.

This instruction is adapted from *First Quality Tissue* and was given in 2022. And our dispute here is that Jazz has not explained why Avadel's proposal is improper or in this case, why Jazz's proposal is instead proper. They merely cited the Federal Rules of Evidence; however, there's nothing prejudicial, confusing or misleading about our proposed instruction which is clearly supported in the law. And Jazz has cited no evidence to the contrary and furthermore, our instruction that they can consider the availability or unavailability also includes Jazz's proposal that they may consider the absence or unavailability.

And for those reasons, we believe that our instruction should be given.

THE COURT: So on this, if I include Avadel's availability or unavailability in cost, then I would include Jazz's proposal that Avadel admitted that there were not and are not any available noninfringing alternatives. So do you want the admission in the instruction or would you rather have Jazz's absence language?

MS. PASVANTIS: We would prefer Jazz's absence language in that instance.

THE COURT: That's what I thought.

MS. PASVANTIS: Thank you, Your Honor.

THE COURT: All right. So that concludes the jury instructions.

All right. You have copies of the verdict form. And the Court looked at both sides' proposed verdict forms and formulated the verdict form using combinations of both and what the Court has done in prior cases with these issues.

MR. THOMPSON: Yes, Your Honor, may I be heard briefly?

THE COURT: Yes.

MR. THOMPSON: I believe, if I'm reading this correctly, that there is actually an error in the verdict form.

On page number 11, it says to answer Question 9 only if you have found one or more of the asserted claims to be infringed, yes to Question 1, invalid, no to each of the Questions 2-8 for that asserted patent and/or claim.

Question 1, however, is addressed only to the '488 patent because Avadel has admitted infringement of the '782 patent and as Your Honor ruled in its judgment as a matter of law ruling, Jazz is entitled to judgment as a matter of law on that issue. And the only question for the jury is whether the patent is valid.

And then if it's valid, the jury actually does have to decide Question Number 9 for the '782 patent.

So we had proposed in our verdict form, including in the instruction, the language, "because, Avadel admits infringement of the '782 patent, you, the jury, are not being asked to determine Avadel's infringement for that patent, you are, however, being asked to decide Avadel's invalidity defenses with respect to the '782 patent and damages for Avadel's infringement for the '782 patent."

So I think that should be included in the instruction.

And then we'll have to fix the way the questions go, because they have to answer Question 9 unless they determine invalidity -- that both the '488 and the '782 patent are invalid and if they do not determine that the '782 patent is invalid, they still have to determine damages even if they haven't answered "yes" to Question 1.

We tried to account for this in our verdict form proposal. I do think that the way we proposed our verdict form is simpler, it's fewer questions for the jury to answer and easier for them to follow as sort of a matter of logic. So Jazz would propose that the Court adopt Jazz's verdict form. If it doesn't, however, these changes need to be made to the verdict form to account for the fact that the jury is not deciding infringement of the '782 patent.

THE COURT: The jury is not deciding infringement of the '782 patent, that's true. And there's

no question asking them to decide infringement, that's why there is no question asking them to decide infringement for the '782 patent.

But they do have to decide whether Avadel has proven invalidity of the '782 patent and that's included in Questions Number 6, Question Number 7, and Question Number 8. And, thus, that's why the instruction reads that they only have to answer Question 9. If Avadel has -- if they find that both the -- with respect to the '488 patent, that there's infringement and with both the '488 patent and the '782 patent, that they're not invalid.

MR. THOMPSON: Yes, Your Honor --

THE COURT: And it has to be "no" to all of those questions, 2-8.

MR. THOMPSON: The problem, Your Honor, is in the first sentence of that instruction: "Answer Question 9 only if you have found one or more of the asserted claims to be infringed ('yes' to Question 1)," that is inaccurate because one, they do not have to find that the '782 patent is infringed, that has been determined as a matter of law that it is infringed; and, two, that "yes" to Question 1, therefore, is wrong.

This makes it seem like they have to answer "yes" to Question 1, which is only on the '488 patent. So this needs to be modified --

THE COURT: So it should be "and/or," so give me some proposed language to present in that introductory paragraph but we're not changing the orders of the questions.

MR. THOMPSON: Understood, Your Honor. So what I would propose is in the instructions on -- it's on page 2 of the verdict form, but the first page with text after the caption page, is to add what Avadel had proposed to add to the end of the instructions:

"Because Avadel admits infringement of the '782 patent, you, the jury, are not being asked to determine Avadel's infringement for that patent. You are, however, being asked to decide Avadel's invalidity defenses with respect to the '782 patent and damages for Avadel's infringement of the '782 patent."

And then I'm trying to figure out a way to make the logic on page 11 work, I think that it would be...

MS. DAVIS: Avadel has a proposal.

THE COURT: Let me hear Avadel's proposal.

MS. DAVIS: And just briefly, so the record is clear, Avadel would --

(Reporter clarification.)

MS. DAVIS: The proposal made by Jazz just now, Avadel vehemently objects to, but in terms of the proposal for the current verdict form, we would propose:

"Answer Question 8 only if you have found one or more of the asserted claims to be infringed," and then remove the parenthetical that says, "yes to Question 1," the sentence would then go on, "and that such claim is valid."

Does that work?

MR. THOMPSON: That --

THE COURT: That still doesn't deal with the '782 patent, which I get Jazz's point regarding that. So, yeah.

MR. THOMPSON: So I think it would be something like:

"Answer Question 9 if you find, if you have not found -- if you have not answered 'yes' to Question 6-8," which I think were the '782, and, "if you answered 'yes' to Question 1..." I just think it's a little confusing which is why we tried to avoid this in our verdict form, so...

THE COURT: But your verdict form was not balanced.

MR. THOMPSON: Understood, Your Honor. I'm just saying that it does get very confusing for the jury, so...

MR. SILVER: May I try, Your Honor, third time is a charm?

THE COURT: Let's see what you have.

MR. SILVER: Okay. So for -- we could say -- at the outset of Question 9, we could say:

"The jury is not being asked to decide if Claim 24 of the '782 patent is infringed."

And then we could say:

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

MR. THOMPSON: Your Honor, that's -- that would be okay, but only if the Court adds the instruction from Jazz that the '782 patent, they have admitted infringement, because, otherwise, it's very confusing to the jury since they didn't have to decide infringement of the '782 patent.

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

Then continue, Mr. Silver.

MR. SILVER: Like Mr. LoCastro, I hope the court reporter got it, because I don't know if I can say it the same way twice but I'll try.

So we would indicate that Claim 24 of the '782 patent is -- infringement of that is stipulated, and then we would say:

"Answer Question 9 only if there is a claim that is both infringed and not found invalid."

So there's --

MR. THOMPSON: I think that's --

MR. SILVER: And there's one wrinkle there, Your Honor, I'm not sure it's something we need to put to the jury, we can deal with it depending on how the verdict form comes out. But if they were to invalidate any claim on the inventorship basis that we talked about, that would render the entire patent invalid, but I think we could deal with that --

THE COURT: Right.

MR. SILVER: -- with Your Honor post-verdict. I just want to make sure for the record we're not waiving that aspect of our inventorship defense.

THE COURT: Okay.

MR. THOMPSON: I think that's acceptable to Jazz, the proposal relating to the language in Question Number 9.

THE COURT: Okay.

MR. THOMPSON: Thank you.

THE COURT: Thank you.

So the instruction will read:

"The jury is not being asked to decide if Claim 24 of the '782 patent is infringed. Infringement of Claim 24 the '782 patent has been stipulated to by the parties. Answer Question 9 only if there is a claim that is both infringed and not found to be invalid."

All right. So we'll make that change.

All right. That completes the verdict form. Make sure the parties have met and conferred and have the joint -- the copy of the exhibits that are to go back to the jury ready for after -- once the Court gives the jury instructions, for the jury to begin their deliberations.

All right. Anything else before we adjourn?

MS. DAVIS: Nothing, Your Honor.

MR. LoCASTRO: No, Your Honor, thank you.

THE COURT: All right. We're adjourned.

(Whereupon, the following proceeding concluded at 4:55 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.