UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

INTAS PHARMACEUTICALS LTD.,

Petitioner,

V.

ATOSSA THERAPEUTICS, INC.,

Patent Owner.

_____

Case PGR2025-00043
Patent No. 12,071,391
Case IPR2025-00799
Patent No. 11,261,151

_____

Deposition of RON BIHOVSKY, Ph.D.

CONDUCTED VIRTUALLY

Tuesday, January 20, 2026

10:02 a.m.

Job No.: 614362

Pages: 1 - 306

Stenographically Reported By:

Brooklyn E. Schweitzer, RPR, CRR, CA CSR No. 14612

Deposition of RON BIHOVSKY, Ph.D., was conducted virtually.

*** ALL PARTIES ATTENDED REMOTELY. ***

Pursuant to Notice, before Brooklyn E. Schweitzer, Registered Professional Reporter, Certified Realtime Reporter, California CSR No. 14612, and Notary Public in and for the Commonwealth of Pennsylvania.

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A P P E A R A N C E S

ON BEHALF OF PETITIONER:

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ON BEHALF OF THE PATENT OWNER:

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ALSO PRESENT: Ky Shaklin, Technician

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P R O C E E D I N G S

RON BIHOVSKY, Ph.D.,

was called, and having been duly sworn,

testified as follows:

EXAMINATION

BY MR. MILEA:

Q Good morning, Doctor. Thank you for being here today.

Please state your full name for the record.

A First name is Ron, and that is the entirety of it, middle initial H, last name Bihovsky, B-I-H-O-V-S-K-Y.

Q What is your address?

A 804 Primrose, P-R-I-M-R-O-S-E, Lane, Wynnewood, that's going to be W-Y-N-N-E-W-O-O-D, Pennsylvania.

Q Are you currently employed?

A Yes.

Q Where are you employed?

A I'm self-employed. I am the founder and president of Key Synthesis.

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Q What is Key Synthesis?

A Key Synthesis is a combination of -- it's a laboratory where I can do organic chemistry and medicinal chemistry experiments, and in addition to that, I do some consulting, and some of that involves support of patent litigation cases.

And just to elaborate, Key Synthesis I founded approximately 25 years ago.

Q You mentioned organic chemistry and medicinal chemistry. The case that brings us together today, would you say that is organic chemistry or medicinal chemistry or both?

A I haven't thought about that too much, but I would say it is organic chemistry. Certainly most of the issues are organic chemistry. Any that are not would be outside of -- outside of my assignment to evaluate.

Q You understand that you submitted a declaration in an IPR proceeding related to the '151 patent, right?

A I do. Yes.

Q And you also submitted a declaration in a

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PGR proceeding related to the '391 patent, right?
A That's correct.
Q Do you understand this deposition is -- withdrawn.
Do you understand this deposition pertains to both of those proceedings today?
A I understand that.
MR. MILEA: If we could please bring up the first exhibit, which will be IPR Exhibit 1033, and I believe we can paste that in the chat.
(PGR Exhibit 1033 was marked for identification and is attached to the transcript.)
BY MR. MILEA:
Q And, Doctor, I should ask: Do you have any papers with you in the room today?
A Not much.
Q What do you have with you?
A I'll -- a piece of paper where I've written down your name and your firm. I do have copies of the various documents that were supplied to me, but they're not in front of me.
Q Okay. If it's okay with you, what we'll

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do is display the documents on the screen, and you should get a link in the chat. I think there's a link already to this, the first document, and you should be able to click that and be able to scroll around in the documents as you need to.

A And if -- just volunteering. If for some reason there's a huge document and you'd like me to -- if I printed it out and you'd like me to refer to that, if that's ever easier, let me know.

Q Sure. And if those are clean copies and you want, maybe during the next break or something, to get those, I'm totally fine if you work in hard copy and want to look at those, but if you're okay to proceed with the electronic copies, at least for now, let's go ahead and do that.

Is that all right?

A Sure, great.

Q So you should have Exhibit 1033 to the IPR on your screen.

Do you have that?

A I don't see the exhibit number on -- on

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the part of the screen that I'm looking at.

Q Okay. Perhaps we can scroll down.

A Okay. I agree -- I agree that I have 1033.

Q Do you recognize Exhibit 1033?

A Yes.

Q What is it?

A Expert declaration of me.

Q This is the expert declaration you submitted in the IPR proceeding?

A Yes.

Q If you'd please turn to Page 56, using the bottom middle page numbers, and if you use the stamps, it's Page 59 of 95.

A So are you moving it or am I?

Q So the tech is moving it, but there should be a link in the chat where you can -- you can actually click on that link and get the PDF of this and open it separately on your computer. So you can scroll yourself, if you'd like to do that. And, frankly, that might be easier.

A Okay. So tell me how to do that.

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Q So do you see in the Zoom chat, if you click the chat button --

A Where -- where would that be? I just see a bunch of icons.

TECHNICIAN: Counsel, the check -- this is the technician, I'm sorry. The chat button will be at the bottom of the Zoom video. So if you put your mouse down there, you should see a row, and that way you can select chat.

THE WITNESS: Is that the icon that shows a representation of the pen with the line under it?

TECHNICIAN: No. It shows pretty much a top box with three dots.

THE WITNESS: And that's at the bottom of the screen?

TECHNICIAN: Yeah. It should be at the bottom of the Zoom screen.

THE WITNESS: No, I --

TECHNICIAN: And I can -- I can remove this. Let me see if this helps you out.

Now put your -- check your -- put your

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mouse down at the bottom of the Zoom screen, and you should see chat at the bottom there, participants checked. Almost like you were doing the audio settings for the court reporter. You would just be looking for the chat button to the right.

THE WITNESS: Yeah. I've seen that in other Zoom interactions, but I -- I don't see the chat over the three dots anywhere here.

TECHNICIAN: That's fine. I can give you control. So once I share, you'll have control. Let me give you control real quick.

THE WITNESS: What I'm seeing that might be an issue is it says this meeting is being recorded, and there's a box to say okay. Would that change anything?

TECHNICIAN: Yeah. Click -- yeah, click off that. Maybe that's --

THE WITNESS: Okay.

TECHNICIAN: Maybe that's the reason you're not getting --

THE WITNESS: Right now, I'm seeing the

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same thing you're seeing --

TECHNICIAN: Okay.

THE WITNESS: -- the list of files that are available.

TECHNICIAN: Yep. Just click on that. Double-click on that, and then you'll have to save it, and then you'll have to open it.

THE WITNESS: Okay. Double-click where?

TECHNICIAN: Just double-click on the file.

THE WITNESS: There it is. So I'm clicking on the Tab 33?

TECHNICIAN: Yes.

MR. MILEA: Maybe we should go off the record while we sort this out. And, Doctor, perhaps maybe you want to get your paper copy of your declarations.

THE WITNESS: Sure, I can do that. It will take me a minute.

MR. MILEA: That's okay.

(A recess was taken.)

BY MR. MILEA:

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Q Dr. Bihovsky, do you have Exhibit 1033 in front of you on your computer screen?

A Yes, I do.

Q Is that your declaration in the IPR related to the '151 patent?

A Yes, it is.

Q Please turn to Page 56 using the bottom middle page numbers.

A Okay. I'm on 56.

Q Do you also see the Zoom screen?

A If I could make it so I also see the Zoom screen.

Q Okay. Well, let me just ask you. What do you see on Page 56 on your screen?

A I see three lines of text followed by a signature line and date.

Q Is that your signature on Page 56?

A Absolutely.

Q Okay. Let's now look at Exhibit 1034 in the PGR, so that's your declaration related to the '391 patent. If you could please pull that up, Doctor.

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(PGR Exhibit 1034 was marked for identification and is attached to the transcript.)

Q Please turn to Page 46 using the page numbers in the bottom middle.

A Okay.

Q Is your signature on that page?

A I see five lines of text followed by a signature line and the date. The copy that I have I did not sign, but I am certain that this is the version of my declaration that was submitted.

Q Okay. Let's -- I want to make sure we're working from the same document. So why don't you close that document, and we can --

MR. MILEA: Ben, maybe during a break or later, you can send him the final submitted document. We don't need to look at this right now. We can come back to it. But I don't -- I don't want to be working from a different document.

Q So let's just move on for now, if that's okay.

A Okay.

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Q Have you been an expert witness before in a patent litigation or an IPR or PGR?
A Yes.
Q About how many times have you done that?
A I've been deposed approximately 15 times, and I've testified at trial approximately seven times.
Q In those cases, were you on -- withdrawn.
In those cases, were you retained by the patent owner, the patent challenger, or a mix, if you can remember?
A Generally, by the challenger, sometimes by the owner.
Q What would be the split, generally?
A I would say 90 percent by the challenger.
Q Given that, I take it you've sat for several depositions, if not more; is that right?
A Yeah. As I said, I've sat for approximately 15 depositions.
Q 15. Okay. I'm sorry. I missed that.
So I think you know the rules, but I'll just go through it so we're on the same page, if

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that's okay.

A Okay.

Q You understand that I'll be asking you a series of questions today. You'll be doing your best to answer them?

A I understand.

Q If you don't understand a question, will you please let me know?

A I will.

Q And if you don't let me know, I'll assume that you've understood my question. Is that fair?

A Yes.

Q You understand that everything we're saying today is being transcribed by the court reporter, right?

A Yes.

Q So it's important that you give a clear verbal answer to all of my questions, and we'll try not to speak over each other. Is that fair?

A Yes.

Q I will try to take a break every hour. I may lose track of time. So if you do need a

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break, just let me know, and as long as we're not in the middle of a question, we'll try to take one.

Is that okay?

A Yes.

Q Okay. Where did you perform the experiments that you discuss in your declarations in the IPR and PGR?

A I performed them in my laboratory. That is, Key Synthesis.

Q Before you began your experiments, did you have any samples of endoxifen in your laboratory?

A Absolutely not.

Q During the synthesis, did you have any samples of endoxifen during your laboratory -- withdrawn.

During the synthesis, did you have any samples of endoxifen in your laboratory?

A I had no samples of endoxifen -- of endoxifen until I synthesized it. So just to be clear, I received no external samples of endoxifen at any point ever.

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Q Okay. Thank you.

In chemistry, what is a polymorph?

A Well, it's a bit of a misnomer, but I think of that as a layman means many -- well, bodies or what we take as many structures. So I'll get to why it's a bit of a misnomer in a second, but it accrues to the idea that a particular compound, chemistry compound, a particular chemical, can exist in more than one crystalline form, and the misnomer is a compound can form single polymorph and no other polymorph might ever exist. So it really wouldn't -- it really wouldn't be the polymorph because it's a single entity.

But this is the way that we use the term. So, yeah. It -- it means a particular crystalline structure.

Q How is it -- withdrawn.

How does it come to be that the same molecule can take on different crystalline forms?

A Well, a crystalline form occurs because of attractions between the separate individual

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molecules in the crystal, and those attractions between the molecule kind of -- between the molecules pull the whole crystal together, and generally the ones that have the strongest bonding to each other, other ones that would form the crystal, if there were several different geometries which were similar in energy, then one could form -- one polymorph could form or a different polymorph could form.

And sometimes you see that. Sometimes that is observed. Sometimes it's not. Sometimes there's only a single polymorph, and sometimes there are no crystalline structures. We call that amorphous.

Q For a molecule that has several possible polymorphs, what dictates what polymorph that molecule adopts in a given situation?

A The conditions of the crystallization.

Q What do you mean by that?

A Depending on how the compound is crystallized, it could form different polymorphs.

Q Those conditions, do you mean external

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factors?

A Yeah. I'll give you some concrete examples.

Different solvents could but do not necessarily -- different -- different solvents could but not necessarily give different crystals.

Sometimes material is crystallized. I'll use the term "crystallized" and "recrystallized" more or less synonymously, unless I say otherwise.

Sometimes a way to crystallize a material is by dissolving it at a high temperature and then cooling it down where the compound becomes less soluble. So the temperature -- the initial temperature and the final temperature could conceivably cause different polymorphs.

Another way of forming crystals is to dissolve the compound in one solvent and cause it to precipitate by adding another solvent. So that -- that's kind of a variation on the first thing that I said. That depends on the solvent.

In this case, you could have the solvent -- the initial solvent that it's soluble

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in and the other solvent that causes it to precipitate. All those things could but don't necessarily cause different polymorphs to form.

Q You said different solvents and temperature. Did you say anything else, or are those the main two that you discussed?

A Those are the main two that I can think of.

Q Are there any other external conditions you can think of that would affect what polymorph a material adopts?

A As I said, that's -- that's what comes to mind at the moment. That would be the case -- those would be the two factors that generally would cause polymorphism.

Q Would impurities in a mixture affect what polymorph a material adopts?

A Possibly, but that's not usually the case. The impurity -- the crystallization, which is what's used to obtain the crystalline material and to create the particular polymorph that's going to form, crystallization tends to remove the very

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great majority of impurities, and certainly that's the case in the crystallization of endoxifen.

So in this particular case, there aren't any significant amounts of materials. So even if they could change the crystalline form, the polymorph, they would be very unlikely to do so in the case of endoxifen.

Q So it's fair to say if there were trace amount of impurities in the mixture that is being crystallized to form endoxifen, those could possibly affect the polymorphic form of the endoxifen?

A I think that's what I already answered, but just to repeat it, in the case of endoxifen, and in the case of the experiments that I carried out and that others in the references that I have carried out, the endoxifen going into the recrystallization was quite pure, and after the first crystallization, in the case that there are multiple recrystallizations, which is the procedure that I carried out, no -- no major impurities were detected.

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So I -- I don't think it's an issue in this case.

Q Is it possible there were trace impurities that you did not detect in your recrystallization mixture?

A It would be -- there would be very trace amounts, if any. And the evidence to support that is thin-layer chromatography, which I perform on -- at every step of the synthesis and recrystallization, and in many cases, NMR spectroscopy, which generally shows the very high purity -- particularly after the first crystallization.

Q You said generally showed very high purity. Does that mean there were some impurities?

A I think occasionally there were trace impurities by NMR and TLC, particularly, as I recall, before the first recrystallization. But just for example -- we'll get to this later, I'm sure -- the undesired (E)-endoxifen crystallizes out quite readily, and that's actually used, as

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we'll talk about later, to -- as I summarized, to the Z.

But going back to the (E)-endoxifen, which is precipitated, crystallized, that's highly pure. There's -- I don't recall seeing any impurities in that by NMR or TLC.

Q Make sure we're on the same page. In your recrystallization mixture that you used to recreate Liu, Example 7, there's (Z)-endoxifen and there's (E)-endoxifen; is that right?

A Could you repeat the question, please?

Q So you mentioned (E)-endoxifen and (Z)-endoxifen, right?

A Yes.

Q Are you referring to the recrystallization mixture that you used to synthesize the (Z)-endoxifen that you discuss in your declaration?

A No.

Q What are you referring to?

A When I say (E)- and (Z)-endoxifen?

Q Yes.

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A I'm referring to the compounds represented by the structures in many of the references that I have. Particularly in -- in Liu, he shows two structures, and they're also in my report, actually. Maybe that would be where I should look to find them for you.

Q Sure.

A Would that be --

Q Maybe I can just short-cut this.

So you mentioned that the (E)-endoxifen you were working with was highly pure by NMR and TLC. Do you recall that?

A Yes.

Q What (E)-endoxifen are you referring to? What step of your experiment were you referring to?

A I see. Okay. I was answering a different question, then I'll loop back. The structures of (E)- and (Z)-endoxifen are presented in my declarations.

Now, to be sure, I would have to go back -- to be sure which step I'm talking about,

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I'd have to go back to my expert report and find the first time that -- that that precipitated. I think I know where that is, but I don't want to say anything incorrect.

Q Sure. Let's do that. So if you have Exhibit 1033 in front of you, feel free to flip through that, and let me know when you found what you had in mind.

A Okay. Great.

Okay. So in answer to the first question, on Page 45, this is the foundation of the whole thing. At the top of Page 45, there are two structures. Structure 1 is -- the structure with the 1 under it is (Z)-endoxifen, and Structure 2 is (E)-endoxifen.

So the compound of interest -- most interest is Structure 1. The (Z)-endoxifen is the more biologically active of the two.

Q And then going back to my question about which experiment you had in mind when you were referring to the highly pure (E)-endoxifen --

A Yeah.

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Q -- if you need to flip through your declaration and figure that out, please do so.

A Okay. So I constructed a caret, which is a lot easier to follow than the text, and that is on Page 42.

Tell me when you're there.

Q Yes, I'm there.

A Okay. So just overall, what this shows is the purification scheme that was described by Liu. And the -- looking at the top where it says crude endoxifen, just for example, there's a number under 15-27-1. That is my notebook number, the notebook number of a particular sample.

And then following that, the numbers in parentheses are the ratio of the Z to E isomers. And so just to elaborate on that, 15-27-1 is a 48 to 52 mixture in my hands of the Z to E. Then the first operation that's done is recrystallization from acetone, that is to precipitate, and which is 15-33-1P. And that has a ratio of Z to E of 33 to 67.

In other words, that is enriched in the

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(E)-isomer, and so that's the first recrystallization, and that precipitate is -- is quite pure. As I recall, I see no impurities there.

Q When you say you see no impurities there, do you mean major impurities?

A I'd really have to check my NMR and TLC to be sure, but I don't recall seeing any impurities, only a mixture of the signals for the Z to E isomers.

Q Is it possible there were trace impurities in that mixture that would not have come up on the NMR?

A NMR tends to be -- accurate isn't the word -- sensitive to impurities, depending on what they are, to impurities in approximately the 1 percent to 5 percent realm.

So it's -- it is conceivable that there could have been, let's say, 1 percent of some impurity or impurities. I would doubt that that would have any effect on the crystallization. I certainly have no evidence that that occurred.

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Q Are you familiar with the term "limit of detection"?

A I am.

Q What is limit of detection?

A It's the -- it is pretty much what it says it is. Utilizing a particular method of detection, it is the smallest amount that can be detected.

Q If something were present below the limit of detection, then it would not get detected by whatever method you're using to look for things like that; is that fair?

A You know, I always say nothing is completely pure. Back when I was a kid, there used to be Ivory Snow that advertised itself as being 99.999 percent pure, I think it was, a pure number of 9s, adding decimal points. I think they actually made that number up.

But the point is there -- according to their advertisements, there could have been 0.0001 percent of impurity.

So nothing's absolutely pure, but

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chemicals can be extremely pure. And I think, in my experience, trace amounts of impurities are not going to change the crystalline form that one obtains.

Just to amplify on that, what's more commonly seen is that if there's a lot of impurity, sometimes it prevents any crystal from forming, and so the impurities sometimes have to be removed before any further crystallization can occur. But that's actually the purpose of the very first step, the acetone recrystallization at the top of the -- of this scheme.

Q We'll come to that. I do want to talk about every sample of Liu in detail.

Withdrawn.

What is the limit of detection of the NMR method that you used to check for impurities in the substances that you used in your experiments?

A Well, that's difficult to answer. Typically when we do a limit of detection experiment, you have to have the impurity -- you know, a sample of the impurity. You usually have

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to know what it is, and then you have to what's called spike. You have to spike a pure sample of the compound of interest with various amounts, let's say, 1 percent, 2 percent, 3 percent, and see what the limit of detection is.

In this case, I did not have any samples of impurities, and I didn't identify any impurities, but what I can say is that if you take a look at the notebook number in the right-hand lower side above Paragraph 72, it says that the ratio Z to E was 93 to 7.

So the 7 percent represents an impurity. The impurity, I know, is (E)-endoxifen contaminated (Z)-endoxifen so the NMR can certainly detect seven percent impurity.

If you look up two -- basically two samples higher to 15-34-1P, there is, in this case, 5 percent of the (Z)-isomer contaminated (E)-isomer. So NMR can detect 5 percent.

And going to the bottom on the left side, sample 15-35-2P, I have indicated that that is a 100 percent (Z)-isomer.

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So from all this, I certainly can -- I know that I can detect 5 percent of an impurity. And in other cases, I believe I can detect down to 1 percent impurity. So, bottom line, the limit of detection for E and Z is probably about 1 percent.

Q Can you say what the limit of detection would be for other impurities?

A They should be similar because they would be related in structure.

Q The 15-35-2P sample that you just mentioned in the bottom left of the figure on Page 45 of 95 of your declaration, you said that's 100 percent pure?

A Yes.

Q Is it possible there were trace impurities of some substance in that material that you couldn't detect by NMR?

A Well, again, I want to emphasize that nothing in the world is 100 percent pure, but to the sensitivity of the NMR instrument for the particular sample we're talking about, there was no trace of any impurity.

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Q Is it fair to say that the limit of detection for the other impurities other than (E)- and (Z)-endoxifen is also about 1 percent?

A Yeah, that's what I just said. That because there's -- they would be structurally related to (E)- and (Z)-endoxifen, it's reasonable to assume that they would have a similar -- NMR would have a similar sensitivity toward them.

Q Were there other impurities that are not structurally related to (E)- and (Z)-endoxifen in the mixtures that you were working with?

A I have no evidence that there would be. We haven't gone through the entire three steps of the synthesis, but at every stage, I purified the material.

And so there really shouldn't be anything -- there shouldn't be any stray materials in there or really anything else that would be an undetectable impurity. There could be -- there could conceivably be solvents from the last -- residual solvents remaining from whatever the prior step was, but the solvents that I used,

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particularly acetone, isopropyl acetate, Dichloromethane, all have very sharp, well-defined peaks, and if they were there, I would see them.

So the answer -- the answer, then, is no, I don't -- I don't see anything that's unrelated in my NMR spectra or TLC.

Q After a substance adopts a polymorphic form, can it change that polymorphic form?

A It -- it can if one purposefully tries to do so. So we can talk later about the isomerization, which is both in Liu and other references, and which I repeated, and that's a case in which the (E)-endoxifen is converted partially to the (Z)-endoxifen. In fact, approximately a 50/50 mix of the two.

So that's done purposefully, and that's done, if I didn't say so, at refrosting temperature for many hours.

Outside of that, I believe that other substances other than endoxifen have been sometimes recorded to isomerize if they are allowed to set usually at an elevated temperature

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for a long period of time, but there's no evidence that that has occurred with endoxifen.

Q So for at least some substances, it's possible that after you synthesize it and it's sitting there on a shelf, it -- it could change polymorphic form on its own?

A I don't think I've ever seen that in the 25 years -- well, more than that -- that I've worked in this area, but theoretically it could exist. I don't see it in the case of endoxifen.

Q Do you recall -- I'm sorry. Go ahead.

A I'm sorry. Right. The other point I wanted to make is these samples did not sit on a shelf. These samples were stored either in a freezer, which is at minus 20 degrees in my laboratory, or in a refrigerator, which is at 4 degrees. All degrees that I mentioned are Celsius degrees. So they were not stored at -- at room temperature in a hot environment or anything like that.

Q Okay.

A So we had -- it's -- it's unlikely. The

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other evidence I have is that I did store one sample of pure (Z)-endoxifen in the freezer, minus 20 degrees, for one year, and reevaluated it, and there was no change.

Let me amplify: No change in the E to Z ratio, and I'd have to look and see if I -- if I did evaluate the polymorphic structure.

Q The one-year storage and testing that you just mentioned, is that anywhere in your declaration?

A No. It's in my notebook.

Q Okay. Where --

A So --

Q I'm sorry. Go ahead.

A It was -- it was not meant to be a test. It was simply that I stored the material for a year, and then after a year, I was asked to look at it again. So that's -- it was sort of an experiment that I hadn't necessarily planned to do, but since I had the sample, I decided I would look at that stability.

Q Is that in the pages of the lab notebook

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that are appended to your declarations in this case, or is that in a different set of pages of your lab notebook that are not part of your declaration?

A That's on Page 35 of my notebook.

Q Let's -- let's look at that, please.

A Okay. Do you want me to pull that up?

Q Yes, please. If we're looking at Exhibit 1033. And this is Page 94 of 95 using the stamps in the bottom right, I think, if I'm understanding you correctly, Doctor.

A You're looking at the notebook actually, right?

Q Yeah. At the very end of your declaration, there's a notebook page that says 35 in the top right, and if you look at the --

A I -- that was appended. Let me get to that.

Okay. Right. My notebook. There it is.

Okay. I misspoke. I'm looking at Page 35, and there's a -- only half of it is filled out. This goes up to 2024, and when I did

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this further testing, I wrote at the bottom of the page a description of the experiment that I had done with the storage and with stability experiments.

I think I summarized the stability experiments -- I did -- I believe I did in my declaration. So I -- there is a new page 35. The rest of the document, I believe, is up to date, but the copy that's at the bottom here only goes up to, it looks like, February 2024. So there is new information.

Q Do you recall when you did that additional experiment that you just described?

A You know, what I remember the additional text saying was is that it was stored for one year at minus 20 degrees. So that would have been February -- approximately February 2025.

Q And that information is not in the copy of the lab notebook that you appended to your declaration in either the IPR or the PGR; is that fair?

A Yeah. Apparently, it was an earlier copy

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that didn't include that additional experiment.

Q And I think you mentioned that you --

A I --

Q I'm sorry. Go ahead.

A Yeah, I apologize for that omission.

Q And I think you mentioned some stability testing discussed in your declaration. If you can please turn to Paragraph 97 of your IPR declaration. And that's on Page 58 of 95 using the stamps in the bottom right, for the record.

A Okay. Paragraph 97, right?

Q Yes.

A Okay. I'm seeing that as Page 55.

Q 55 using the middle numbers, and 58 using the stamps in the bottom right.

A Okay. For some reason -- I see -- great. I see the stamps. Yeah.

So we're at Paragraph 97. And so what was the question?

Q Actually, I'm sorry. Let's -- I'm on the wrong paragraph. Let's please go instead to Paragraph 94, which is using the bottom middle

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numbers, Page 52, and using the stamp, Page 55.

A Okay.

Q And it goes on to the next page. And I'll give you a moment to read this.

A You said Paragraph 96?

Q 94, please.

A Okay. Go ahead.

Q Do you see in Paragraph 94 you're reporting on some testing you did that spanned ten days?

A Yes.

Q So that's not the testing for one year that you were just discussing, right?

A Well, it -- it kind of is. Let's see what I said.

Let me start by saying that at the top of Page -- three lines down, I state -- you see where I am? I sealed samples of (Z)-endoxifen under nitrogen --

Q This is Page 53?

A Yeah, Page 53, three lines down.

Q Yes, I see that.

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A So I probably can't say that any better than I wrote. I'll just read this. I sealed samples of (Z)-endoxifen under nitrogen in capped vials inside Ziploc plastic bags. I kept one sample of (Z)-endoxifen at 25 degrees centigrade, 60 percent relative humidity for ten days, and another sample at 40 degrees and 75 relative -- percent relative humidity for ten days. Neither sample indicated isomerization of Z to E after ten days.

That's the experiment, and that's what's detailed on page -- the page that I inadvertently didn't send you an update on Page 35 of my notebook.

Now, that -- the experiment I just described that I just read was done one year after that sample was created, and during that time, the sample was stored at minus 20 degrees, and -- so that also showed no isomerization.

Q I see. So what you're saying is for one year you kept a sample at minus 20 degrees centigrade, and then you changed the conditions to

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what you've listed in Paragraph 94 of your declaration, and after ten days of those new conditions, you checked the -- whether there had been isomerization of (Z)-endoxifen to (E)-endoxifen?

A Yeah. I -- I -- I kind of differ with the word "changed." Perhaps I'll put it this way.

The samples that I created, all the samples that I created in this work, were stored, and they were stored at minus 20 degrees, which I anticipated -- under which conditions I anticipated they would be stable, and testing showed that they were, that the -- for example, pure (Z)-endoxifen still remained pure (Z)-endoxifen at minus 20.

I didn't even mention that here because it's understood that if there is no (Z)-isomer after storing at 25 degrees and 40 degrees, at the relative humidities stated in this paragraph, that under the colder conditions, without humidity, that they would also be stable.

It's -- that's -- that's the way these

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things work. Organic compounds, I would say in all cases, certainly all relevant cases, are more stable at the colder the temperature.

Q Just so I understand the timeline of events here, you synthesized the samples, and then you stored them at minus 20 degrees Celsius for a year?

A Yes. And, in fact, they're still stored. So it's been almost two years now.

Q Okay. And then after that one year, you took some portion of those samples, and you put them into 25 degrees Celsius and 60 percent relative humidity condition for ten days?

A The only correction I would make is, as it says, one sample of (Z)-endoxifen was subjected to these 25 degrees and 40 degrees at the state of relative humidity, just one sample.

Q I see.

A And that was pure (Z)-endoxifen.

Q So after one -- one year at negative 20, you took one sample and put it at 25 degrees Celsius and 60 percent relative humidity for ten

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days, and then another sample, and put that sample at 40 degrees Celsius and 75 percent relative humidity for ten days; is that right?

A Yes, with one clarification. When I say one sample and another sample, it's the same sample as (Z)-endoxifen. It's just -- what I'm saying is I subjected -- maybe it's not written as clearly as I could have, but I did two experiments with the same sample, and -- and so one was 25 degrees, 60 percent, and the other on the same -- on a batch of the same sample was maintained at 40 degrees and 75 percent relative humidity, both for ten days.

Q Those were consecutive experiments?

A They were concurrent -- I'd have to check my notebook. Either they were -- they were two different vials of the same sample, and I think they were done simultaneously. It wouldn't -- it would be a waste of time to do it consecutively, but I would have the dates on the notebook page.

Q Okay. And just to be clear, that information is not in the notebook that's attached

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to your declaration, right?

A It's -- the page that I submitted inadvertently doesn't have that information because it was obtained a year later, but I do have that in the notebook itself, and -- so it -- it's definitely there.

Q Okay. I want to circle back to something we were discussing towards the beginning of the deposition, and that is the things that can dictate what form -- what polymorphic form a molecule takes.

Is that okay?

A Yeah.

Q And earlier we talked about solvents can potentially dictate what polymorphic form a molecule takes and temperature could possibly dictate what polymorphic form a molecule takes.

Is that right?

A Yes.

Q What -- withdrawn.

And can the amount of stirring of a mixture during the crystallization process dictate

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what polymorphic form a molecule takes?

A In principle, it might. I've never -- in my hands have never seen that occur, and it does not seem to occur in the case of endoxifen because on Song and Liu, the sub samples were not stirred during crystallization, and some samples were.

In particular, I remember that there was one recrystallization that was done with stirring at a reduced temperature. I think it was at approximately 4 degrees.

I remember it particularly because the only way I could easily do that in my laboratory was -- was to put a magnetic stirrer inside my refrigerator, which is something that I would not normally do. So I remember it distinctly.

Q Okay.

A I had to run an extension cord into the -- into the refrigerator.

Q And I do want to talk specifically about each experiment you performed, but just more generally, I want to talk about the things that can affect polymorphs -- withdrawn.

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So it sounds like it is possible that the amount of stirring in some situations could affect a polymorphic form that a molecule takes on. Is that fair?

A Hypothetically, maybe possibly, but as I said, I've never seen it on any compound that I've dealt with, and I've certainly never seen it with endoxifen.

Q What is a disappearing polymorph?

A What is it?

Q Yes.

A The formation of a polymorph is generally, as I said, governed by the attractions between the molecules that make up the crystal, and the ones that have -- the one that has the lowest energy is generally the one that crystallizes out.

It's been noted particularly in the pharmaceutical industry that sometimes a polymorph -- let's call it polymorph A, arbitrarily. Polymorph A is formed, and it's formed over and over again, and then all of a sudden, somehow, a different polymorph B is formed

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in the laboratory. Could be under a different solvent, different temperature. Who knows.

And now there's B in the laboratory. Particularly if it's a laboratory that's a production laboratory where there's a lot of large amounts of material. Tiny amounts of B could be in the air or on the laboratory equipment, and then every time that -- or predominantly when you try to recrystallize and get A by the same conditions, now all of a sudden you end up with B. So A is referred to as a disappearing polymorph because it is difficult or impossible to create again.

But I just want to clarify: I have not seen that, and the authors of the -- the inventors of the '334 patent did not report that. It's always Form 1.

Q You said the '334 patent. You understand we're talking about the '151 and '391 patents in this proceeding?

A I do. The disclosure in all three of those patents, I believe, and which contains the

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experimental data and conditions, I believe the disclosure in all three is -- is essentially the same.

Q Do you agree that Liu does not disclose what polymorphic form of (Z)-endoxifen its experiments produced?

A To my knowledge, Liu does not discuss polymorphs. That's why I reproduced Liu so that I could see as close as possible to Liu's conditions what the polymorph would be.

And so I think the legal term is implicit. Since I had obtained the same material, the same (Z)-endoxifen as Liu, the crystalline form, the polymorph in Liu is implicit -- implicitly the same as what I got, which is Form 1.

Q Do you recall in Liu there's a discussion of (Z)-endoxifen with an isometric purity of 99 percent?

A I -- I guess I'd have to review and see. There are -- there are a lot of numbers in there.

Q Sure. We can look at Liu. That is IPR Exhibit 1003.

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A I'm sorry. Not -- I'm sorry to interrupt you, but --

Q Yeah.

A -- there is an error in -- in my expert report, and one -- I just want to -- while I'm thinking of it, I want to correct.

Q Okay.

A In one case, I reversed the NMR assignments for Z and E. I'll see if I can find it.

Actually, I have to search for it. Let's see. It's in Paragraph 46. Six lines from the bottom in Paragraph 46. As I say, I utilized NMR to determine the ratios of (E)- to (Z)-endoxifen through integration of the NMR signals at 3.85 and 4.01 ppm, respectively.

That -- that sentence should correctly read, instead of E to Z, it should say Z to E.

Q Okay. Are there any other errors in your declaration you'd like to correct?

A There may be an error referring to one of the references. I think the -- I think the author

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was Richardson.

Yeah. Paragraph 96.

Q Okay.

A I'm not sure it's an error. The -- in 96, the first mention of Richardson is correct. Richardson has numerous purification techniques. But there should be another reference which -- which I believe is in the collection of documents that -- that we both have, and crystallization -- the crystallization reference, additional reference, and perhaps a better one, is Wieckhusen. That's W-I-E-C-K-H-U-S-E-N.

Q Thank you.

Why don't we take a ten-minute break. It's been over an hour.

A Okay.

Q And then when I come back, I'd like to look at Exhibit 1003, which is the Liu reference in the IPR.

A Okay. I'll -- I'll get that pulled up.

MR. MILEA: Okay. Let's -- let's come back at 11:25 Eastern.

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(A recess was taken.)

(IPR Exhibit 1003 was marked for identification and is attached to the transcript.)

BY MR. MILEA:

Q Welcome back, Doctor.

A Thank you.

Q Before the break, we were starting to talk about the Liu reference.

Do you have that in front of you?

A I'll get it in front of me. Let's see.

Q And for the record, that is Exhibit 1003, 1-0-0-3, in the IPR.

A I've got it under a different number. I'll have to find it.

Q In PGR, it is 1004, if that's helpful.

A The publication ending 651, right?

Q Yes.

A Okay. Got it.

Q Is the copy of Liu that you have stamped in the bottom right corner of every page?

A Yes, it is.

Q Okay. What is it -- what does that stamp

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say?

A Mine is recorded Exhibit 1004, Page such-and-such out of 27, PGR2023-00043.

Q Okay. Just for the record, I think you're working from a copy of Liu that was submitted in a prior PGR of the '334 patent. I think that's okay.

A Okay.

Q But as long as we're looking at the document on the top that says WO 2017/070651.

Is that what you have?

A Can you repeat that? That's WO 2027/070651, right?

Q Yes.

A Yes.

Q And the first numbers are 2017. I think you might have said 2027, or maybe I misheard.

Is that right?

A 2017.

Q Okay. Great. I just want to make sure we have the same document.

A Yes.

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Q So please turn in Liu to Paragraph 76. And I think the stamps should be the same, but I'm looking at Page 19 of 27.

A Yes.

Q Is -- do you see a description of Example 7 of Liu on your screen?

A Yes.

Q And towards the bottom, right before the NMR results -- or, excuse me, right before the NMR specifications, do you see a sentence that begins, The solid was dried?

A Yes.

Q And at the end of that sentence, it refers to an isometric [sic] purity of 99 percent by HPLC analysis.

Do you see that?

A I think you meant to say isomeric.

Q Oh, isomeric. I'm sorry. Yes. Thank you.

A Yes, I see that.

Q What is HPLC analysis?

A Oh, HPLC, obviously, is an abbreviation,

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and it stands for either high-pressure liquid chromatography or high-performance liquid chromatography.

Q Okay. And what this sentence is saying is that Liu is reporting that it produced 99 percent pure (Z)-endoxifen as tested by HPLC analysis?

A Yes.

Q Is that right?

A I believe that's what he's saying.

Q Can you tell from Liu what polymorphic form that 99 percent (Z)-endoxifen reference takes?

A Liu does not describe polymorphic form, which is why I repeated Liu's experiments and then submitted samples for x-ray diffraction analysis, XRPD, in order to determine whether the form was that which is described as Form 1.

Q Is that because you can't tell from -- withdrawn.

Is that because HPLC analysis is not able to discern what polymorphic form a particular material has taken on?

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A That's correct. HPLC does not distinguish polymorphs.

Q Is NMR different than HPLC?

A Totally.

Q Can NMR report -- withdrawn.

Can NMR analysis discern what polymorphic form a particular material has taken on?

A Sometimes, but not the experiment that -- the typical experiment which is being reported here, which is the NMR under conditions after the -- inside the parentheses, after the word NMR.

Q Okay. So it's fair to say that the only way to know whether the material referenced in Paragraph 76 of Liu is Form 1 or some other form is to perform an XRPD analysis?

A I would basically agree with you. Hypothetically, the other way that that could have been done -- Liu could have done that. Liu could have taken this material or another material that was predominantly (Z)-endoxifen and submitted it for XRPD analysis, or -- or other analyses that would indicate a polymorphic form, and Liu may

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have done that, but Liu does not disclose that in this patent application.

Q Without that additional XRPD analysis, it's fair to say that you just can't know what form the 99 percent (Z)-endoxifen referenced in Liu Paragraph 76 has taken on?

A That's partially true. There are other methods for determining polymorphic form, but XRPD is, in my opinion, the less common that's used.

Q And that's what you asked Dr. Miller to do here, right?

A Right. Just to be clear, I submitted several of my samples to H and M, Dr. Miller at H and M, and -- and requested that he do XRPD analysis.

Q And those are the results that tell you what form of (Z)-endoxifen you obtained, right?

A Yes. There are -- are other analyses that I could have asked him to do or that could be done in other laboratories, but those are the results I would say that I relied on. That is, XRPD is what I relied upon to compare the results of XRPD of my

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sample with those reported by Atossa.

Q And without those results, you don't know what form of (Z)-endoxifen you obtained, right?

A Well, again, with the caveat that there are other ways of distinguishing polymorphs besides XRPD, but that's what I used, and that is probably the most common method.

Q And so without the XRPD results or the other types of results that you could have obtained, is it fair to say that you could not tell what form of (Z)-endoxifen you obtained?

A I -- I think that's fair.

Q Okay. Let's talk about scaling of experiments, if that's okay.

A Okay.

Q Is it fair to say that chemical reactions can be run at different scales?

A Yes, certainly.

Q Are there names for the different scales? I think Liu maybe refers to commercial scale, or maybe you do. But are there names for different size reactions?

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A Well, the best description would be to say that it was done on a certain number of grams of material. You know, a reaction was done on 10 milligrams or 10 grams or 10 kilograms.

There are sort of informal designations, but there's no firm -- you know, there's no exact quantitative description. A small scale meaning, I don't know, from a few milligrams to several grams would be -- it'd be referred to as experimental scale or small scale, then there's large scale and commercial scale.

If it involves -- if a reaction involves, let's say, tons of material, it certainly would be considered commercial scale, but again, there's no bright line that defines where one category starts and the other ends.

Q Would you consider the reactions described in Liu to be commercial scale?

A I'm not sure. I would certainly call them large scale. I can see that on Example 7, for instance, just looking at the endoxifen, there's slightly more than 5 kilograms endoxifen, and the

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amount of acetone is 50 liters, which involves large-scale equipment.

I'm not sure I would call it commercial scale because literally commercial would mean obtaining enough material that you could sell it, ultimately. And the amount that is ultimately obtained might not be enough for that depending on what the dose is.

So it's -- I would say -- certainly call it large scale. I think I'll just call this -- wording it commercial scale, I guess I would say maybe you could call it that, maybe not.

Q Okay. And I just want to make sure we're using the same vocabulary and that I'm using the right vocabulary when I talk about these things, so that's why I'm asking. Withdrawn.

So if I call Liu a large-scale reaction, is that okay with you?

A Yeah. Yeah. Yeah, or you could talk about the number of grams utilized or the volume of solvent.

Q Okay. What scale would you call the

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reactions that you ran in your lab?

A Well, I prefer to say quantitatively, for example, that I worked on a scale originally -- in -- in the first step, a scale that was at 1/1000th the scale of Liu, just for -- to get some preliminary results.

The reason is that it's my practice to -- unless I'm really sure that a reaction is going to go well, it's my practice to work on a small scale and -- and one size, verify that the parameters and the reaction work, but would increase the scale.

I actually had to do the first step, I believe, preliminarily four times until I felt comfortable with increasing the scale, and then I did it at about approximately 1 percent the scale of Liu.

Q So is it -- withdrawn.

So is it fair to say that your recreation -- withdrawn.

Is it fair to say that your attempts to recreate Liu involved some trial-and-error

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experiments?

A I would rather call it optimization. So the first time that I did -- that I repeated the first step in Liu, it appeared to me that the reaction didn't go to completion, but nonetheless, I did obtain the product, but it was only in the 13 percent yield. So I tried to increase that, and I succeeded in doing that.

Q And so that first experiment where you got only a 13 percent yield, was that following Liu as written except for the fact that you scaled it down to 1/1000th?

A I -- I believe that is correct. The only -- there may have been some slight differences in time. I think Liu runs the reaction for 16 hours, which is a bit inconvenient, so I think I did it for 22 hours. It wouldn't make any material difference.

But the other thing is that, as I said, I had a lot of starting material at the end of the 22 hours. So I think it -- we can look at the notebook, but I think in that case, I increased

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the time and let it stir for another 20 hours or so.

Oh, and the other -- the other difference was -- so at the end of the reaction, I could see what appeared to be the product, but mostly starting material. And so to verify that I had the product, I performed column chromatography to isolate the product. Liu did not do column chromatography after that first step.

And that -- that was necessary that I do chromatography so that I could get the pure compound out that I thought was the product, and I isolated it, again, by column chromatography, I ran NMR on it, and the NMR matched Liu's NMR. So everything was fine, but the yield was too low.

Q I see. So without adding the column chromatography step to Liu, you had product that was too low of yield; is that right?

A Yeah. And to put it a different way, I followed the progress of all reactions and monitored the progress of all reactions that I do, almost all reactions that I do. I monitored by

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TLC, that's thin-layer chromatography, which indicated that I had much starting material and some of the presumed product, which NMR testing after isolation showed was, in fact, the product.

So, in other words, the reaction appeared not to go to completion, which is what we'd prefer, that a reaction go to completion.

Q In your experiments, what was the consequence of having a product that was too low of yield?

A It would be okay to proceed with that material, but it's very wasteful because if the yield was 13 percent, you're throwing away something like 87 percent of the starting material, and it would -- in the end, there wouldn't be the desired amount of endoxifen at the end of the synthesis.

So it's -- it's preferable and good laboratory practice to try to determine why the reaction's not going to completion and get it to go to completion or mostly to completion before stopping the reaction.

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Q Had you proceeded with that low-yield material all the way through Liu's Example 7, you're saying that you would have gotten a lower quantity or a lower purity material than you wanted?

A A lower quantity. The purity would have been the same or better because in that reaction, in the first preliminary reaction, I purified it. I believe NMR showed it was completely pure. Certainly it was highly pure.

And -- and so the -- the quantity would have been -- of endoxifen in the end would have been less, but the quality would have been the same or better in my hands.

Q If you would have followed Liu as written and not added the column chromatography step and proceeded to the next example using whatever material you wound up with at the end of Example 2, what would have been the consequence of that?

A Well, I guess that would require speculation. So Liu basically, as I understand it, precipitated his product out in the first

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step, as I recall, because it's not -- actually, we could go up and -- and look at Example 2 and see exactly so I don't misstate.

Q Sure, let's do that.

A Let's see. Okay. That is --

Q It's Paragraphs 62 through 64 --

A Yeah.

Q -- of Exhibit 1003.

A So I'm looking at the end -- you know, maybe you can see it. But I may have misstated it. I thought that in Paragraph 63, that the crude material was washed with methyl t-butyl ether, but I don't see that.

Q It is -- I do see that.

A Oh, I see it. Yeah. Okay.

I was looking for the abbreviation, MTBE. Okay. So it's about five or six lines from the bottom, washed with -- so that is probably -- I can infer from this that the solid in that sentence was -- which was the product was not soluble in methyl t-butyl ether, so that was a step in purifying it, and I don't recall doing

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that. I think I simply -- in my first preliminary experiment at this stage I did chromatography.

So I know that my material was pure by NMR. I don't know how pure that Liu's material at the end of Paragraph 63 was.

Does that answer your question?

Q Partially. Let me -- let me try this. Withdrawn.

Is column chromatography like you used a better purification method than what Liu did?

A It's more time-consuming, but generally it will give purer product.

Q I see. So the column chromatography step that you added to Liu would result in more pure product than -- withdrawn.

So the column chromatography step that you added to Liu would -- you would expect would result in pure product than the washing step that Liu performed; is that fair?

A That would be my expectation. I don't know for sure, but I guess would want to point out that, again, the reason that I did chromatography

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was to isolate the product from the reaction and prove that it was the desired product, because until I did -- by NMR, because before I did that, all I knew was that there was a spot on the thin-layer chromatography plate, TLC, that corresponded to starting material, and a new spot which I only could assume was the product. The column chromatography followed by NMR proved that it was, in fact, the desired product.

Q And without that additional chromatography step, had you used the product that you got in the next step, which is Example 3, what would have happened?

A In other words, if I had taken a material that was only 13 percent pure and used that in the next step?

Q Right. Is the 13 percent pure material what you had before you used column chromatography?

A Approximately 13 percent, depending on the efficiency of the chromatography and what other impurities, if any, would have been present.

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Q Okay. So you -- if you had taken that approximately 13 percent material and not used column chromatography, but instead went on to Example 3 of Liu, what would have happened?

A I haven't thought about that, and it would be kind of speculation.

In Liu's Step 3, Liu does column chromatography. So I'm speculating, but I probably would have gotten some of the desired product, but you wouldn't know until you try it.

But I want to point out that that would be -- that's not standard laboratory practice or good laboratory practice. Ideally, one would want to purify the crude product after every step and get pure product, because if you don't do that, you just end up accumulating more and more impurities. So it's best to purify after every step.

Q I see. So the -- the chromatography step that you added in Example 2 to Liu, that took out impurities that would have otherwise been in the material that you would have then used in the

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later examples of Liu?

A I think that's more or less correct. Again, the purpose in my first preliminary experiment was to isolate the apparent product and prove that it was the product. Then I went on with further experiments to basically vary the temperature at which the reaction was performed.

Just to give a little explanation, when a reaction doesn't go to completion, a POSA would know that usually either it wasn't allowed to run for a long enough time or the temperature -- temperature was too low. I suspect that the temperature was too low, for reasons I could explain, and so I increased the temperature, and the yield increased significantly.

I'm not sure --

Q I -- sorry. Go ahead.

A -- if that's answering the question. The idea was that originally chromatography was done to verify the identity of the product, and then subsequently, when I had conditions that were working well on a small scale in preliminary

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experiments, then I went to this larger scale reaction, which was done at about 1 percent the scale of Liu, and that's what I proceeded with. That's -- that's the source of ultimately the endoxifen that I synthesized.

Q And that reaction -- so after -- withdrawn.

I think you said you -- you tried Liu's Example 2 four times before you then proceeded with the experiment that generated the material that you used for the rest of your recreation of Liu; is that right?

A More or less. I'd have to check my notebook. I assume we used the material from my last synthesis following Liu's Example 2 with the modifications.

I certainly used that predominantly to carry forward ultimately to endoxifen. I'd have to check my notebook. I may have used -- I may have added that to the material that I obtained from the four preliminary experiments. It would be my nature to not throw away material that I had

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synthesized, but I'd have to check to be sure.

Q And the last time you performed Liu Example 2, which is at least some of the material that you carried forward to the next part of Liu, you also performed the column chromatography step; is that right?

A Yeah.

Q Would that column chromatography step have removed impurities from the material you generated in Example 2?

A The material -- I'm almost certain I verified that that material was tested by NMR, and I believe it showed that -- that the material was -- was very pure. And also yield was -- had increased.

Q That NMR testing was done after you performed the column chromatography?

A Yes, absolutely.

Q And is it fair to say that as a result of that column chromatography, impurities that were present in the material you synthesized in Example 2 were removed?

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A I think what you're asking is after I did chromatography on my larger scale repetition of Liu's Step 2, I think you're asking again if that material had low impurity.

Is that basically the question?

Q Let me re-ask it.

So you did column chromatography on the material you generated in your larger scale version of Example 2, right?

A Yes. Correct.

Q After you did the column chromatography, were there fewer impurities as compared to before you did the column chromatography?

A I would have assessed that by column chromatography. And, again, I could look at my notebook, but my recollection is that it certainly was purer after column chromatography, which is what one would expect. That's by TLC. And NMR also showed high purity.

Q And the implication of it being purer after the column chromatography is that some impurities were removed by the column

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chromatography?

A Yes. That's the whole idea of chromatography. And, furthermore, if the -- if the yield of the reaction, of any reaction, is less than 100 percent of theoretical, that means that -- after chromatography, that means that some undesired materials were removed.

Q And you think that was the case in your larger scale version of Example 2, right?

A Yes. I believe I obtained a 46 percent yield on that reaction, so there was another approximately 54 percent of either starting material or side products, or material that -- you know, it's possible some material, a tiny amount of material was also retained on the column, but those would be the approximate numbers.

In other words, it was -- it was -- the column chromatography was -- was effective in removing some of the impurities.

Q Absent the column chromatography step, those impurities would have been in the material that you used in Liu's Example 3, right?

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A Yes. Those -- those impurities or starting materials would have been present if I had not performed chromatography, but on -- Liu claims to have obtained -- in the paragraph you're looking at, Liu claims to have obtained 85 percent of the same materials, and Liu says that HPLC showed that it was 90 percent pure -- 90- -- sorry -- 97 percent pure.

So even though Liu and I purified by different methods, slightly different methods, and Liu did not do chromatography, somehow he got 87 percent yield and 97 percent pure material.

So it's an important point. Therefore, the material going into Liu's Example 3 was highly pure, as performed by Liu, and also highly pure as performed by me.

Q Is it possible that the impurities in Liu's material and the impurities in your material were different?

A It's possible, but you're really talking about comparing a 3 percent impurity in Liu's and I don't -- I don't think there were any detectible

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impurities in mine after chromatography.

So I would say between -- Liu and I are pretty much going forward into Step 3 with the same quality of material.

Q But there are some differences in the quality of your material and the quality of Liu's material that you used for Example 3; is that fair?

A No, I don't see any evidence to support that.

Q What's the purity of the material you had going into Example 3?

A I'd have to look at the NMR, which I don't readily have. It's in my lab. But I don't recall seeing any impurities in -- in my sample of product of Liu's Example 3 in my hands.

Q I mean, Liu had 3 percent impurities; is that right?

A Liu used HPLC to determine that he had -- well, 97 percent purity, which infers 3 percent of other peaks, by HPLC. I did not perform HPLC at this stage.

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Q Those other peaks would be considered impurities; is that fair?

A Yeah.

Q Okay. Let's go back to scale, which we were talking about before we moved off to impurities.

Withdrawn.

In general, is it easier to run an experiment at a smaller scale rather than a larger scale?

A Well, sometimes I've run some reactions at pretty large scale, and -- you know, a lot of chemistry is kind of like cooking. You know, if you -- if you're trying to make -- I actually did this once. I make a -- something out of spaghetti, and I usually do it with one pound or half a pound of spaghetti at home, and it's pretty easy.

And then one time, just to prove that I could do it, I started with 15 pounds of dry spaghetti, which gives about 45 to 50 pounds of cooked spaghetti, plus 100 to 200 pounds of

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boiling water. And when I do it on a one-pound scale, you just pour it into a sieve -- I'm sure you've cooked spaghetti -- and it's pretty straightforward.

When you're doing it on 200 or more pounds of -- of boiling water, it's kind of difficult to pour that into a strainer. So it -- you know, it's the same thing with chemistry. You have to have -- you have to have special equipment to -- to work on -- to work with, you know, multiple kilograms.

So, yes, it's difficult to do a reaction on -- on a large scale. You need special equipment.

On the other hand, I've done a reaction recently where the yield I've replicated for, actually, another patent litigation, replicated a procedure and was told to do it on scale, and the yield in the literature was 6 milligrams. So -- which then had to be characterized. So it's kind of difficult to get 6 milligrams out of a flask, but I did it, but it's difficult.

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So there's -- there's a spot in the middle of doing reactions on, I don't know, maybe 100 milligrams to a gram that -- that is probably the easiest to do.

Q There are challenges associated with reactions that are large, and perhaps different challenges associated with reactions that are very small; is that fair to say?

A That's a concise way of stating my little story about spaghetti. There we go.

Q One of the challenges is -- is physically adding and -- withdrawn.

It sounds like one of the challenges is physically adding the material on a large-scale reaction. Are there other challenges with a large-scale reaction?

A Addition isn't that bad, in my experience. I guess two of the issues that come to mind for a reaction that would be carried out on many liters of -- using many liters of solvent, one -- one issue is that it takes longer for the reaction to heat up after -- if the reaction's being conducted

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at a high temperature, at an elevated temperature, and it also takes much longer for it to cool down.

And I want to come back to that. Make sure I don't forget.

And the second -- the second issue is stirring. You have to have special stirring equipment when you get to a larger scale. For small scale, we usually are able to use what's called a magnetic stirrer. It -- there's a -- there's a motor underneath with a magnet, and then there's a stir rod that's magnetic, so you print it out -- it's a magnetic round, and it's pretty easy to set up.

Alternatively, if you're doing it on a large scale, you have to use mechanical stirring. That's a motor with some sort of a paddle or something on it. It's not -- it's not a big deal, but it does take longer to set up and -- and remove. Going --

Q When -- sorry.

A I'm sorry. Let me just continue.

Going back to the temperature control

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issue, so Liu did his reaction at -- at 50 degrees and then allowed -- as I understand it, allowed the reaction to cool down for a period of time.

While it was -- while the reaction was cooling down, the reaction was probably still proceeding because it didn't cool down to room temperature immediately. It occurred after several hours.

That's probably why I had to let the reaction go for a longer period of time or raise the temperature to reaction, because my reaction temperature was more easily controlled, the cooling. I would do the cooling quite quickly, whereas Liu could not, on a large scale.

Q And does the fact that you could do the cooling quite quickly as compared to Liu affect the outcome of your experiments?

A Yeah. I believe that's why -- what I -- in my first preliminary experiment, Liu's Example 2, I believe that's why my reaction only gave a 13 percent yield, whereas his gave, I believe, an 85 percent yield. It would be at

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least one of the reasons.

Q So the difference in scale between Liu's experiment and your experiment is one of the reasons why you had to make various changes to your experiments as compared to what Liu did?

A Yeah. The various changes are basically -- the most important change was elevating the temperature of the reaction, and I may have utilized a longer time than Liu.

Because -- again, because Liu's reaction was probably still occurring after he removed the heat source.

Q Is it -- while we're on the subject of temperature, is it easier to maintain a constant temperature across a mixture when it's on a smaller scale as opposed to on a larger scale?

A Well, that -- that's a good point. During -- that's why stirring is very important. If you -- if you stir rapidly on a large scale, it shouldn't be a problem. If -- if -- to take the opposite constraint, if you didn't stir a reaction at all, then the temperature on the walls of the

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flask, the temperature closest -- the reaction closest to the walls of the flask would probably be higher than in the center of the reaction, with an exception.

If the reaction is refluxing, which is a fancy word for boiling, then it probably would be more controlled. But, again, it would be best practice always to stir.

And you can see at the top of Paragraph 62 in Liu, he says, stirred well. So, you know, what I said is theoretically true, but it has to have applicability with respect to Liu's Step 2 -- Example 2, I mean.

Q Is there a difference between refluxing and boiling, or are they just two ways to say the same thing?

A They're the same thing.

Q It sounds like if something is refluxing as opposed to simply just being below the boiling point and hot, there could be a difference in temperature consistency across the mixture?

A I'm sorry. Say that again.

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Q Sorry. Earlier you said that if something is refluxing, then the temperature might be more controlled than if it was not refluxing?

A Yeah. That's kind of a -- actually, I want to go back and modify slightly my definition of boiling and refluxing.

Boiling, you know, is -- could mean in the kitchen, if you have a pot of water and put it on a burner until that is rapidly boiling. Refluxing, strictly speaking, means that there was a -- what's called a column, which is cooled, above the reaction flask -- or whatever -- that is boiling, and the column -- the cooled column condenses the vapor and sends it back into the mixture.

That's why -- that's what the "re" of refluxing means. So there -- in the laboratory, in pretty much all cases, we would use that condenser that sends the solvent back in to the reaction mixture.

So refluxing and boiling are essentially the same thing, but good laboratory practice would

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be to -- to reflux with a condenser above it rather than just below.

Q Is one way to summarize the differences between refluxing and boiling is refluxing is a closed system and boiling may or may not be a closed system?

A Yeah. I hesitate to use the word "closed" because it implies that it's a stopper or something, and in which case it would build up pressure.

Without going into details -- we could, if you want to -- but there are ways to have the system -- to allow the system not to build up the pressure, which in a totally sealed system could be dangerous, but still not allow air or water vapor into it, if that makes sense.

We would usually call that refluxing under an atmosphere of nitrogen, for example.

Q Okay. And so when you did your experiments described in your declarations and you specified that something was refluxing, you followed the procedure you outlined in which

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there's a column that's catching the vapor and cooling it down and putting it back into the liquid?

A Yeah, and that column is called a condenser.

Q Okay. And when something is boiling, you would understand that to mean that there's no condenser and the vapor is just escaping off into the atmosphere or the container?

A Yeah, it could mean that. And generally we would use the word "reflux," and generally we wouldn't -- unless it's for a very short period, we would not just boil the solvent to reaction. We would reflux it, generally.

Q Okay. Something is hot as opposed to refluxing -- well, withdrawn.

Do you understand the word "hot" to mean something different than refluxing?

A Yes.

Q What are the consequences of using a hot mixture as opposed to a refluxing mixture? Would that affect some aspect of the experiment or the

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results?

A Yes.

Q In what ways?

A Generally what matters in a reaction in terms of the temperature is the internal temperature of the reaction. So the maximum temperature that you can get in a reaction, unless it is conducted under pressure, which none of these were, the maximum temperature would be the boiling point, which we also call the reflux temperature of the solvent.

So let's just say that the boiling point of the solvent is 80 degrees. If you immerse the reaction vessel in a temperature bath that's at 80 degrees, the reaction won't quite get -- the internal temperature of the reaction won't quite get to 80 degrees. It would probably be, let's say, 3 or 5 degrees -- very roughly, 3 or 5 degrees less than 80. In other words, 75, 77.

And that small change in temperature would make a small change in the rate of the reaction.

Q Did you say the rate of reaction?

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A Yes.

Q What is the -- withdrawn.

What are the consequences of changing the rate of a reaction?

A Generally, the higher the temperature, the slower the rate. And if the rate is slower, it will take longer for the reaction to go to completion.

There's a caveat that it would be -- from what I just said, you'd think that it would be beneficial to heat a reaction to the highest possible temperature that you could. But, again, it's just like cooking. If you're baking a cake at an oven temperature of 300 degrees and it's not -- it's not quickly coming to the right consistency, you might say, well, let's try to turn up the oven temperature to 500 degrees, and of course you get charcoal.

So there's kind of a happy medium between increasing the rate and destroying the product.

Q In your answer, you said the higher the temperature, the slower the rate. Did you mean

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the lower the temperature, the slower the rate?

A That's what I meant. I apologize if I misstated.

Q Okay. I thought I -- I thought maybe I had a fundamental misunderstanding of chemistry. Withdrawn.

What is a consequence of the reaction rate being slower? Could that affect the final product, the impurities, any other aspects of it?

A You said rate slower, correct?

Q Correct.

A It would take longer to complete the reaction. The -- in fact, the reaction might not even go to completion in -- after a long period of time.

If it -- if it did proceed, then the rate -- I'm sorry -- the yield would be lower after the same amount of time. And that's what I saw in -- in my first preliminary experiment, repeating Liu's Example 2. That's -- I surmised that that's why I got only a 13 percent yield.

Q Would the impurity profile be different in

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a lower temperature reaction as opposed to the same reaction done at a higher temperature?

A It's important to distinguish between impurities and starting material. So there -- if the reaction has not gone to completion, if the reaction rate is slow, then, by definition, there will be starting material in there, which is not desirable.

Besides starting materials, the other impurities, not starting material, could become more of an issue at higher temperatures. So the -- the temperature that's chosen is a compromise between obtaining a relatively rapid rate and too high a temperature generating impurities other than the starting material.

Q And are those impurities generated because at higher temperatures -- withdrawn.

Are those impurities generated because higher temperatures may cause reactions to start that would have not otherwise started at lower temperatures?

A Yeah. You could say that -- higher

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temperatures, I would say -- higher temperatures could lead to other side products, which would be categorized as impurities.

Q And those impurities wouldn't be present at the lower temperature possibly?

A Possibly. So it's -- it's always a compromise, but the experienced chemist would try to find conditions, temperature and time, which give reasonable reaction rate and relatively pure product, and that's -- that's what I achieved before I scaled up my reaction to about ten times the preliminary reaction scale, which is to say I scaled my reaction finally up to almost 9 grams.

And just to repeat, purified the material by chromatography, and it was highly purified, NMR and TLC.

Q You said that -- withdrawn.

I think you said there were -- there could be starting material left in a reaction that's partially incomplete and that would not be desirable. Why would that not be desirable?

A Well, I can think of two reasons. One is

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it's a waste of starting material, and it would generate organic chemical waste, and the less of that you can generate, the better it is.

And it's just not a -- not an efficient use of the starting material. So you want -- you -- in all cases, you want to try to come as close as possible to consuming all of the starting material.

Q If there's starting material left over in a product, and then that product is used to perform a subsequent experimental step, could the presence of starting material affect the outcome of that subsequent experimental step?

A Yeah. As I previously said, it's good practice to purify after every step so that doesn't happen.

Q If it did happen, would there possibly be a consequence on the subsequent experiment?

A Well, there could be. That's what you're trying to avoid, but that's not the case, apparently, in what Liu did, and that was not the case with what I did.

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Both -- both products of Example 2 were purified, and both of them showed a high degree of purity, Liu's by HPLC, and apparently NMR, and mine by NMR and TLC.

Q Going back to the scaling issue we were talking about before, is it easier to keep a mixture homogeneous in a smaller scale experiment as opposed to a larger scale experiment?

A Yeah. I think that's what I was describing previously. So small scale experiment frequently can be mixed by a magnetic stirrer, which is easier to set up, and a larger scale reaction, magnetic stirring wouldn't work, and one would have to use mechanical stirring, which, again, involves a motor attached to a rod and a paddle.

And in terms of homogeneous, stirring here after the reaction has been initiated, the stirring is, I would say, more intended to keep the temperature uniform, as we discussed previously, not to keep it homogeneous. You mentioned homogeneous. In -- because once the --

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once the compounds, the starting materials are mixed, they are not going to unmix.

Let me just add another caveat here. What I said about magnetic stirring is true in general. It is not -- as I recall, it is not true for Liu's Example 2, even on a small scale, because the -- basically the solvent which is being used is called polyphosphoric acid, and that is a very thick liquid. It -- as I recall, it proved even difficult to stir with the magnetic stirrer in my hands on a small scale.

So I -- I can check my notebook, but I think the rate -- certainly on the -- reacted on the larger scale, I used the magnetic stirrer, and I think I may have in most of my preliminary experiments as well.

Q If a mixture is not homogeneous, is it possible that there could be different concentrations of materials in different parts of the mixture?

A Yeah. I think I just answered that in my last answer.

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Once the material is mixed, it cannot be unmixed. That doesn't -- and that doesn't happen, as long as everything is soluble, which it would be in this case.

Actually, I should check. I believe it was, but I'd have to check my notebook to see if I recorded any precipitate.

So as long as everything starts off homogeneous and no precipitate is observed, in principle, everything will remain homogeneous. But, again, it's not -- it's not an issue. Everything -- Liu stirs -- what's he say -- well stirred, or stirred well, and I also stirred my reaction in all cases. So stirring was never turned off, if you will.

Q If you have a suspension as opposed to a solution, is it possible that the suspension might not be homogeneous across the entire mixture?

A Well, by definition, a suspension is not homogeneous. Your question is does that affect the reactions? Some reactions can be done where there is a suspension, and they can be carried out

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successfully. If -- if everything is homogeneous and the product doesn't precipitate out, then it remains homogeneous.

Q When scaling up or scaling down an experiment, is it important to scale up or down each ingredient proportionally?

A I would say yes, but you don't scale up or down the time or the temperature.

Q I see. So if you were doubling an experiment in size, it would be best practice to double the amount of each ingredient that you're using in the experiment?

A That's generally true. You know, and everything you're asking there are exceptions to, and I don't want to be misleading in this, so I'll just say sometimes when scaling up a reaction to a quite large scale, the cost of the solvent, which is generally trivial on a small scale, suddenly becomes expensive, and it also has to be disposed of properly, which is also expensive.

So sometimes when a reaction is scaled up through a large, large scale, there's an attempt

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made to decrease the amount of solvent.

Q That's not the situation we're dealing with here, right?

A I don't think it is, because I think if you -- I think when you look at examples, Liu's Examples 3 and 4, he's still generally, as I recall, using about ten times as much solvent as starting materials.

Q Certainly in your smaller scale experiments, that's not an issue, right?

A Dispose -- the cost of the solvent and disposal of the solvent afterwards is generally not -- not an issue on a small scale.

Q What are the consequences of not scaling up or down ingredients proportionally when you're adjusting the scale of an experiment?

A First, I want to say, I'm not going to not say anything in my answer with respect to the quantity of solvent. So let's just talk about the starting material and the -- what we call the agents or things that react.

Q Okay. That's fine.

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A With that caveat, could you ask the question again?

Q Sure. Let me try. Withdrawn.

Other than solvents, what are the consequences of not scaling up or down -- withdrawn.

Other than solvents, what are the consequences of not scaling up or down reagents and starting material proportionally when you're adjusting the scale of an experiment?

A It's possible or likely that the reaction would not proceed as it did -- as it would have if everything was kept proportional.

Q And so the end results could possibly be different?

A Yeah. They -- they could be. For example, if X reacts with Y to produce Z, frequently there would be a molar ratio of at least 1 to 1, depending on the action. Let's say 1 to 1.

So if, instead, you scaled up and you -- and you used a proportion of 1 to 0.1, there

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wouldn't be enough of the reagent to -- for the reaction to proceed to completion. In fact, it would only proceed, at most, to 10 percent completion if the -- what we call Stoichiometry of the reaction required a 1 to 1 ratio of starting material to that reagent.

Q Would -- withdrawn.

Is it possible that the purity of the final product of that experiment could be different?

A Are you speaking of a reaction in which the proportion of the reagent, the starting material, was not adjusted properly?

Q Yes.

A Well, if the reaction didn't go to completion, then there would be a lot of starting material left over. The --

Q Would -- I'm sorry. Go ahead.

A I'm sorry. But, you know, the bottom line is that an experienced chemist would scale everything possibly, except solvent, would scale all the reagent and the starting material up

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proportionately. That would be -- that would generally be the wisest thing to do.

Again, it doesn't -- I don't believe it applies here. I tried to follow Liu as closely as possible.

Q Would you generally -- withdrawn.

If someone had not scaled the starting materials and reagents other than the solvents in proportion to one another when scaling up or scaling down an experiment, would you consider that to be the same experiment as the original one or a different one?

MR. MAHON: Object to form.

A Any -- even a repetition would not be the same experiment, but certainly if you're taking the proportions, that is a different experiment. Yeah. I don't think that applies here.

MR. MILEA: We have been going for over an hour, and it is 12:40 Eastern. Would you like to take a lunch break?

THE WITNESS: We could take it now, we could take it in an hour. I mean, we could take a

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break now. Whatever you guys want to do. It's early for you. Are you in New York?

MR. MILEA: I'm actually in -- we can go off the record for this.

(A recess was taken.)

BY MR. MILEA:

Q Doctor, if it were the case that in your experiments here the ingredients were not scaled down from Liu in proportion to one another, would that have affected the results that you obtained?

A It -- it could, but I'm not aware that I did that. In fact, my preliminary experiments -- just to ensure that I didn't make a mistake, my preliminary experiments were done at precisely 1/1000th the scale of Liu's in Example 2, in Liu's Example 2, and so I don't think any error was made.

And then in my -- after I was done with the preliminary experiments, I multiplied the quantity of everything by a factor of 9. I'm not sure why I didn't use 10, but that's what I did. And so I also don't think that any error was made

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there.

Q If there was a difference in the ratios between the ingredients, though, would you consider that to be something that could have changed your results?

A Possibly. If you'd like to show me if I made a mistake in the particular examples that I carried out, I can comment on that.

Q Okay. I think we will come to that when we go through each example. We can talk about your starting materials and things like that, but for now, I'd like to turn to a different topic. Withdrawn.

Can impurities in a reaction such as the ones described in Liu inhibit certain reactions from beginning?

A I'm sorry. Repeat the question. Could impurities...

Q Can impurities in a reaction such as the reactions described by Liu inhibit different chemical reactions from beginning?

A In the first -- in Example 2 of Liu, as

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long as you start with your starting materials -- let's see.

Yeah, that's -- that's characterized at the top of Page 15.

Yeah. I guess I have to deal with each one of these separately. So the first chemical that's mentioned is zinc bromide. Zinc bromide is microscopic. It's water from the atmosphere. So it's important that it be pre of that.

For that purpose, as I recall, I drive the zinc bromide to an elevated temperature to remove any water which might possibly be present as a precaution.

Liu doesn't -- Liu doesn't comment on the zinc bromide, but with all of -- that I'm going to go through, the other reagents, I'll say that Liu's results speak for themselves. If he got, as he states, an 85 percent yield of 97 percent pure material, he must have been doing something right.

The next ingredient is polyphosphoric acid. I purchased that material from Aldrich, a chemical supplier. There should not have been any

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problem with that. It's -- the only impurity that I can think of would be if -- if it absorbed water from the atmosphere, but it was a new bottle. That shouldn't be the case.

Hydroxybenzoic acid -- by the way, that would have been characterized -- it was characterized from the column chromatography as a single spot. There's no reason to think that there would be anything wrong with that, and the same thing with phenoxyethyl bromide. The funnel of -- the phosphorus tribromide, that can also absorb water. Therefore, as a precaution, I distilled the phosphorus tribromide before using it.

So long answer to a short question, the main impurity that I can think of here would be water, and all precautions were taken to exclude water, including -- although Liu doesn't say it, I carried the reaction out under a nitrogen atmosphere, I'm pretty sure. We could look at the notebook and verify that.

Q Is that -- withdrawn.

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Was that nitrogen atmosphere used for all of the examples or just the particular ones where Liu says that something was done under an atmosphere?

A It's my recollection that -- I'm sorry.

What Liu says was done under an atmosphere or where I say it?

Q Unless I'm misunderstanding your answer, it sounds like you just said for every step of your experiments, you carried them out under a certain atmosphere whether or not Liu said to do that?

A I believe that -- I believe that's correct. It probably -- that's for Examples 2, 3, and 4, I think. We could verify it.

The recrystallizations were probably -- may not have been done under an atmosphere. I'd have to check.

Q We can check that, because we are going to talk about, hopefully, each example, if we have time.

A Okay.

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Q What is crystal nucleation?

A A lot of theoretical work and some experimental work has gone into the process of crystal formation. I don't think it's settled science, but the prevailing theory is that in order for crystallization to occur, first there's a microscopic article in precipitate that forms, and once that happens, then frequently the whole mixture develops crystals.

So the nucleation means sort of the first stage in crystallization on a microscopic level.

Q Does the temperature at which a reaction is performed affect crystal nucleation?

A You're talking about two different things. One is the temperature of the reaction. The other is the temperature of crystallization. They're generally two different things.

Q How so?

A Well, let's see if I can -- and it's not clearcut in Example 2. It'd be hard to point out. I'll just say in general, first the reaction is carried out, and then there's the process where

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the reaction is -- we usually use the term "worked up," which is to say the product is -- the crude product is isolated.

And then that crude product is purified. Frequently that would be done by crystallization from a totally different solvent, but it could be the same solvent.

So there are different stages in the process.

Q At what stage is nucleation occurring in that process you just outlined?

A Crystallization.

Q Is the temperature at which the crystallization is performed -- withdrawn.

Does the temperature at which crystallization is performed affect crystal nucleation in any way?

A Yes.

Q How so?

A As I mentioned more than an hour ago, there are various ways of causing crystals to form as a method of purification. The most common way

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is to dissolve at a high temperature and then cool the reaction to a lower temperature, or allow the -- I'm sorry. Shouldn't have used the word "reaction."

To allow the mixture to cool to a lower temperature, which could be room temperature or could be below room temperature or it could be somewhat above room temperature.

So that's -- that's the process of crystallization. Typically the compound -- typically, but not always -- the compound would be cycled with a higher temperature and would form crystals at the lower temperature.

The -- at high temperature, there would probably be -- if it's outside of it, it wouldn't be any crystallization at all. Generally, the lower the temperature, the more -- the higher the yield of the material that is being crystallized.

Q When you say the lower the temperature, the higher the yield of the material, do you mean the temperature to which the material is cooled or the temperature that you use when you first

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dissolve the material into the -- withdrawn.

When you say the lower temperature, the higher the yield of the material, do you mean the temperature to which the material is cooled?

A Yes, that's what I mean.

Q Okay. When we're first dissolving the material into the high temperature solvent, does the temperature of the solvent make a difference?

A Yes. The -- in general, organic compounds are more soluble at high temperature, and so -- and, also, usually the yield of material will be increased when the difference between the high temperature and the low temperature are increased.

Q Would increasing the difference between the high temperature and the low temperature influence the polymorphic form that you get at the end of your reaction?

A Hypothetically, it could, but I don't see any evidence of that here.

Q Would increasing the difference between the high temperature and low temperature influence the purity of the material that you get at the

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conclusion of the crystallization process?

A Yes. There's always a tradeoff -- with my usual caveat, maybe with some exception I can't think of, there's always a tradeoff between yield and purity, which is why you might not make that difference between a high temperature and the low temperature as -- as -- as great as possible.

Again, the tradeoff is yield versus purity.

Q While we're on the topic of nucleation -- we're going back to the topic of nucleation -- I wanted to talk about scratching a flask, if that's okay.

A Sure.

Q What is the purpose of scratching a flask during the crystallization process?

A The purpose of it is to induce the mixture to yield crystals if it is, one might say, reluctant to do so.

Q There could be a situation in which you don't scratch the flask, and you don't get any crystallization and then you do scratch the flask,

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and that scratching causes you to get crystallization?

A I think that's fair. Let me just add that this is a -- some -- some compounds for some reason are reluctant to crystallize, even from a super saturated solution, and scratching is a very well-known and established technique -- I'm sure done for a couple of centuries by now -- to induce crystallization, and it is explained in undergraduate laboratory textbooks.

Q Is stirring another way to induce crystallization?

A You know, I've never seen a reference that says that, but in my hands, I typically would not stir a mixture to -- to get crystallization. But in this case, in Liu -- in one case, as I already stated, Liu discloses that a reaction -- sorry -- a crystallization mixture is cooled with stirring. So I would follow that, if that's what Liu has specified.

But, generally, I would not stir. And that's -- some people do, and some people don't.

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Most people would not stir, but I know some who say that they do routinely.

Q Would adding more stirring to what Liu disclosed increase crystallization?

A I guess, to be honest, I'd have to say I don't know the answer to that. You'd have to do the experiment.

Q It's possible that it could, though?

A I don't know.

Q In your recreation of Liu's Example 7, do you recall that you scratched the flask, at least in your recrystallization experiment?

A I think so. Let me just get Example 7.

Okay. So Example 7 is entitled Recrystallization of an Endoxifen Mixture Enriched in Z Isomer.

Q If it is helpful, you could also turn, please, to Paragraph 61 of your IPR declaration.

A Okay. Paragraph 61.

Yeah. Yeah, this is the experiment that I mentioned before where I say that I cooled and stirred for 40 hours at 4 degrees, and I

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particularly remember that experiment because 4 degrees is the temperature of the refrigerator in my lab, and I don't typically stir at 4 degrees for 40 hours.

And so I recall putting the stirrer at -- a magnetic stirrer into my refrigerator with an extension cord, so that's what I did. "That" meaning cooled and stirred for 40 hours at 4 degrees. And this follows Liu.

Q And after you did that, about the middle of the paragraph, you say, At this stage, a small amount of precipitate was observed.

Do you see that in Paragraph 61 of your IPR declaration?

A Yes.

Q What was that precipitate?

A It -- I did not characterize it. I assumed that that was endoxifen.

Q Was it crystal that was forming or something that was just coming out of the solution?

A Well, what I say is precipitate. There

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are two ways that I can think of to determine whether the precipitate was crystalline material. Now I'm coming up with three. Let's see if I can delineate these.

One way would be to isolate the precipitate and perform XRPD on it. I did not do that.

Another way would be to look at the precipitate under a microscope or magnifying glass, and if -- if they looked like crystals, they were crystals. If they didn't look like crystals, maybe they were, maybe they weren't. There could have been microscopic crystals.

The third way would be to -- essentially the same as the first way, would be after the entire precipitate was obtained, which I describe there, kept in the fridge for 24 more hours, would be to take the entire precipitate and perform XRPD on that. And from that, you can tell whether -- whether there's crystalline material or amorphous material.

Q Well, what's the significance of the fact

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that it was just a small amount of precipitate?

A Well, again, the idea is to try to get reasonable yield or even maximum yield. So when I observed this by eye, not by weight, it was my observations that not much material had crystallized, and so, therefore, I scratched the flask, which is a way of inducing more crystallization, and then continued stirring for another 24 hours at 4 degrees.

Q I think you said before you couldn't tell whether this precipitate was crystallized material or something else, right?

A I could have, but I -- I did not. I assumed that it was the -- predominantly (Z)-endoxifen, and I carried on as -- as stated in Paragraph 61. And in the end, I obtained a sample that had 94 to 6 ratio of (Z)- to (E)-endoxifen. So I think it worked out.

Q At this point when you observed the small amount of precipitate, had you not added the flask scratching and the additional 24 hours of stirring, what would you have done?

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A In other words, if I stopped at -- when I had a small amount of precipitate, what would I have done?

Q Right. Could you have -- let me ask it this way. Withdrawn.

You observed the small amount of precipitate, and then you added a flask-scratching step and 24 more hours of stirring that were not disclosed in Liu; is that fair?

MR. MAHON: Objection; form.

A Yes.

Q Had you not added the flask-scratching step and the 24 more hours of stirring, would you have had enough precipitate to characterize it with NMR?

A Yes.

Q Would you have had enough precipitate to proceed to the next step of Example 7?

A No.

Let me just qualify that. It would be -- it would have been extremely difficult because instead of getting 149 milligrams, I would have

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gotten much less than that, and it would have been -- maybe it would have been possible. I don't want to say the wrong thing. But it would have been tedious, and it wouldn't be a prudent way to go.

Q And just to be sure, you did not run NMR on the small amount of precipitate that you observed before you scratched the flask and added 24 more hours of stirring, right?

A That's right. And this -- you know, a POSA would know to do this. A POSA would see -- now, crystallization rates can vary for unknown -- basically unknown reasons, in my opinion.

So a POSA who saw, wow, there's very little precipitate would probably increase the time and would probably utilize the scratching technique to increase the yield.

Q And you say at the end of Paragraph 61 that NMR indicated a 94 to 6 ratio of (Z)- to (E)-endoxifen. That was NMR of the precipitate that you collected after you added the flask scratching and 24 more hours of stirring, right?

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A Correct.

Q You don't know what the purity would have been of the small amount of precipitate that you observed before you added flask scratching and 24 more hours of stirring; is that fair?

A Yeah. I could only speculate because I didn't run NMR. But, again, the best laboratory procedure, in my opinion, would be to obtain the maximum amount of precipitate that one could and then characterize the entire batch by -- by NMR, which is what I did.

Q Okay. I'd like to go back to talking for a little bit about filtering or purifying more generally, if that's okay.

A Sure.

Q I think in your declaration, you mentioned a few different ways that chemists can filter a purified mixture. Centrifuging is one way; is that right?

A Yeah, centrifuging is basically an alternative to filtration.

Q And we talked about this, but column

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chromatography is another way to purify?

A You know, kind of shifting gears here. Going back to your previous question about filtration and centrifugation, the purpose of filtration as we're discussing it is to separate the product crystals from the filtrate, which is to say mostly the liquid phase. Crystallization does the same thing.

Now you're talking about something totally different.

Q Okay. So let me ask this: Is purifying different than filtering?

A I'll -- I'll answer a different question. Crystallization is a form of -- of purification. And according to Wieckhusen, he states something -- I'm paraphrasing -- that is a very powerful method for obtaining high purity materials.

So crystallization is a form of purification. Generally, crystallization is a form of purification, but purification is not always a form of filtration or crystallization.

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Q Okay. And I'm not trying to trip you up here. I just want to make sure I'm using the right vocabulary. So it sounds like -- withdrawn.

It sounds like in your mind filtration is a different category than purification?

A It's like -- you know, it's like this Venn diagram. Usually all cats have four legs, but not everything that has four legs is a cat.

Q Right.

A There's three-legged cats, I'm sure.

Q So there are types of --

A Most --

Q I'm sorry. Go ahead.

A Most recrystallization is a form of purification, but not all purification involves recrystallization.

Q I see. Is column chromatography another form of purification?

A Absolutely.

Q And centrifuging, is that in the filtering column or the purification column?

A As stated by Liu, when you have a mixture

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of the filtrate or the -- it's not a filtrate yet. The solution and solvent of the compound and the precipitate, the precipitate can be isolated from the filtrate in several ways.

One of those, probably the most common, is filtration through a -- some sort of membrane, usually paper, frequently paper. Another method, I think, disclosed by Liu and well-known in the art would be centrifugation.

Liu also discloses aspiration and decantation, I think, which means sucking the -- excuse the expression -- sucking the liquid off from the crystals or pouring the liquid off from the crystals.

Q Do these various filtration and purification steps you discussed remove impurities from the things being filtered or purified?

A I guess I worded it a different way. The purpose of recrystallization is to remove impurities, and typically the impurities are in a liquid phase, which we call the filtrate, and the desired product is in the crystalline -- generally

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crystalline precipitate.

Q Liu talks about -- is it celite filtering or celite filtering, the pronunciation?

A We say celite.

Q Okay. I'll say celite, then.

So Liu talks about celite filtering in a few places, right?

A Yes.

Q Would you expect celite filtering to remove different impurities than centrifuging?

A Filtration for celite is generally used at a different step than crystallization and filtration and centrifugation and the other methods. I'll explain a little bit.

First of all, celite, just for general knowledge, is this material that's mined from the ocean floor that is the exoskeletons of microscopic organisms, diatoms. That's why -- it's actually called diatomaceous earth. And it's kind of like a -- it's kind of like silica jell, but compounds don't usually adhere to it that much.

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The purpose of celite filtration is not to harvest the desired crystals but to filter out inside the materials which are generally also very small and unretained by the celite. And, again, it's a standard laboratory practice.

Q Just for the benefit of the court reporter, is celite C-E-L-I-T-E? I think I spelled that right.

A Yeah.

Q Okay. With celite filtering, can you target specific impurities, or are you just filtering out things that are either a certain size or not soluble or some other physical characteristic?

A If one is using filtration, there are a couple of techniques that are used. Again, these are explained in undergraduate lab books -- laboratory textbooks.

You can filter through special paper called filter paper, which is readily obtainable. And you can -- or you can filtrate -- filter through celite. Generally, that involves putting

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a layer of celite on top of the filter paper, and its purpose is to remove particles which otherwise might go through the filter paper because they're so small or might clog up the filter paper because they're so small.

Q So in that way, you can target specific impurities with celite filtering?

A Yeah. Again, they're -- they tend to be small particles which would clog up or go through filter paper. So it's a way to -- frequently you'd see -- before filtration -- that there's some turbidity, rather than an internal solution of the -- of the desired material.

And so a skilled chemist would frequently use celite to remove those, the turbidity.

Q Can centrifuging target specific impurities the way that celite can, or does centrifuging just separate out solids and liquids?

A Centrifuging can either -- can be used in -- essentially in similar ways to filtration in that it can be used to harvest the desired crystals, or it can be used to separate the

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precipitate, particularly if the precipitate is fine particles.

Centrifugation typically works better than just allowing a mixture to settle and then pouring it off, which is decantation.

Q Fair to say that the choice between centrifuging and celite filtering depends on what you're trying to accomplish?

A Yeah. I -- I think that's fair.

Just to jump to the elephant in the room, I utilize centrifugation to isolate the desired dioxane, whereas -- and I state this somewhere in my report -- whereas Liu used filtration to accomplish the same thing. The reason that I did that was I was working on a smaller scale and the temperature -- the low temperature and the recrystallization was minus 10 degrees, and what I attempted to do to isolate the product by filtration. As the solution warmed up to room temperature, the precipitate would dissolve.

Centrifugation, I was able to perform more quickly and without allowing the mixture to warm

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up as much, so that I viewed as a better alternative on the scale that I was performing the recrystallization. Better alternative to filtration.

As I said, that -- an explanation of that better than the way I just said it is in one of the footnotes of my report.

Q Do you know whether impurities in a drug can affect its pharmacokinetics?

A Well, that's really a pharmacology question, and that's not my expertise, but I would say it's -- it's possible.

Q Do you know if impurities in a drug can affect the stability of the drug?

A When you say a drug, are you referring to the -- what we call the API, the active pharmaceutical ingredient?

Q Yes.

A Maybe in principle. In this case, in the case of endoxifen, I think the main issue is the possibility that the (E)-isomer will isomerize partially to the (Z)-isomer, and that was -- I

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think all of the references referring to endoxifen mentioned that that does occur, particularly in elevated temperature over a long period of time.

As I said before, the -- I don't see any impurities in my (Z)-endoxifen except for some small amount, 2 percent, of (E)-endoxifen, and I don't think that would affect the stability. I have no evidence that shows that stability was affected.

Q Would that residual acetone affect the stability of (Z)-endoxifen?

A As I said in my report, I would not expect it to. What -- what my experiments have shown is that recrystallization from refluxing acetone does not appear to increase the amount of E.

In fact, you'd really have to look at the numbers, but the precipitate, acetone -- acetone -- sorry. After recrystallization from acetone, the precipitate typically shows an increase in the amount of Z, which is supposed to happen, according to Liu.

You'd have to do some calculations looking

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at the filtrate, but I don't think the filtrate is -- indicates that that acetonic reflux causes a problem.

And so I don't think there's any evidence that a trace of acetone in (Z)-endoxifen at room temperature would -- would cause any problem.

Q Would you have to test to know that for sure?

A I think I could do calculations, but sitting here today, I'd have to look at the number of milligrams of (Z)-endoxifen obtained and how much (E)- there was and also look at the filtrate and how many milligrams there was of that, and do a little bit of arithmetic and see.

But without doing that, it's my strong impression that there's -- that acetone doesn't -- it doesn't do anything even at reflux temperatures.

I just want to clarify. The higher the temperature, the more likely there is to be isomerization. Now, the kind of impurities that would -- the literature shows, the prior art

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shows, would cause decorporation, isomerization between E and Z would be presence of an acid.

That could be various acids that are recorded in the prior art. Particularly, hydrochloric acid is reported by the -- by the Elkins paper. Others have used trifluoroacetic acid, which is a very strong acid, but there's -- that's not present in any of these samples --

Q Next --

A -- that I've worked with.

Q -- you mentioned you'd have to do some calculations to determine whether residual acetone in the (Z)-endoxifen you obtained would affect its stability.

Did I get that right?

A I was speaking of something slightly different. I said I'd have to do calculations to see if the refluxing in acetone, which I did to cause recrystallization of the (Z)-endoxifen, I'd have to do calculations to see if refluxing in acetone increased the overall amount of E from Z.

Again, that's -- that's a great excess of

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acetone at a high temperature. So it -- it doesn't really relate to less than 1 -- excuse me -- less than 1 percent acetone at room temperature or below in (Z)-endoxifen.

Q What's the difference between a suspension and a solution?

A That's a good question, because it will clarify a previous answer.

A solution means that the generally solid material is completely resolved. Suspension means that it is not going to dissolve if it is suspended in the liquid.

Q Some of the material that you've added to the liquid hasn't dissolved in a liquid in the suspension?

A Right. And, by the way, that -- when I said that would clarify, a suspension could be removed to give a solution by filtration through -- for example, by filtration through celite. Possibly through filtering.

Q In a suspension of (Z)- and (E)-endoxifen, is it possible that you could have more

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(Z)-endoxifen that dissolved as compared to (E)-endoxifen?

A I think you're asking about a suspension.

Q Right. Did I say solution? I meant -- let me re-ask the question. Withdrawn.

If you have suspension of (Z)-endoxifen and (E)-endoxifen, is it possible that some of those have dissolved but other portions have not such that you have -- you still have suspension even though certain things have dissolved?

A Let me answer in a slightly different way.

During recrystallization, if a recrystallization proceeds somewhat slowly, the first thing that you'll get is very small crystals, which might look like a suspension because they're insoluble, but they're small.

So I would say that's a suspension. Generally one would wait until all of the material that you want has precipitated out as usually crystalline form, and at that point, one would filter.

Q With suspension, is it possible that the

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concentrations of materials and impurities in different portions of the suspension are different than one another?

A Well, I think -- I suppose so. It's not generally something that we encounter or worry about, but just give me a thought experiment.

The precipitate precipitates from the solution. If it's through suspension, it might not totally precipitate, but taking the extreme, it -- the crystals would be in the precipitate, and the very top of the liquid layer, if it's not stirred, would have none of the -- or essentially none of the material in it, but it's -- it's not something that we would generally worry about or encounter.

Instead, an experienced chemist would wait until they believe the precipitation's complete and then would remove the solid precipitate from the mixture by filtration or a related method.

I mean, so this -- your question's about a suspension. With all due respect, they're not generally relevant to the process that we're

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discussing.

Q Do you consider a suspension -- withdrawn.

If there was an experiment that instructed you to use a suspension and you instead used a solution, would you consider that to be a material difference?

MR. MAHON: Objection; form.

A I don't know if I've ever encountered that. I would say that if I used the same reagents of the same purity and the same volume of solvent at the same temperature as the reference, that if I observed the suspension and they called it a solution -- I'll be a little bit arrogant here -- I would be right and they would be wrong.

But I do see that occasionally. I'll see that a procedure says a solution of this and this was heated to such and such a temperature for such and such a period. I'll look at it. It's not happening. We know that this is not -- I know that this is not soluble in -- in the solution, so it's a -- it's a suspension. And I would note that in my notebook.

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Q Okay. Let's look, please, at Paragraph 71 of your IPR declaration, which is Exhibit 1033. And at the end of that paragraph, there's a chart of your purification scheme, and I want to talk about that for a few minutes.

A Hold on a second. Let me make sure I'm there.

Q Yes, take your time.

A Okay. The copy that's on my screen appears to have an exhibit number. It was here before.

I'm looking -- excuse me.

Q Are you perhaps looking at the other declaration you had open earlier? If so, close that one.

A This one relates to the '391 patent that I'm looking at.

Q Okay. Yeah, if you could close that one, I believe that was the unsigned one, and look at the one that relates to the '151 patent, which should say IPR2025-00799 in the bottom right corner.

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A What exhibit number is that again?
Q 1033.
A Okay. I've got that open.
Q Okay. And I'm looking at the end of Paragraph 71 of Exhibit 1033.
A Now I have a new problem. My scroll bar has stopped working. So I'm going to have to -- I'll close PDF files and load that again.
Q Okay. And if it's helpful, you can look at the Zoom. Ky has very helpfully put up the purification scheme I want to talk about.
But if you want to scroll, you can certainly reopen Acrobat.
A I'll try to do that during a break.
Okay. I think I got the one that he sent, but -- that Ky sent, but I -- the scroll bar is not working there either. But maybe -- maybe I'm looking at the right pages. Above Paragraph 72?
Q Yes. Do you see a chart which is your purification scheme?
A Yes.
Q So at the top of this, you see it says

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Crude Endoxifen, right?

A Yes.

Q That's a material that you synthesized, right?

A Yes, it is.

Q Did you synthesize that material by recreating Liu's Examples 2 and 3 and 4?

A 2 and 3, definitely. I think that includes the crystallization on -- at the end of Liu's Example 4 from -- you know, I -- I'd have to look at the text to -- to be sure, because I think that -- I think the acetone recrystallization step right below the first line there is, in fact, part of Liu's Example 4.

Q I think that's correct, and I think that this crude endoxifen is something that you get partway through Example 4, and we can certainly check that once you get your scroll bar working.

A Yeah.

Q But my question is really focused on where -- whether Examples 2 and 3 were part of obtaining this crude endoxifen, so let me -- let

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me just ask that. Withdrawn.

The crude endoxifen shown at the top of the purification scheme under Paragraph 71 in your declaration, was that synthesized with the materials that you made when you recreated Liu's Examples 2 and 3?

A Yes.

Q And we'll check, but it also may have partly come from some portion of Liu's Example 4; is that fair?

A Yes.

Q And that's the material that you used in all of the subsequent steps that you performed in your experiments, right?

A Well, the 15-27-1?

Q Yes.

A Yes.

Q What do you call the things that you synthesized in Liu's Example 2 and Example 3, generally?

A Generally, they'd be called intermediates.

Q So you synthesized an intermediate in Liu

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Example 2. You used that to synthesize an intermediate in Liu Example 3, and then you used those, perhaps with some other steps, to synthesize the crude endoxifen that is at the top of the chart under Paragraph 71 of your declaration?

A Yes. And as usual, there's a caveat. As I recall on -- so when I -- when I did Liu's Step 4, just like in all the other reactions, rather than take all the material and perform Liu's procedure, I did do, I believe, a couple of preliminary experiments to make sure that it worked so that I wouldn't be discarding material.

So I'm flexing my memory a little bit, but I could look at my notebook. I believe there was another experiment called 15-27-2, which was essentially equivalent to 15-27-1, and I may have used that for some other preliminary work, which is not in -- did not generate these particular notebook numbers.

Q Okay. But it's fair to say that the materials that you synthesized in each step that

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is shown in this chart were then used for the following steps of your purification scheme?

A Yes. To put that another way, this -- this chart, I believe, is an accurate representation of what I did, and so all of the notebook numbers are specified on this chart below the first line, originated with the first sample, 15-27-1.

Q Okay. I think you said that the material 15-27-2 that you generated following some version of Liu's Example 4 was essentially -- essentially equivalent to 15-27-1; is that right?

A That's my recollection.

Q Do you remember how those materials differed?

A I don't recall any difference. The escalated term, though, would be to look at Page 27 of my notebook and see what it says.

Q Okay. And it's almost lunchtime, so I want to do that after lunch, because that will probably take a while. Withdrawn.

In your mind, is essentially equivalent

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the same as equivalent, or does that imply some difference?

A Well, you know, I'm trying to be an honest scientist here, and I believe that they were equivalent, but if there was some difference, I'm trying to accurately reflect what -- that there could be possibly some difference, but I'm not aware of any.

MR. MILEA: Is now a good time for a lunch break for everybody?

THE WITNESS: Fine with me.

MR. MILEA: Okay. Let's go off the record, please.

(A recess was taken.)

BY MR. MILEA:

Q Welcome back. I'd like to now take a look at your version of Liu Example 2. So I -- I would like, if possible, to have Liu open, which is Exhibit 1003, and your IPR declaration, which is Exhibit 1033.

Do you have those documents, Doctor?

A Let's see. I have 1033 open. I will

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reopen Liu in a second.

'651, right?

Q Yes.

A Okay.

Q Please turn to Paragraph 62 of Liu.

A Okay.

Q And right above Liu Paragraph 62 is the title of Example 2, is that right?

A Right.

Q And the purpose of Example 2 is to synthesize this chemical which you and Liu are both calling compound 5; is that right?

A Let's see. Where does Liu call it compound 5?

Q In the title, at the end, there's a little 5.

A Okay, yeah. I call it -- generally call it Example 2.

Q Okay.

A Go ahead.

Q And do you see in Paragraph 51 of your IPR declaration, it says, I synthesize -- oh, I'm

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sorry. I'll wait for you to get there.

A Paragraph?

Q 51.

A Okay.

Q Do you see it says in Paragraph 51 of your IPR declaration, I synthesized compound 5 by a modification of the procedure described by Liu at Paragraph 62 through 63?

A Yes.

Q So what you're saying there is you -- you followed Liu Example 2 with some modifications in order to synthesize what Liu calls compound 5?

A Yes.

Q Generally, what is the purpose of compound 5?

A Well, the purpose of this -- of this whole exercise described -- described by Liu is to generate a first administer of (E)- and (Z)-endoxifen and then to isolate (Z)-endoxifen.

The purpose of compound 5 is so -- this is what we would call an intermediate compound in the entire synthesis. It's -- in fact, it's the first

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intermediate.

Q And compound 5 is used in Liu's Example 3 to synthesize something, and then the thing that is synthesized in Liu's Example 3 is used in the later examples of Liu, including Example 7, recrystallization; is that fair?

A Yes.

Q Let's look at your lab notebook, please, which is appended to your IPR declaration. And if you look -- it will be easier here to use the page numbers in this -- and the exhibit stamp in the bottom right of every page. So if you can please turn to Page 79 of 95 using that exhibit stamp.

A Yeah, I can do that.

Q On Page 79, is this your first attempt at recreating Liu's Example 2?

A Yeah. More generally, I would testify that with the exception of some text on Page 35, I believe with regards to stability, that I neglected to send you the pages reproduced here from my lab notebook represent all of the experiments that I did with regard to endoxifen.

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Q Okay. And specifically on Page 79, is this detailing your first attempt to perform Liu's Example 2?

A Yeah. And we know this because it's the first page of my notebook, and so nothing was done before this.

Q Okay. And it says --

A Let me pull that with my note copy.

Yeah.

Q Are you --

A In the upper corner of this page is the notebook page number, and it starts with Page 20. That's the first experiment that we did.

Q And are you looking at something on paper right now? Do you have a paper copy of this?

A Yeah. I also brought that over because I was looking at the other question you asked before the break.

Q Okay. And that's a paper copy of Exhibit 1033 in the IPR?

A Yeah, it's the same thing.

Q Okay.

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A Exactly.

Q So feel free to look at that if it's easier to you. I'm also looking at a paper copy, because I find it easier, but it's also on the screen at well.

A Yes.

Q So the third line from the top references the Liu publication number ending in 651, and I believe it says Liu, and then next to that, there are two words that I can't read.

Do you know what that says?

A Well, let me confess that my handwriting is not the best handwriting in the world, and it's gotten worse since then, but I believe those would be the other inventors on -- on the publication. So I think it says something like Liu, Denysenko, and Huang.

Q Okay. I think that's right now looking at the names of the other inventors. Okay. Thank you.

Two lines after that, it says, EX 2 times 1 over 1,000.

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Is that just indicating that you were performing Example 2 at 1/1000th scale as Liu?

A Yes.

Q Okay. Then next to that, it says 30 to 75 degrees I.

Is that right?

A Yes.

Q What does that mean?

A It means the reaction was conducted at a temperature of 30 degrees, 75 degrees, I means internal temperature, meaning that there was a thermometer inside the reaction. So that's the actual temperature of the reaction rather than the temperature of the surrounding oil bath or something.

Q The first entry on this page, I believe it says July 17th, 2023.

Do you see that?

A Yes.

Q And the first ingredient is ZnBr2.

Is that zinc bromide?

A I'm going to correct, apparently,

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something that I said before the break. I thought that I had purified the zinc bromide by -- to drive off any possible water by heating it, but I don't see that on this page.

Q So I was actually going to ask you about that. I think you did that in your later steps -- or your later recreations of Example 2.

A Okay. Thank you.

Q And so we can talk about that.

A That makes sense. You know my lab notebook better than I do at this point.

Q I had a fun weekend.

So, okay. Let's go back to the 7/17/23 example, please.

A Yeah.

Q Zinc bromide, is that ZnBr2?

A Yes.

Q And then my question was going to be: Did you dry this in this example?

A It certainly appears not, and I see what you were referring to. On the next page, it says that I dried it at 230 degrees centigrade. So

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by -- in this case, it says zinc bromide, it's got quantities, and then after that, it says T CI. That's the manufacturer from which I bought the zinc bromide.

Q Okay.

A So that means it was not dried on this page.

Q Okay. And you just referred on the next page to a drying set on page 80. Does that say -- it says oven dried at -- and I can't tell if it's 130 degrees or 230 degrees?

A That's a 2.

Q Okay. So let's go back to Page 79.

The second line of this entry says, very thick. And then I believe after that, it says the word "used," and then it goes on to the next line, and I can't read what that says.

Can you please tell me what that says?

A Sure. It says used Cimerac on magnetic stirrer. I have a number of magnetic stirrers in my lab. The Cimerac is, I guess you could say, the most powerful one. And so this indicates that

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I was using -- well, as it says, a magnetic stirrer. That's the -- kind of the thing that contains the motor and the magnet, and then using a Teflon-footed magnet inside the reaction vessel.

Q Okay. And it says "very thick" right before that.

A Yes.

Q What is the significance of that?

A Well, it's -- it's just an observation, and it could be useful -- if I were to repeat this, that -- it's kind of a warning to me that a magnetic stirrer is going to be difficult, and if we scale up, it's going to be even -- when I would scale up, it would be even worse.

The bottom line is magnetic stirring is probably not the best way to go. That's what I'm indicating here.

Q Okay. A few lines after that, maybe four lines after, it looks like it says not exothermic, next to an entry that says -- maybe it says 315.

Do you see that?

A Yes.

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Q What is the significance of that?
A Not exothermic?
Q Yes.
A I believe that Liu states on the larger scale that the reaction was exothermic, or it implies that. So in my hands, reaction not exothermic.
It's, in my opinion, important to note whether a reaction was exothermic because a severely exothermic reaction could get very hot and get out of control, and you wouldn't -- you wouldn't know necessarily the -- what the temperature internally is, you know, without a -- although I -- continuing to the next couple words, it says, stirred to 40 to 50 degrees internal, so it did not get out of control, and it remained at the stated temperature.
Q Why did you say that Liu either implied or stated that its reaction -- withdrawn.
Why did you think Liu's reaction was exothermic?
A Well, let's take a look. That would be

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Example 2 of Liu.

Before I answer, I want to be sure here.

Q Sure. Take your time.

A Yeah. So Liu's Paragraph 62. Tell me when you're there.

Q Yes. Go ahead.

A Okay. The fourth line, it says, Phosphorous tribromide was added via an addition funnel over a period of 2.5 hours at a rate to keep the temperature below 50 degrees.

So since room temperature, even though it's not stated, it's probably about 20 to 25 degrees in Liu's lab, the reaction heats up to 50 degrees when the phosphorous tribromide is added over two and a half hours. So I didn't have to do that because my reaction was not exothermic.

Now, I should explain. When reactions are conducted at higher scale, if there's any heat generated, if there's any exothermicity, that will be more noticeable on the larger scale. Has to do with the surface-to-volume ratio.

Q Right. So there was -- at a larger scale

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reaction, there's a lot more stuff in the middle that's not exposed to the room temperature as opposed to the smaller scale, and at the smaller scale, there might be something going on in the middle, but there's so much surface area relative to what's in the middle of the reaction that you're not actually seeing an increase; is that fair?

A I think that's one way of looking at it.

Q Okay.

A There are all these engineering formulas that deal with surface-to-volume ratio, but it's more or less what you're saying.

Q Okay. Earlier when we were starting to talk about this example, I think you said that the 30 to 75 degrees up at the top of this page indicated that you had performed the reaction in that temperature range; is that right?

A Okay. I see the 30 to 75 degrees internal temperature, and what was your question about it?

Q Is that indicating that the -- withdrawn.

Is that indicating that the internal

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temperature of the material in this experiment ranged between 30 and 75 degrees?

A Well, that's interesting. Unless I'm missing something, I don't see anything on my -- on this page of my lab notebook that says 75 degrees. Wait, I think I see something.

Yeah. Okay. I did not make a mistake. If you see the line that starts off with the date 7/18/23?

Q Yes.

A And then go down one line below that.

Q Okay.

A It says 3:45 -- by the way, that's the time -- p.m. Then it says -- and it says, Then 75 degrees for 20 hours.

Q Okay. Could you take a look, please, at Liu Example 2? Does that say anywhere that you should heat the reaction or the internal temperature of the material to 75 degrees?

A No. The reason that I did that is, as you can see in the line above that, it says that when I carried out the reaction for 22 hours at 45 to

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50 degrees internal temperature, that it was mostly starting material by TLC.

So as I said, an experienced chemist, when you operate as -- an experienced chemist would either carry out the reaction for a longer period of time or raise the temperature.

So I raised the temperature to 75 degrees, and TLC showed more product was -- and that -- the TLC, by the way, is depicted at the very bottom. The dots are -- with -- with captions that say, for example, 50 degrees for one hour, 50 degrees for two hours, 60 degrees for two hours, 75 degrees for 20 hours.

Q Okay. I was going to ask you about that. So that's -- that's the TLC results?

A Yes.

Q And that -- that shows the results at different times of the experiment?

A Correct.

Q And fair -- so -- withdrawn.

So is it fair to say that even on your first attempt to recreate Liu, you were not able

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to get a totally complete reaction following Liu as written?

A That's correct. TLC shows that there was starting material at all these points, and getting ahead of myself, eventually I isolated the compound that I thought was the product, and it -- in fact, it was the product by NMR and by mass spectometry.

So that gave me the ability to know what I was looking for by TLC for future experiments.

Q When you say what you were looking for, what do you mean by that?

A It gave me a -- what we'll call a chromatographic standard that I knew the TLC behavior of so I could compare the results of the first experiment with any future experiments that I -- that I did -- preliminary experiments of the same reaction that I -- that I performed.

Q Was that also partly so you could see what the differences between your experiment were and what the differences -- withdrawn.

Was that also so you could see what the

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differences between your results were and Liu's results were?

A Well, that was -- that wasn't the intention. My intention going into -- into the laboratory is to replicate as closely as possible the experiment or procedure of the prior art, and I didn't intentionally go in to see how my results would be different, but they turned out to be different, and then I had to figure out what to do about that to improve the yield and decrease the amount of starting material that remained.

Q Fair to say that you had to make changes to Liu in order to get results that were similar to Liu?

MR. MAHON: Objection to form.

A Well, yeah. In order to improve the yield and the progress of the reaction, you know, chemistry is an experimental science. I did obtain Liu's product the very first time, but the yield was low.

And, by the way, I mentioned why that could be the case. One -- one possibility was

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that Liu actually had an internal temperature that remained high because it would have taken so long for his to cool at 1,000 times the scale that I did it the first time.

Another possibility that we kind of alluded to was that even though I had zinc bromide from a reputable source, it was possible that it slightly decomposed. Again, water in it. And so that's why I, on the next page, dried it at 235 degrees centigrade.

Q What -- what is the significance of water in the zinc bromide?

A It's well-known that zinc -- I don't want to get, like, overly technical here, but zinc bromide is acting kind of like an acid. It's called a Lewis acid. We learned about this in high school. And if there's water in there, then there would be -- water would actually turn some of that into zinc hydroxide, and it would interfere with the reaction.

Q Would the water potentially turn into hydrochloric acid as well?

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A Hydrobromic acid.
Q Hydrobromic acid, you said?
A Yeah.
Q And you said that that could interfere with the reaction?
A Yeah. I mean, I'd have to think about this a little bit, but basically what's going on in this reaction is one of the side products is water, or -- because if you look at the reaction, water is eliminated when these two starting materials are put together.
So any water that creeps into the reaction is not going to be good for it. I would -- I would -- that was my hypothesis, and I think that's -- generally, in this kind of reaction, the use of Lewis acid, you want to make sure that water is eliminated from -- from the starting materials.
Q Was the zinc bromide that you purchased anhydrous?
A Well, it was supposed to be. Yeah.
Q You --

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A As I said, it does have a tendency to absorb water.

Q Does it say somewhere on Page 79 that you suspected there was water and that it was turning into zinc hydroxide?

A No. And I don't usually note my hypotheses, which may or may not be right, in my notebook.

What I simply did was to repeat the reaction on the next page using zinc bromide, which was dried, and on PDR 3, which was the scope.

Q Okay.

A So that, needless to say, is a shorthand way of describing what my concerns were.

Q Okay. Going back to --

A And it worked. The yield was -- was improved.

Q Okay. If we go back, please, to the 7/17/23 entry on Page 79, and I want to talk about the last line of that entry before the 7/18 entry. I think it starts with 22 hours.

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Do you see that?
A Yes.
Q And then I think it says, the last three words of that line, Hard to stir.
Is that right?
A Yes.
Q What is the significance of that?
A Basically, an observation. And it's also perhaps a notation for me, if I do this in the future, that particularly on a larger scale, it might be advantageous to use mechanical stirring rather than magnetic stirring.
Q If you look now in the 7/18/23 entry, the fourth line of that entry, the second -- it looks like the second word is 1K.
Do you see what I'm talking about?
A That's 2H.
Q 2H. Okay. What's the word before that?
A Stir.
Q Stir two hours.
Okay. And then later, I think it says, initial oily PPT, which is precipitate; is that

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right?

A Yes.

Q And then after that, I think it says, Most dissolved except clumps and fine precipitate?

A Yes.

Q What is the significance of most of it dissolving except for the clumps?

A Frankly, I don't know without further testing. I don't know what the chemical significance of that is. I just try to write -- write down my observations, particularly on ones that are maybe unexpected or possibly significant. But I -- I don't know what the -- I don't know what the actual chemical significance of this is.

Q And if we go several lines down, there's a line where most of it is blank, and if you go all the way to the right, it says 15-20-1.

Do you see that?

A Yes.

Q And I believe below that is the chromatography step that we discussed?

A Yes.

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Q Okay. And then -- withdrawn.

That's the chromatography step that wasn't in Liu but that you added, right?

A Yes. I added that so that I could basically analyze what the TLC spots represented by running NMR on the materials that I isolated by chromatography.

Q Why did you want to do that analysis?

A I think I answered that before. Basically so they would have a chromatographic standard of the authentic material so that I could monitor the progress of subsequent preliminary reactions or the fine-level reaction that I did in this series by TLC. So I --

Q And that you couldn't -- I'm sorry.

A So I would have an authentic sample of material, authenticated by NMR, which I could then use as a standard for TLC so that I would know what the TLC was telling me.

Q So that you could adjust your experiments accordingly to make sure that the TLC was matching the chromatographic standard that you acquired?

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A Yeah.

Q Okay.

A To put it a little differently, so that I would know the interpretation of a TLC. In the absence of -- in the absence of a standard, all I can say is I started out with one spot of TLC, and I ended up with a different spot, but I don't know what either one is until I run the NMR.

Q And so adding that step was the only way that you knew whether you were getting the same results as Liu?

A Adding what step?

Q Adding the chromatography step was the only way that you knew whether you were getting the same results as Liu?

A It was the only way that I would know that I was getting the same product from Example 2 as Liu got.

Q Underneath that, down two lines, it looks like SL.SIM. and unknown. I'm not sure I read that right. Can you tell what that says?

A Yeah.

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Q What is that?
A Let me go back up a couple lines.
Do you see where it says yellow band?
Q Yes.
A 40 milligrams. It turns out that the product, the 40 milligrams represents a 13 percent yield, and it says that it's an orange glass -- it says it's siloed in chloroform, in small parentheses, the NMR, I think it's in CD3OD, which is -- I'll just say it's an NMR solvent, is okay, and then aspect is okay.
Then there's an orange -- the next line, orange band, 35 milligrams. Orange glass. Inside ON CHCO3, NMR, and the same solvent as above, shows slight starting material plus unknown compound.
Q Is the unknown compound an impurity?
A It's -- it is a side product, but it's not an impurity in 1A because it's separated chromatographically from 1A.
Q Before it was separated, was it an impurity?

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A Yes.
Q And so adding this chromatography step allows you to remove that impurity. Is that fair?
A Yes.
Q And had you not added the chromatography step, would that impurity have been in the final material that you made in Example 2?
A Apparently.
Q And then you would have used that final material to perform Example 3?
A No. I would have -- as I said before, I would have purified.
Q Okay.
A I purify -- I generally purify after I reset, as I mentioned before. Otherwise, you'd go through the entire synthesis and end up with an inseparable mess.
Q Right. So the purification steps that you added allowed you to avoid the problem of ending up with an inseparable mess at the end of the synthesis process; is that fair?
A Yes, but we're getting ahead of ourselves

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because that hadn't really been accomplished until I did this preliminary experiment under specific conditions four times and then scaled it up for the fifth time.

Q Okay. But the fifth time, you also added this purification step?

A Yes.

And just to point out, Liu did not do chromatography, but Liu precipitated the product with methyl t-butyl ether, and that may have gotten rid of some impurities.

Q You don't know what this impurity was, right?

A In Liu's synthesis?

Q I -- on Page 79, this unknown impurity, it was unknown, right? You didn't know what it was?

A Right. I mean, that's -- that's what it says. It says there's slight starting material, plus an unknown.

Q But you don't know whether Liu's precipitating step would have gotten rid of this unknown impurity; is that fair?

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A Well, Liu says that he had material that was determined to be 79 percent pure by HPLC -- I'm sorry. A little dyslexic there. 97 percent pure by HPLC.

Q So there was a 3 percent impurity in Liu's material?

A Yeah, which, by the way, for an intermediate compound in a series, 3 percent impurity is generally not something to be concerned with.

Q Okay. Let's turn the page, please, and go to Page 80, which I believe is your second attempt at recreating Liu's Example 2; is that right?

A Yes.

Q And, again, this is at 1/1000th scale?

A Yes.

Q And here it says, up at the top, repeat: 50 to 75 degrees I.

A Yes.

Q Does that mean 50 to 70 degrees internal temperature?

A Yes.

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Q And before, you did 30 to 75 degrees in your first attempt?

A Yes.

Q So you've now raised the lowest -- withdrawn.

So you've now raised the lower end of your temperature range by 20 degrees Celsius?

A Yes.

Q And there's an entry, 7/24/23, and you're discussing zinc bromide, and then all the way on the right, it says oven dried, 230 degrees Celsius?

A Yes.

Q And while we're talking about oven drying, if you go all the way to the bottom, right above your TLC diagram, it says, I believe, some product and NGHCO3.

Right?

A NAHCO3.

Q NAHCO3. And then what are the words after that?

A Well, there's an asterisk there that --

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we'll see what that refers to, and it says some product, and that's sodium bicarbonate layer after the plus HCL. I think that means after the addition of HCL, and extraction with FOCA, which is methyl acetate.

Q Okay. Go back up to the July 24th, 2023, entry. The third line says, heat 50 degrees internal. What does it say after that.

A Again, that's the name of the stirrer, Cimerac.

Q Okay.

A And the temperature of the Cimerac, the bath -- that's what -- that's what the B is -- was 53 degrees, which gave an internal temperature of 50 degrees.

Q And then after that, you heated to 75 degrees?

A Yes.

Q If we go to the last line of that entry right before the July 26th entry, do you see it says, about halfway through that line, heat 55 degrees internal, 58 degrees bath, and then

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heat 95?

A Yeah. On -- just a little bit shorthand. I can understand it.

The Cimerac stirrer is also a heater, and it has settings. So when you set it for 95, the bath temperature is 58.

Q Okay. And then in the next line again, heat to 75, and you obtained an orange clump separate from orange fluid. And after that, you note, contains most product.

Is that right?

A Yeah. I'm still thinking about your previous question.

Yeah. I believe what I said is correct about the meaning of the number 95 for 21 hours. Yeah, because you can see -- yeah. You can see that when the digits after the pound sign, the number sign, increase, so the bath temperature increases. So, again, that's just a way that I know where to set the heater/stirrer in order to achieve the required bath temperatures.

I'm sorry. You had another question?

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Q The next line, the 7/26/23 entry talks about heating to 75 degrees. And then, skipping ahead, it says, orange clump separate from orange fluid, parentheses, contains most product.

Is that right?

A Yes.

Q Are you saying that the orange fluid contained most product or the orange clump?

A I admit it's a bit ambiguous, but since the words "contained most product" are after orange fluid, I believe that the orange fluid at that point contained most of the product.

Q Did you know that the orange fluid contained most of the product because of the TLC results at the bottom of this page?

A As far as I can see -- okay.

Yeah, this is a little bit hard to interpret, but on the TLC results at the very bottom of the page, there is apparently a word that says "clump," and it looks like the clump is somewhat more enriched in the product than the reaction itself. But I would -- I would be a

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little hesitant with that conclusion.

Q Do you say that because there are more dots in the TLC diagram at the bottom of the page? How do you know that?

A Okay. The final product from this -- let me sure that's right before I say anything. Yeah. The final product on -- is the one that the TLC results that's labeled -2, and that consists mostly of the higher spot. So that's what -- that's what I'm looking for. That -- that shows what the reaction is doing.

And so the clump looks like it has more of that higher spot than the reaction at 75 degrees, the TLC result to the left of that, that 75 -- that says 75 degrees for 1.5 hours.

It's not -- it's kind of qualitative. So I -- I would not necessarily report that, and I didn't report that in my actual write-up because it's speculative.

Q Okay. And if we go to the July 26th, 2023, entry, three lines from the bottom of that entry, I think it says stir clump in solution.

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Is that right?

A Still clump -- still clump insoluble.

Q Oh, still clump insoluble. And that's after some additional stirring that you did?

A That's what we call -- what we would call the workup of the reaction, which is pouring the reaction into ice water and stirring.

Q Okay. And then if we go to the July 27th, 2023, entry, three lines down toward the end of the third line, I think it's referring to chromatography, a particular medium?

A Yes. That's correct. It refers to chromatography.

Q And that's, again, the purification step you added that wasn't in Liu so that you could remove impurities from your final product of Example 2, right?

A It's both to remove impurities and to determine what the yield is, because the objective here is to increase the yield, which, by the way, this did. So the yield here is 33 percent; the yield on the previous page was 13 percent. So

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it's more than doubled the yield.

Q Got it. And it says 33 percent yield on the line after that?

A Yes.

Q Okay. Let's look at the next page, please.

Is this your third attempt at recreating Liu's Example 2?

A Yes.

Q And, again, here you're making some tweaks to what's written in Liu?

A Yes.

Q And then if we look at the next page, which is Page 82, is this your fourth attempt at recreating Liu?

A I may -- if this is correct, I may have misstated the number of repetitions of preliminary experiments, because this is the fourth attempt, but this is scaled up by a factor of 9.

So I revise what I said before. It looks like I did three preliminary experiments and then went to the experiment on the page we're currently

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looking at.

Q If you go back to Page 81, do you see there's an entry -- the page starts with July 27th, 2023, and then there's another entry, July 28th, 2023.

A Yeah. Of course. Okay. So I -- I revise my revision.

Q So the experiment -- I'm sorry. Go ahead.

A So the one on -- on the bottom of this page that's dated 7/28/23 is the fourth preliminary repetition.

Q And so the experiment reported on Page 82 of the lab notebook is the fifth attempt at Liu Example 2, right?

A Yes.

Q And does this fifth attempt -- withdrawn.

Does this fifth attempt at Liu Example 2 on Page 82 of your notebook have further tweaks to it over your prior four attempts?

A I'd have to, you know, go through the text word by word, but the major thing that I see is here I say stirring mechanically, which is what I

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hinted at before. That's the line below the one stir at 1:30.

Q And stirring mechanically, that's something you figured out you had to do based on your four prior Liu attempts for Example 2? Withdrawn.

A Yeah. That's what I was indicating -- the text, like I said, it's difficult to stir is an indication that mechanical stirring would be superior, and --

Q Just --

A -- so, you know, based on the smallest scale results, I chose mechanical stirring.

Q Okay. And just to make sure the record's clear, because I started to withdraw my prior question, I'm just going to ask it again, if that's okay.

A Okay.

Q Stirring mechanically in the experiment on Page 82 of your lab notebook, that's something you figured out how to do based on your four prior attempts to recreate Liu's Example 2?

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A I take a little issue with the wording, but I'll say that is something that I decided I should do based on the preliminary experiments and the fact that I was scaling up to a larger weight and a larger volume, which would be even more difficult to -- always is more difficult to stir by magnetic means.

Q The July 28th, 2023, entry, the very last line, there are four words. Can you read those, please?

A The very last line?

Q Yes.

A I think what you're referring to is it says, after high vacuum, parentheses, GEM.

Q What does that mean?

A GEM is the name -- I have a number of vacuum pumps, and one of them is called GEM pump, and that's -- they all have different characteristics, and so I note the name of it.

Q What was the yield of your July 28th, 2023, experiment?

A It says 27 percent.

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Q So it was less than your July 24th experiment?

A Yeah. 27 versus 3.

Q What was the yield of your July 27th experiment on Page 81?

A For some reason, it looks like I didn't want to spend the time doing chromatography and determining what the yield was.

Q Is that possible because it didn't work and you could tell by TLC or some other way?

A That appears to be the case. I haven't looked at this in two years, but the name of the two compounds, that from the fluid is one-half, and that from the clock is 1C with the appropriate numbers before it indicating the notebook and the page.

And then when you look at the TLC results, yes. Neither one of those contains -- 1F contains apparently none of the product, and 1C contains only a small amount. That's why I didn't do chromatography to purify.

Q So fair to say that your July 27th, 2023,

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entry attempting to follow Liu Example 2 yielded an incomplete reaction with no usable product?

A Little, little usable product. And I'm not sure -- looking at it right now, I'm not sure why that was the case, but I must have learned from it.

Q You concluded while performing that reaction that it wasn't actually worth the time to even try to go on and figure out what the yield was?

A Right. The TLC of the 1C fraction, if you will, the 1C material, indicated that there was some product, but mostly either starting material or some side product.

So, no, it was not worth going forward. And I'd have to look line by line to see why this -- why this happened.

Q Fair to say that this July 27th, 2023, attempt to follow Liu Example 2 was a failed experiment?

A Well, it -- it was an experiment that gave results, so it was a good experiment that way.

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Practically speaking, it didn't provide much product, but it did provide some.

Nonetheless, I must have changed the procedure somewhat and ended up getting a much better yield.

Q You mean from the -- withdrawn.

You mean you changed the procedure and ended up getting a much better yield in a subsequent experiment?

A Much better yield in subsequent experiments, yes. The 27 percent yield at the bottom of this page, and the 46 percent yield at the bottom of the next page.

Q The 46 percent yield, that's the experiment on Page 82 of your lab notebook?

A Yes.

Q And is this experiment, which is dated August 1st, 2023, the experiment that you used to generate the material that you then used in Example 3?

A I believe so. That would be on the -- for the next page -- well, actually, those things were

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also done on a small scale, but it would -- yeah. The -- that would be the material that I used predominantly going forward, in part because that's the material I had the most of.

I'm not sure if -- I could check, but I'm not sure if I had some of the material from the preliminary experiments or if I simply discarded it. I'd have to look to make sure.

Q Let's talk about the experiment on Page 82, please.

A Would you mind using the notebook numbers that are at the top of the page?

Q Not at all. I'll say those, and I'll also say the stamp numbers, if that's okay, just so the record's clean.

A Okay.

Q So if we look at what is Page 23 of the scan of your lab notebook, and that corresponds to the stamp Page 82, we see an experiment performed on August 1st, 2023, and the first line says, scale up 15-22-2 times 9.

Do you see that?

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A Yes.

Q What does that mean?

A It means what it says. Scale up the experiment, which is on the previous page, Page 22. That's the one that gave 27 percent yield. Scaled it up. You know, all -- all reagents were increased by a factor of 9.

Q Why did you increase all the reagents by a factor of 9?

A I was attempting to get a quantity of material 1 percent the weight of what Liu did so that I could carry on with Liu at that appropriate scale.

Q Why did you need to have a bigger scale than you had previously been doing?

A Well, the previous experiments that we discussed were just preliminary experiments, as I mentioned, to be carried out on a small scale so that I wouldn't waste material.

Now that I thought I had a reasonable procedure, I could carry those out on -- on a larger scale, and I wanted to ensure that I had

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enough material to go through the rest of Liu's procedure.

Q And in this experiment, you say that you dried the zinc bromide at 230 degrees Celsius; is that right?

A Yes.

Q And you were already using commercial grade anhydrous zinc bromide?

A I was using commercial zinc bromide, which I did not know if it actually had absorbed water or not. So this was probably the same batch of zinc bromide that I had dried at 230 degrees before.

Does that make sense?

Q Yes. Was it commercial grade anhydrous zinc bromide that you purchased, or you purchased commercial grade zinc bromide without regard to whether it was anhydrous?

A It was represented to be anhydrous.

Q Is drying at 230 degrees Celsius a standard way to get an anhydrous material, or are there other ways to do that?

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A That would be the most common way. I think if you look in Merck Index, it will reiterate that that's how you can dry even hydrous zinc bromide, but I'd have to check.

Q And, then, this reaction, unlike Liu's, was not exothermic; is that right?

A That's what my notes say, yeah.

Q And then it says, the next line after the 1:30, I assume p.m., time, slowly heat to 68 to 70 degrees over one hour?

A Yes.

Q Is that right?

And so this is a change to Liu's temperature, right?

A I believe Liu's temperature is 50 degrees.

Again, this is based on the results of my preliminary experiments.

Q Right. So you figured out in your preliminary experiments that certain aspects of Liu wouldn't work as written, and so you modified them so you could perform this experiment on Page 82?

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MR. MAHON: Objection; form.

A Yeah. I modified Liu's procedure, particularly the temperature, because I found that the lower temperature gave -- gave a poor yield. That --

Q And that was because -- I'm sorry. Go ahead.

A Maybe I'm not answering. And that may have been because of the surface-to-volume ratio issue where Liu was working on a larger volume.

Q And that issue was caused because of the difference in scale of your experiment and Liu's experiment?

A That's correct.

Q And then at the bottom of the August 1st, 2023, entry on the right, it says you obtained the material 15-23-1.

A Yes.

Q And then there's an August 11th entry in which it looks like you performed chromatography on that material; is that right?

A That's right.

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Q And, again, that was to remove impurities?
A Yes.
Q And then that yielded what you've written here as 15-23-1A?
A Yes.
Q Is 15-23-1A the material that you then used to attempt to recreate Liu's Example 3?
A Yes, but I -- I think on the next page -- let's see here -- yeah. On the next page, at least for preliminary experiment, I used -- the starting material was 15-21-2A. So it was an equivalent material but from a different lot.
And then I -- I think subsequently -- yeah.
Q So on Page 83 onto 84, this is another series of trial and error attempts at Liu's Example 3 now; is that fair?
A Yes.
Q Okay.
A Just to -- to answer your question, if you look at my notebook Page 25 --
Q I'm sorry. What page? I'm sorry. I know

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you said you prefer the top -- the top numbers.

A Yes.

Q Yes. Page 25 on the top right, Page 84 on the stamp. Yes, I'm there.

A Okay. About the fifth line, it says the SM, starting material, was a mixture of 15-22-2A plus 15-23-1A.

So -- and 9.99 grams total.

So there was that next step then on my notebook Page 25 was conducted using a mixture of those two, but it's going to be predominantly 15-23-1A, which is the scale-up that we just were talking about.

Q I see. And does 15-22-2A come from the July 28th, 2023, experiment on notebook Page 22?

A That's correct.

Q And so in order to perform Example 3 of Liu, you took some material from one of your earlier experiments and other material from a different earlier experiment, both of which were attempting to recreate Liu Example 2?

A That's correct, and both of which had the

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same major spot by TLC. So I judged them based on the history and the TLC to be essentially equivalent.

Q Okay. Are there differences between the July 28th, 2023, experiment on Page 22 of your lab notebook and the August 1st, 2023, experiment on Page 23 of your notebook other than the scale that you used?

A I'd probably have to go through it line by line, which would be tedious, but the major difference I see is the stirring was mechanical on notebook Page 23, and it was magnetic on Page 22.

Q Do you see the July 28th, 2023, experiment, it says, stop with ice water after four hours?

A I'm sorry. Where are you?

Q On Page 22 of your lab notebook, there's the July 28th, 2023, entry, and it says, repeat 15-22-1, which is the --

A At the top.

Q And then it says, but stop with ice water after four hours?

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A Yes.
Q What is the significance of that?
A That's a cursory repetition, since I was doing this over and over again, of the experiment a couple lines above it where it says pour the fluid onto ice water.
Q Okay. And in the July 27th, 2023, experiment, about -- one, two, three, four -- five lines down, it says, I think, heat 78 degrees Celsius bath equals 75 degrees internal?
A Yeah.
Q And because in this July 2028th (sic) experiment you're repeating this July 27th experiment, you would have done that same heating step to those same temperatures?
A Yes.
Q And in the July -- excuse me. Withdrawn.
In the August 1st, 2023, experiment, you're heating to -- from 68 to 70 degrees instead; is that right?
A That appears to be the case.
Q And so you're using some of the material

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from your July 28th, 2023, experiment in which you heated to 75 degrees internal and some of the material from your August 1st, 2023, experiment, in which you heated to 70 degrees internal, and you're taking all of that -- or portions of that and using it to attempt to recreate Example 3 as shown on Page 25 of your lab notebook; is that right?

A Yeah. I felt that I would do that because the TLC on both those samples was approximately the same. In other words, it was the same major compound and approximately the same purity by TLC.

MR. MILEA: We've been going for about an hour and 15 minutes. Would you like to take a break?

THE WITNESS: Okay.

MR. MILEA: We can go off the record now.

(A recess was taken.)

BY MR. MILEA:

Q Let's look at your Example 3 experiments, please, Doctor, and I'm now looking at Page 24 of your lab notebook, which is Page 83 of 95 in

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Exhibit 1003 in the IPR.

A Okay.

Q And it looks like on Pages 83 and 84, you're again doing some trial and error testing of Liu Example 3 this time; is that right?

A I would prefer to call it a preliminary experiment.

Q And the purpose of the preliminary experiment is to try to figure out what in Liu works and what doesn't work so that you can modify as appropriate and obtain the material that you need to go on to the next steps?

A Yeah. I would -- I would call it to confirm that the Liu procedure works on a small scale before I take all the material that I spent the effort to create in previous experiments. I don't want to waste that material, so I would perform them -- the next step on a small scale. And that's what I would do pretty much every time I do an experiment.

Q August 14th, 2023, looks like the first version of Example 3 that you performed, and it

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says you used 2.2 grams of zinc; is that right?

A Yes.

Q And what percentage scale-down was this from Liu?

A I would have to pull up Liu.

Q Yeah. Please --

A Do you want --

Q Yeah, yeah. Please go ahead and do that, and that's Exhibit 1003 in the IPR, and it's Paragraph 65 of Liu.

A Okay. So just going by the zinc and assuming I did everything else right, Liu uses 4.3 milligrams.

Is that what that says?

Q Yes.

A Okay. And I used 2.2 grams. So 2.2 -- I should do it differently.

43 divided by -- it looks like it is approximately a decrease in scale by 2000 fold.

Q Why did you choose a 2000 fold approximately decrease in scale for Example 3?

A I would really have to speculate that

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maybe the arithmetic was easy and I didn't want to make a mistake.

Q In the August 14th --

A It looks like --

Q Sorry.

A As I look at the numbers, it looks like I probably just divided all the quantities by 2000 because I felt that was an appropriate scale where I would gain information but not waste a lot of material.

I -- I think that's the answer, but I can't recall on that.

Q You say gain information. What kind of information?

A Well, you know, the same -- same kind of information that it -- that I gained with -- in Liu's Example 2. Does the reaction work, can I isolate the product, what is the TLC of the product, is it exothermic, is it not exothermic, things like that. The normal things that one would check for in a reaction.

Q The August 14th, 2023, entry on Page 24 of

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your lab notebook, about four lines down, you note that the reaction's exothermic.

A Yes.

Q Do you see that?

A Yes, I do.

Q What is the significance of that?

A Well, as I mentioned before, it's very important to note if something's exothermic because if it is majorly exothermic, significantly exothermic on a small scale, it is going to be very exothermic on a large scale and could get out of control.

So there's precautions that one could take to prevent that sort of situation. It is my practice always to do -- almost always to do reactions on a small scale first.

Q Is there less risk that the reaction creates a lot of heat in a potentially dangerous situation?

A No, it could create heat, it could create -- not this one, but a reaction could create a lot of gas, a lot of pressure, could be

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explosive. So it's good to have a small problem than a large disaster.

Q About two lines before the August 15th, 2023, entry, it says at the end of that line, stirring impossible after about two hours.

A Yes.

Q What is the significance of the fact that stirring was impossible after about two hours?

A Well, as I said before, it's mostly just an observation. It could be important for scaling up. If I don't note how it was stirred, chances are that it was stirred magnetically, and that when I scale it up -- we'll see if this is true or not. When I scale it up, I might have wanted to use mechanical stirring instead. We'll see if that's true.

Q Okay. And then if we go to the August 15th, 2023, reaction, it looks like -- there's a blank line, and then after that, it looks like you're discussing chromatography again, and then on the line after that, towards the end, it says, something badly where -- try high vac GEM

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on --

Can you -- do you know what that says?

A You are very brave for reading my -- attempting to read my handwriting.

Q My handwriting is terrible as well, so I can empathize.

A Okay. The word is foams.

Q Foams?

A It foams badly when you try to -- it's not good English, but when you try to high vac, when you put it on a high vacuum. My shorthand.

Q With the GEM vacuum that you have?

A Yes. And so the significance of that is to know that -- I mean, these are all things that you learn with a preliminary experiment. You asked why I would do a preliminary experiment. This is why.

So if it foams badly, presumably I prevented that from foaming -- prevented the foaming from making me lose product, but that would mean that when I do this again, I should use an oversized flask so that I definitely don't lose

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any material. As I recall, that's what I did.

Q Okay. And is this prior series of entries on Page 24 of your lab notebook just one attempt at recreating Liu Example 3?

A That's certainly what it looks like, yes.

Q Okay. And so let's please turn to the next page of your lab notebook, which is Page 25, or Page 84 of 95 if we're looking at the exhibit stamp.

A Yep.

Q Is this entry -- withdrawn.

It looks like this is an August 17th, 2023, entry.

A Yes.

Q And it says repeat times 14.65 scale.

Is that indicating that you're re-doing the experiment on the prior page, but you're scaling it up by 14.65 times?

A That's correct.

Q Why did you choose 14.65 scale?

A That -- I think the idea was to use up essentially all of the starting material, which is

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C -- on the fifth line where it says SM indicates the two blocks that were used in that 9.99 grams. That's about how much I would have.

Q So that scale-up was just a function of how much starting material you had and the goal was to just use all of it?

A Yeah, the starting material being the material from Liu Example 2.

Q Okay. And then two lines later, it says in the last part of the line, stirring impossible after five minutes.

A Yeah.

Q Do you see that?

A Yes.

Q Do you recall in Liu Example 3, Liu discloses, in Paragraph 65, stirring for six hours?

A Yes. It says the mixture was stirred and heated at reflux for six hours.

Q And so one difference between what you did and what Liu did was the time of stirring; is that right?

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A Not necessarily. I'm pretty careful at writing down what I observed. Since I followed this procedure with -- admittedly on a smaller scale, I think Liu may have stirred initially, and then stirring may have become impossible and he didn't notice it or he didn't bother to write it down. I think that's likely because the reaction is what it is. In my hands, stirring quickly becomes impossible, so I would think it's probably the same thing for Liu, and that he failed to note that.

Q So is it your testimony that Liu's statement that the mixture was stirred and heated at reflux for six hours a statement that Liu only stirred for five minutes?

A I can only hypothesize, but based on my results, I think that stirring would have been very difficult or impossible in Liu's case also.

But keep in mind it looks like I actually used magnetic stirring since I don't say mechanical. So Liu may have had -- especially for the large volume uses, he may have had a much more

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powerful stirrer, mechanical stirrer, and maybe he did. So I can't really say with certainty whether Liu was able to stir for the entire time.

But I will note that -- if you have ever heard the expression the proof is in the pudding, let's see, I got at the end of this a 59 percent yield, if you scroll down to the bottom of this page, whereas Liu got a lower yield. I think it was -- let's see -- you want to go -- okay. I'm looking at -- I'm looking at Liu Paragraph 65, and I want to go to Paragraph 66.

Can I control this or not? Okay. There you go.

Okay. Liu obtained 644 grams.

Is this the -- this is Example 3. Yes.

Q Yes.

A And I think I calculated this, and it is something like 37 percent yield, and I got a 59 percent yield.

So everything worked out. And, you know, I got almost twice the yield as Liu.

Q Why would the yield of your experiment be

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so much higher than the yield of Liu's experiment?

A Better laboratory procedure. No, I can only speculate. One -- one -- I don't -- I don't know. Maybe -- there are all sorts of possible reasons, but I'm happy to say that I improved on Liu's yield.

It really -- you know, you'd have to do more experiments and deliberately try to get a lower yield. It could be that -- one possibility is that my chromatography in the previous step removed other impurities that were still removed, but I -- I don't know. I shouldn't even say that.

It's really speculation because Liu says that HPLC indicated -- what was it, 97 percent purity after Example 2? Sorry. I don't know.

Q What are some possible differences caused by stirring a reaction on the one hand and not stirring the same reaction on the other hand?

A Again, that's an interesting question. So in my hands, it was stirrable initially, and then it wasn't stirrable.

If everything was originally homogeneous,

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then all the reacting molecules, the molecules that react with one another, would be very close together physically, and so it may not be necessary to stir even though it would probably be preferable.

So, you know, this -- I encountered this occasionally where you just can't stir a reaction after a certain period of time, but, again, the -- my results speak for themselves. I got a better yield than Liu did.

But, you know, Liu got a usable yield, and he continued with the synthesis.

Q Do you recall at this step that is in Example 3 you used an argon atmosphere -- excuse me, Liu used an argon atmosphere and you used a nitrogen atmosphere?

A Yes.

Q Why did you choose to use a nitrogen atmosphere instead of an argon atmosphere?

A They're basically interchangeable in reactions like this. The idea is to keep air and water vapor out of the reaction, and either argon

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or nitrogen are the two commonly used choices to accomplish that.

Q Where in your lab notebook, either on Page 24 or 25, does it specify the atmosphere that you used?

A I am not seeing it on Page 25. And looking quickly, I don't see it on Page 24.

So when I was writing up the results for my expert report, I probably -- I'm speculating a little bit here, but I probably noticed that Liu had said that he used an inert atmosphere of argon, and I added that information, realizing that I would definitely have carried it out under an atmosphere, and I know that the inert gas that I used was nitrogen.

Q On Page 25, does it give a sample number for the final product that you generated in that experiment?

A I believe so.

Q Do you see it anywhere? I'm just not seeing it, to be candid.

A Okay. Bottom of Page 25, one line from

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the bottom, it says -1AS -- nope. That's not it.

So two lines before that, the line that begins, then in vacua remains yields 7.72 grams, 59 percent -- that means yield -- solid. On that line, it says -1AP.

And that is the experiment number on Page 25. So the full number would be 14. It's the same on all these pages. It would be -- a lot of times I don't have the notebook -- so it would be 15-25-1AP.

Real quick, I may leave off the notebook number, and I leave off the page number because that's up at the top of the page. So that -- the number I mentioned is the full notebook number.

Q Okay. What does --

A Just -- just to follow that through, then the -- the TLC at the bottom of the page shows that the TLC for that sample shows apparently complete purity.

Q Okay. And combines after, it says 1AP, it says 1AS.

What is 1AS?

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A So there was a precipitate, apparently, which was dried in air, and then vacua, et cetera, melting point specified, and then one line from the bottom, it says evaporate filtrate yields 622 milligrams, white semisolid, and it looks like that's predominantly also the product by TLC, but it's a little bit less pure than the precipitate.

The SSR, I discarded that.

Q Okay. If you look, please, at your declaration on Page -- excuse me, Paragraph 55. Do you see right before the NMR information, you say that --

A I'm still -- I'm still trying to get to it.

Q I'm sorry. I thought you were looking at the screen. Let me know when you're there, please.

A Is it on the screen? Okay.

You put it on the screen?

Q It should be in the Zoom window. At least I'm seeing it in the Zoom window.

A And it's highlighted in blue?

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Q Yes.
A Great. Okay. I'm there.
Q So do you see right before the NMR information, it says that you generated a compound -- a mixture of E and Z, compound 3 -- I'm not going to try to read that.
Do you see that?
A Yes.
Q And then after that, it says 7.72 grams, 15-25-1AS?
A Yes.
Q Is that the final product from your Example 3 experiment?
A That's -- thank you for pointing that out. That's a misprint. You can see four lines up, on Page 25, that that should read 15-25-1AP, not AS.
Q Okay.
A I apologize there.
Q Okay. So the material that you generated from Example 3 that you would then go on to use in Example 4 is 15-25-1AP?
A Yes. And -- and so I copied that wrong.

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So the melting point is -- is also incorrect. It should be approximately 103 to 110. The NMR is correct.

Q Okay. Let's talk about Example 4, please.

So on Page 26 and Page 27 of your notebook, I believe that there are two versions of Example 4; is that right?

A I believe that's correct.

Q And then if you could please turn to Page 33 of your notebook.

A Yes.

Q It looks like this is another either version or part of Example 4?

A Yeah. It identifies it as such at the very top line.

Q Okay. What -- why are you reporting on Example 4 on 85 -- excuse me, on 26 and 27 of your notebook and then skipping ahead to Page 33 of your notebook? Why are those separated like that?

A Yeah. Well, this is the order in which I did the experiments. So if I have to dissect this a little bit, the experiment on Page 26 is the

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reaction of the material from Liu, Example 3, with a methylol mean and ethanol to give a little mixture of (E)- and (Z)-endoxifen.

That's at the top of my laboratory notebook Page 25. And then there's a further processing, according to Liu. That's toward the bottom. And then things got kind of interesting.

So I obtained a precipitate, which is designated 1X on this page, and a filtrate designated as 1S. And I think we talked about this before. This was -- this was where I used vacuum filtration to try to isolate the precipitate, but as it says, the filtration should have been done at minus 10 degrees, but with the small volume, that was difficult. It heated up, and I obtained only 16 milligrams of precipitate. So very little, I believe because it warmed up.

So that --

Q (Inaudible.)

A I'm sorry. What?

Q It warmed up on its own? I'm sorry. I didn't mean to interrupt you.

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A Yeah, it -- it warmed up on its own rapidly, which on a larger scale would be less of a problem. And so then I did another experiment where I did centrifugation, a quick centrifugation more reactively than I could do the filtration.

That is the first explanation for what's happening on these intervening pages.

Q Just for the record --

A (Inaudible) experiments after that, which are also on these intervening page.

Q Yes. And just for the record, Doctor, I think at some point in your answer, you referred to Notebook Page 25. You're looking at Page 26, right?

A Yes.

Q Okay.

A Sorry I misstated.

Q And on Page 26, the August 17th, 2023, entry says, starting material 15-246-1AP.

Is that right?

A Yeah.

Q So would that be the material that you

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created in the experiments that are on Page 24 of your lab notebook?

A Yeah.

Q And that was one of your dry runs at Example 3?

A Yeah, preliminary experiment.

Q Okay. And so you used the information from your Example 3 -- excuse me. Withdrawn.

You used the material from your Example 3 small-scale experiment in your Example 4 preliminary experiment; is that fair?

A Yes.

Q Okay. On Page 26, the August 21st, 2023, entry, says -- it looks like it starts with dissolve, and it goes on, and there's a second line, and in parentheses, it looks like scratch.

Do you see that?

A Yes.

Q What does that refer to?

A Scratching the, I think, side of the flask to induce crystallization.

Q Why did you do that?

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A I don't think I had any previous data, so probably just to ensure that there would be a precipitate.

In other words, it can help but not hurt anything.

Q On Page 27 of your lab notebook, it looks like you're repeating that experiment.

A Yes, using the material from my Page 25, rev 24.

Q Right. And the experiment you're repeating is the one we were just talking about on Page 26?

A Yes.

Q Can you tell from Page 27 whether you also performed that scratching step?

A I don't see any scratching here.

Q Given that --

A But apparently it didn't need it, because if I'm reading this correctly, at the bottom of -- of that first block of text before the blank line, it says that I got an 82 percent yield.

Q Then given that it says repeat on the top

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of Page 27, is that indicating that you did the steps of the prior experiment? Or I guess -- withdrawn.

Why does it say repeat on the top of Page 27?

A Two years later, I'm not certain why it said repeat, but I -- it either means that I repeated the reaction essentially as stated on the previous page but a larger scale, or it could just be an indication like, okay, I'm doing the same reaction. The conditions might be a little bit different. I -- I don't recall.

Q Do you see on Page 26 in the August 21st entry, there's a line, it starts at indented, and it looks like you're giving the melting point of the (Z)-endoxifen that you produced?

A Okay. I'm going to have to disagree with the summation of the question. I got a white precipitate, 16 milligrams. I state what the melting point was. I compare that to the literature, and then I -- then on the indented line, I say what the Z melting point was.

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At this point, I didn't definitively know whether I had the Z or the E or a mixture.

So then continuing on that line, I took the NMR and DMSL -- that means -- technically, DSMO, D6, and then I say that according to the '263 patent, which I believe is Song, that I obtained the (Z)-isomer, but according to '651, I had the (E)-isomer.

So it was a bit confusing. It took some time to decipher was going on. It looks like two more references on the final two lines of Page 26. So some people say it's -- most everybody except Song says that the NMR indicates that it is a -- I've got to take it back.

The MCL reference, Z, and Journal of Pharmaceutical and Biomedical Analysis apparently says it's E. So which one is it?

It took me a while -- getting a little ahead of myself, but eventually after carefully reading all the other references, I relied on the majority of references that said that that material was the (E)-isomer, and I looked

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particularly at Elkins, who carried out a more sophisticated NMR experiment called an NOE experiment, which rather decisively shows that the material that was the precipitate here was E.

But I didn't know that for weeks. But on the next page, we'll shed some light on what happened.

Q Why did it take weeks for you to find out?

A Well, historically -- well, let's see. It's not -- yeah, it's the page after this. Page 28.

Okay. So the top line references patents, the '651 is Liu publication, and the second one is the '263, which I believe was Song.

And Song discloses the very simple procedures for obtaining what he says is the (Z)-isomer. Much simpler than Liu. One step, recrystallized from acetone or methanol or ethanol, isopropanol. Then I repeated those and I got a nice crystalline material in most cases, but still the question was, am I getting the (E)-isomer or the (Z)-isomer?

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And eventually I looked at the NOE results and pulled the NMR results and concluded that Song was -- assigned the isomers incorrectly.

Q And so your conclusion was what? That you had the (Z)-isomer or the (E)-isomer?

A Okay. Two conclusions. One was that on Song's NMR the assignments were incorrect, which, by the way, Davies also agrees is the case. And the second was that these simple recrystallizations that Song used gave a precipitate which was the (E)-isomer, which was not desired.

So I had to then use the more elaborate procedure of Liu.

Q Let's please look at Page 27, the August 25th entry.

And am I right that the end result of the first block of text before the blank line is that you obtained a 52 to 48 mixture of (E)- to (Z)-endoxifen?

A Yes, which, I believe, is identical to Liu.

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Q And that sample is designated 15-27-1?
A Yes.
Q And then it looks like after the blank line, you say, repeat with starting material.
Do you see that?
A Yes.
Q And then what's the word after starting material?
A Less pure, 15-24-1AS and 15-25-1AS.
Q Okay. And let's just take each of those separately, please.
15-24-1AS, that would come from your experiment on Page 24; is that right?
A Yes.
Q And that one is referring to -- withdrawn.
And on 24 is one of your versions of Example 3 of Liu, right?
A I'm sorry. Say that again.
Q On Page 24 of your notebook, that is the first attempt at Liu Example 3 that you performed?
A Yes.
Q And that one, if you look at the bottom, I

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believe right above the NMR diagram, says, -1AS.

A Right above the TLC diagram.

Q I'm sorry. Right above the TLC diagram, it says -- let me just re-ask it. Withdrawn.

On Page 83, right above the TLC diagram -- and this is lab notebook Page 24 -- it says 1AS.

A Yes.

Q And that would be sample 15-24-1AS?

A Correct.

Q And that is the sample with which you experienced some bad foaming when you tried to vacuum it?

A No.

Q What sample was the 1AS sample?

A That was the filtrate.

Q That was the filtrate. Okay. Where did that come from?

A It starts on the line that begins with the date 8/15/23.

Q Okay. And this material that you used for stirring with heptane, that was not the material with the foaming? That was something else?

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A That was the material that foamed. That would be the material that led to 1A. So it's a step before that.

Q Okay. So just to make sure I get it all in order, the material that foamed badly was 1A, right?

A Yes.

Q And then 1A you stirred with heptane, and that produced what?

A That produced a precipitate and filtrate, and the -- I don't know if we discussed this. It looks like on my copy, the -- the end of the sample number is cut off. So the last line of the text reads -1AS, and the last -- and the sample number before that should be 15-24-1AP.

Q Okay.

A And you can see, by TLC, that they're both same material and both totally pure to the extent of TLC detection.

Q Now let's please go back to Page 27 of your lab notebook, and we just talked about this repeat with starting material less pure 15-24-1AS.

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The other part of that starting material is 15-25-1AS; is that right?

A Okay. You were -- you were kind of the second paragraph of Page 27, right?

Q Yes.

A Okay. Yes, that's correct.

Q 15-25-1AS comes from the experiment you performed on Page 25 of your lab notebook, right?

A Yes.

Q And two lines up from the bottom, it refers to 1AS.

Do you see that? On Page 25.

I'm not sure if the court reporter heard your answer.

A The answer is yes.

Q Okay. So if we go back, please, to Page 27 of your lab notebook. The result of using 15-24-1AS and 15-25-1AS as your starting material was what you've called 15-27-2, right?

A Correct.

Q Then if you could please skip ahead to Page 33 of your lab notebook.

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A Okay.

Q Is this where you were performing the second part of Liu Example 4?

A Yes, meaning this is where I attempt to separate the (E)- and -- or partially separate the (E)- and (Z)-isomer.

Q If you look at your purification scheme at Paragraph 71 of your report -- I'm sorry. That's Paragraph 71 of Liu. Paragraph 71 of the declaration.

A Yep.

Q Do you see your purification scheme at Paragraph 71 of your declaration?

A I see it, but it's cut off at the bottom.

MR. MILEA: Can you please scroll down? Thank you.

Q And so the step that we're talking about on Page 33 of your lab notebook, that's the very first step in this diagram which says acetone recrystallization?

A Yes.

Q And in your purification scheme, you say

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that you used 15-27-1, right?

A Yes.

Q And in --

A Now, in reality, I used predominantly 15-27-1, but I also combine that with 15-27-2 because the two were identical by TLC.

Q How do you know that you used predominantly 15-27-1?

A Because going back to Page 27, I generated over 7 grams of 15-27-1, and only 642 milligrams, less than -- less than 1/10th the amount of 15-27-2.

And even -- even if I used all of 15-27-2, that 642 milligrams, that would be less than half of the amount indicated on the second line of my lab notebook Page 33.

So strictly speaking, the top line on my diagram on Paragraph 71 of my report perhaps should read 15-27-1 plus 15-27-2, but I didn't want to confuse things.

Q If you turn back, please, to Page 27 of your lab notebook.

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A I'm there, on that page.
Q Sorry. Do you see there's a 9/19/23 entry?
A What was the date, 9 --
Q I think it says September 19th, 2023, on Page 27 of your lab notebook.
A Yes.
Q And then on the next page of your lab notebook, Page 28, the first entry is September 8th, 2023.
A Yes.
Q Why are the entries out of order there?
A Usually I'll put related information on the same page. Usually that's in chronological order.

In this case, I did the experiments above starting on September 25th. I got the material out, the material being 15-27-1, and then I wanted to take an HPLC of that material.

Now, I have an HPLC in my lab, but it takes -- it takes some time to set it up and find the solvent system, inject the compounds.

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So logic, so that's -- that's why it took something like three weeks to run the HPLC. It's on this page because logically it fits on this page. It is the HPLC of 15-27-1, and so logically it would not belong on the next page, that is Page 28.

Q Why did you run HPLC of sample 15-27-1?

A 15-27-1, according to NMR, is 52 to 48 percent E and Z. Several of the prior art citations describe HPLC using the rare and elaborate column in which HPLC can separate the E from the Z.

I wanted to use a regular available column that I had at hand, which is what's referred to on the second line where it says, column like a sphere RP18. I go on to give the dimensions, et cetera, the UV absorbance for the detector, and I mention what the solvent is, and I found no separation.

Then I used a different solvent, and it says possible shoulder, meaning there didn't really seem to be significant separation, if any.

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What I was trying to do here, the objective of this experiment was to see if I could use this more readily available column and get separation, analytical separation of the isomers so that I wouldn't have to send each sample out for IMR [sic], but that didn't succeed; so therefore, all samples were analyzed for E and Z content by NMR, which Dr. Davies acknowledges is a legitimate way to determine the isomeric ratio.

Q I think you mentioned -- and I'm hoping we can move through this quickly if my recollection of what you mentioned is correct -- on Page 28 of your lab notebook, were you trying to recreate experiments from this WO 2012/050263 reference?

A That's Song, correct?

Q I'm not sure what the named inventor is on that reference, but I can tell you.

Yes, that is the Song reference.

A Yeah.

Q As best as I can tell.

A This is -- yeah. I'm pretty sure it is. I think I already answered that, but Song presents

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a -- or discloses a way of separating the alleged Z from E by recrystallizing from these solvents acetone or methanol, methanol -- I think isopropyl, maybe ethyl acetate.

Very seq-quant procedure. Unfortunately, Song missed a sign of the E and Z NMR signals, and it took me a while to figure that out, but it was a great way of producing E, but that's not the final product that we want.

So the experiment's on Page 28. I learned something, but they weren't particularly useful for producing the (Z)-isomer.

Q So all of Page 28 is your attempt at performing Song's methods?

A I would have to check. I -- I think Song reported all of these solvents, but I might have -- I might have used one additional that I came up with myself.

Q Let me ask it another way. Page 28, are you attempting to recreate Liu at all on this page?

A No.

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Q And then on the top of Page 29, the August 15th, 2023, entry, is that also Song?

A I don't recall it. I'd have to look at Song, which I can easily do.

Q Is the August 15th, 2023, entry an attempt at recreating Liu?

A Don't think so, because Liu, as you know, recrystallizes from acetone, and then isopropyl acetate, which this is, and then acetone again.

I can get Song right in front of me, if you wish.

Q I'm not sure we need to look at Song, but perhaps we can come back to that.

Can we please skip to Page 31 of your lab notebook?

A Okay.

Q And up at the top of this page, it says '651 Paragraph 70.

A Yes.

Q Is Paragraph 70 part of Liu's Example 4?

What are you doing here on Page 31 of your lab notebook with respect to Liu Example 4?

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A I missed the last part of your question. What are we doing what?

Q What are you doing here on Page 31 of your lab notebook with respect to Liu Example 4?

A I'd have to check to make sure, but it looks like it is an attempt to reproduce Liu's conditions from Paragraph 70.

Q Do you see you've used 15-27-1, which is the material you generated from one of your recreations of Liu Example 3?

A Yes.

Q And then if you skip to second -- the second line from the blank line at the bottom, it says, 80 percent Z plus impurities.

A Yep.

Q What is the significance of that?

A It is what it says. I got an 80/20 mixture of Z and E, so the 80 is great, and there are impurities.

And this information would have been from NMR.

Q What -- withdrawn.

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Do you know why you generated those impurities in this example?

A They were probably present in 15-27-1. And, you know, I -- I can access that NMR and let you know. My recollection is that the impurities were relatively minor, but they would disappear and be carried forward to additional crystallization steps, and those impurities should vanish, and I believe they did.

Q Okay. The second line from the very bottom of this series of entries says, very little precipitate after nine plus days.

What's the significance of that?

A Exactly what it says, that there wasn't very much precipitate after nine days, and then after an additional -- looks like two months, there were some needles, but not much material was obtained.

Q What does needles refer to?

A Needles is a term we use to describe a precipitate that is probably crystalline, almost certainly crystalline, and it is in the shape of

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little crystals that kind of look like miniature needles.

Q So what you found here in this attempted recreation of Liu Example 4 was that you were unable to get crystals?

A Not -- not very much precipitate.

Q And did Liu Example 4 get precipitate?

A I'd really have to check on -- check on this, but -- yeah. If you put the flowchart back up, that's the easiest way to decipher what's going on. The -- that's from my Paragraph 71.

Right. Okay. So the experiment on Page 31 didn't work very well. I could take a look at this and try to explain why that is. I don't know off the top of my head.

Then I figured out how to do the first -- I accessed recrystallization in a different way, and that is indicated in the notebook Page 15-33-1P.

Q Is this experiment on Page 31 an example of a time that you tried to follow Liu's Example 4 but produced no usable material?

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A I -- I'd have to go through this. I knew at the time, but I don't know sitting here today what happened here. We can figure it out if I look at Page 33.

I think I deviated somewhat from Liu's procedure, and that's why there was no precipitate.

MR. MILEA: Why don't we take a ten-minute break.

THE WITNESS: Okay.

MR. MILEA: Or more if others need it, but we can go off the record.

(A recess was taken.)

BY MR. MILEA:

Q Doctor, can we please look at Page 30 of your lab notebook?

Are you there on Page 30?

Doctor, do you have Page 30 of your lab notebook?

A Yes.

Q Okay. Sorry. I couldn't hear you.

Is Page 30 one of your attempts to

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recreate Liu Example 6?

A Based on the heading, it is recreation of Paragraph 73.

Q And if you look at Paragraph 73 of Liu, do you see that as part of Liu Example 6?

A I need to scroll down.

Could you scroll down a little so I can take a look at 73? That was the example. I think I saw that that was example -- yeah, well, apparently it's Example 6. Yes.

Q Would you mind please just scrolling up to the -- yeah. Thank you.

So Paragraph 73 of Liu is Example 6 of Liu?

A Yes.

Yes, that's correct.

Q Okay. Thanks. And do you see the October 12th, 2023, entry right at the top of Page 30 of your lab notebook?

A Yeah.

Can you hear me okay?

Q Yeah, sorry. I'm looking at my notes, but

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I did hear you. Thank you.

And in this entry, it looks like you're combining several different samples from your prior experiments; is that right?

A That's correct, yes.

Q And you report in the bottom of this entry right before the blank line that you obtained 100 percent E.

Do you see that?

A Yes.

Q And 100 percent E is 100 percent (E)-endoxifen?

A Yes.

Q Next to that, you write, XRPD not Form 1.

Do you see that?

A Yes.

Q How did you know that you had achieved not Form 1 in this experiment?

A I just want to point out what the purpose of the experiment is. If you look at the first line, I combined those samples. All of those samples were (E)-endoxifen precipitates, and then

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I re-crystalized -- what I'm doing in this little paragraph that follows is recrystallizing those from refluxing isopropyl acetate.

And then the one that you referred to, I had 100 percent E. So there was purification achieved. I get crystalline material, and I submitted that for SRPA, and the result did not match that for Form 1, and the reason for that is that this was recrystallized from isopropyl acetate. In order to get Form 1, blue recrystallizes -- well, I'm sorry. What's the word that you used? Delete that.

This is not Form 1. This is -- there's another one that my verbiage applied to. In this case, I got 100 percent E, and E is never Form 1. Z can be Form 1.

Q Were you expecting to get 100 percent E from this experiment?

A Yeah, I think so. I sort it off as E precipitates and recrystallizes, and so I would expect, you know, recrystallization of E would give E.

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Q What is the purpose of this experiment on Page 30 of your lab notebook?

A That's a good question. I can't be certain in retrospect. Well, actually -- actually, looking at this for a second, I think I know what I'm doing.

This material on the -- on the first paragraph of Page 30 is the precipitate which was 100 percent E, is called 15-30-1P, and then that is the material used in the second step where it says 10/16/23.

So that was refluxed with isopropyl acetate, was stirring for ten hours, cooled to 30 degrees, et cetera, and without going through the whole thing, but the bottom line at the end of that experiment was that I got 68 percent E, which is to say 68 to 32 percent E to Z.

So what this experiment shows or confirms is what Liu states, which is that if you treat the (E)-isomer with refluxing isopropyl acetate, you get isomerization to a mixture of Z and E. That's the purpose of this experiment.

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Q Where does Liu say that?

A Certainly in his disclosure where he talks about isomerization. He says that -- as I recall, he says that you can print the (E)-isomer with resolving solvent, and I think he gives several different solvent examples, and it isomerizes.

Furthermore, I think if you go to Example 8. You want to scroll down?

Q I don't believe there's an Example 8.

A You're right. Okay. Then there's a heading actually above this that says something like isomerization and recrystallization of the (Z)-isomer. So scroll up, please.

Q Is it the Example 6 heading you're thinking of? Right there at the bottom of that page.

A Oh, there it is. Yes. And so you'll see, I think, in the paragraph that starts on the next page -- yeah. Endoxifen, there's a ratio of E to Z, 70/30, suspended isopropyl acetate, heated at 85 degrees for two hours, the E to Z ratio is determined to be 1 to 1.

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So there's that -- the example shows what I summarized.

Q And so this is one of your attempts at performing Example 6 of Liu?

A Yes.

Q And going back to the October 12th, 2023, entry, where it says XRPD not Form 1 --

A Yep.

Q -- how did you know it wasn't Form 1?

A I submitted the samples to Steve Miller at H and M. He ran the XRPD, and it was distinct from Form 1.

Q How was that reported to you?

A He sent the -- he sent all the data that he normally sends, which included the -- what's called the diffractogram. That's kind of like -- looks kind of like a spectrum, and then he sends also the crude data, which is recorded in degrees and intensity. It's a whole long table.

It's generally, for me, most instructive to look at the diffractogram, the visual display.

Q Are those data that you discussed anywhere

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in your declaration?

A Probably not because it doesn't prove anything. It just proves that the (E)-isomer isn't Form 1, which you wouldn't expect it to be.

Q Is the end result of your experiments on Page 30 the 4S sample at the bottom?

A Yep.

Go ahead.

Q Well, before we go to that, I have a couple more questions about this October 12th, 2023, entry.

Why did you decide to send it for XRPD analysis?

A I -- you know, I can only speculate on -- that perhaps I wanted to be sure that I got my NMR assignments correct.

If the material that I believe -- everything's an experiment. If I -- if I suspected the material that was 100 percent E was actually misassigned to 100 percent Z, if it had come back as being Form 1, I would have had to rethink everything that I did.

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Does that -- does that make sense to you?

Q I think I understand. So you were worried that perhaps your results were wrong and you wanted to check to make sure they were not at this point?

A Right. It was just an additional reassurance, because as you can imagine with all the contradictory NMR information from the different references, there was some chance that -- that Liu's example -- Liu's assignment of Z and E could possibly be wrong, and this experiment was -- where I said was not Form B [sic] is actually reassuring.

I think I -- I think I made these -- that's not Form 1. I think I said something else by mistake.

Q Thank you. I believe you said Form B.

A Yeah. So, correct. Correct.

Q If you can please turn to Page 34 of your lab notebook.

A Okay.

Q And up at the top -- wait. Excuse me one

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second.

Please turn to Page 32. I'm sorry.

And do you see up at the top an entry for October 24th, 2023?

A Yes.

Q And then here you're dissolving the 4S material that you got from your work on Page 30 that we were just discussing; is that right?

A Yes.

Q And what are you attempting to do here on this page?

A I'm attempting to -- let me take a look at Page 30 to see what's there.

Okay. Compound, which is 15-30-4S was used in the procedure that we're discussing, that material is an 78 to 22 percent mixture of Z and E.

In other words, it's rich in Z, but it's not -- it's not a sufficient purity. So, therefore, it was recrystallized from isopropyl acetate, and that gave -- on the top of -- on the top of Page 32, that gave 97 percent of pure Z.

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That is 97 to 3 Z to E.

Q I'm sorry.

A So that -- that was submitted -- that was before XRPD, and that was also not Form 1, even though it was 97 percent pure Z.

Now, I guess I'll -- I'll just beg the question, if that's the right word, why is it not Form 1? Because it was recrystallized through isopropyl acetate rather than acetone. What Liu teaches is that in order to get Form 1, you must recrystallize from acetone.

And just proceeding, logically, go to the next line, the next experiment performed -- performed on 10/24/23, basically it was recrystallized from acetone, and I got now the sample that is 1532-2P, and that is Form 1.

So, again, recrystallizing from acetone gives you Form 1; recrystallizing from isopropyl acetate gives you a different form.

Q And the October -- withdrawn.

In the first October 24th, 2023, entry, what were you attempting to do?

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A I guess I was attempting to see if the recrystallization from isopropyl acetate would increase the purity that is the Z content, which it did, and also wanted to determine whether the crystals that were formed would be Form 1 or not Form 1, and they were not Form 1.

Q Why did you want to know that?

A I guess to just understand the system, what was going on, and how one could obtain the Form 1 sample. So I was -- I guess you could say I was purposefully deviating from Liu. That's my recollection.

Q And were you -- other than changing the acetone to isopropyl alcohol [sic] in this first entry on October 24th on Page 32, did you make any other changes to Liu's procedures?

MR. MAHON: Objection to form.

A The first line says IPR OAC. That's not isopropanol.

Q I'm sorry. Isopropyl acetate, thank you. So let me -- let me re-ask the question.

The first -- withdrawn.

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The first entry on Page 32 of your lab notebook says that you dissolved 15-30-4S in isopropyl acetate; is that right?

A Yes.

Q And that it was refluxing?

A Reflux.

Q Okay. Was this a modified version of Liu Example 7 that you were performing in this first entry on Page 32 of your lab notebook?

MR. MAHON: Form.

A Reading it today, it doesn't look like it. Paragraph 76 is a recrystallization from acetone, whereas I recrystallized from isopropyl acetate in this particular experiment.

Q Other than the change from acetone to isopropyl acetate in this experiment, were you attempting to reproduce Liu Example 7?

A I'd have to look carefully, but since the solvent is different, it doesn't even matter if everything else is the same.

Q Do you see in the left column of Page 32 under the 10/24/23 date in the first entry, it

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says, reference 6510054?

A Yes. As I said, you've looked at my lab notebook more recently than I have. So, yes, let's go to Paragraph 54 of --

Q Liu?

A Liu, the Liu patent -- Liu publication.

I think he gives -- he gives some -- it's right at the end. You may have to scroll down.

Yeah. So in Paragraph 54, he says, in some embodiments, the third solvent is isopropyl acetate.

If that means -- I'd have to go through this whole thing, but if that means that the final solvent that was used was isopropyl acetate, then, in fact, I was attempting to reproduce Paragraph 54 as I understood it.

That did not give Form 1.

Q Do you know what third solvent in Paragraph 54 Liu is referring to?

A That's defined in the paragraphs above where he says the first solvent can be chosen from -- and it gives a list, and it could be a

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second solvent, and it gives a list, and then he says sometimes there's a third solvent, and the solvent can be another list, and here he's refining that, narrowing it to saying in some embodiments, the third solvent is isopropyl acetate.

So that was what I was following thinking, well, maybe that will work.

Q Is the third solvent referring to a solvent that's supposed to be used in Liu's example seven, in the third step of example seven?

A You'd have to read the paragraphs and the disclosure very carefully in order to be sure of what that refers to. I think it's what I just said. It's a very long paragraph, which defines the first, second, and third solvent.

You could scroll up there, if you'd like.

MR, MILEA: Yes, please. Please do scroll up.

Q And, Doctor, please see if you can answer that question by reading Liu.

A I'm looking for a long paragraph. I'm not

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reading every word. Just looking for a long paragraph. Probably before that.

Q Perhaps Paragraph 26?

A Yeah, okay. This is the area.

So here in Paragraph 26, it's talking about the second solvent, and it's a long paragraph.

Then logically after that somewhere it would define what the third solvent is. I think it's before that.

And before any of this, he would define what the first solvent is. It would be -- it would be before this. It's before that big -- okay.

So this is Paragraph -- what number was that? 21, I think.

Q It may -- it may be helpful if we look at Paragraph 46.

A Wow, there's even a fourth step, but I'm not sure that that is the fourth solvent.

Frankly, what Liu is doing here is he's taking the examples that he actually carried out,

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which we've been discussing, and I think he's disclosing options beyond -- I guess the word is his teaching alternatives which could be considered.

Q I see. So Paragraph 46 of Liu is a different embodiment than Example 6 of Liu?

A Without reading it carefully, my recollection is that 46 is -- now, I'm not even -- reading this now, from my recollection, Paragraph 46 would be a broadening teaching beyond the examples --

Q Okay. So it's not --

A -- the examples that were recorded. I'm sure he did other experiments that he did not report.

Q Paragraph 46, then, is just a different procedure than Example 6; is that fair?

A I guess I'd have to read it carefully. Could you scroll up so I can see all of Paragraph 46?

It's that long? Okay. Could you unhighlight it, please? Thank you.

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Okay. Got it. No. Paragraph 46 is actually very important. It's not -- what I may have said about it is -- is -- previously is incorrect.

As he says, this is a -- another step, a fourth step which involves isomerizing -- what he says here is isomerizing the (E)-endoxifen to a mixture of E and Z, which he says at the bottom of that 46 to (E)-endoxifen -- sorry -- (E)- to (Z)-endoxifen of approximately 1 to 1, which is to say approximately 50/50.

So this is -- this is actually very important in the process. I -- Liu reports -- Liu discloses, and I confirmed, that it's pretty easy to get a highly enriched sample of the (E)-endoxifen which is free of other impurities, and what Liu is teaching in 46 is that you can take that material that's essentially pure (E)- with very few impurities, reflux that in isopropyl -- well, does he say isopropyl acetate? That's what he means.

Reflux that in a solvent, and isomerize

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the E to partially Z. And then what he doesn't say here yet is that then you can crystallize out the Z, ideally from acetone, and get Form 1 of the -- of the Z iso.

And that -- all of this is I think best illustrated in the flowchart that I presented.

Q Okay. Just so I understand, are you saying Paragraph 46 is a separate experiment than Example 6?

A It's -- I think we just saw that it is in Example 6 in the portion that's entitled, essentially, isomerization and recrystallization of (Z)-endoxifen. It's the one we just saw.

Do you recall that?

Q Are you referring to Paragraph 73 or 74 of Liu?

A Probably. Let's scroll down.

So it's not Example 7. It must be Example 6. Which -- which paragraph number did you say?

Q 73 and 74.

A Okay. Yeah. Yeah, it says here

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endoxifen, suspended in isopropyl acetate, heated to 85 degrees for two hours, whereas in Paragraph 46, I think he mentions up to four hours.

Q So in Paragraph 46 is a different way -- withdrawn.

Paragraph 46 is an exemplary embodiment in Liu; is that fair?

A I'm not quite sure of the legal terminology, but if I say it in layman's terms, 73 gives you an actual procedure, which in the end is 48 percent (Z)-isomer, I believe. No, sorry. 73 percent Z.

So it's 73 to 27. So it's highly enriched in Z.

So that's fair, 73. Again, it gives an actual procedure for an isomerizing so that you get enrichment in (Z)-isomer.

Paragraph -- what was it, 40 --

Q 46.

A -- 46 is a general disclosure of how this could be done. It doesn't -- it doesn't give the

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quantities. It gives a range of times, et cetera. That's the difference between the two, but they're -- the general procedure is the same.

Q So Paragraph 46 gives different times and different temperatures -- withdrawn.

Is Example 6 a specific way of doing the general procedure described in Paragraph 46?

A I think that's fair.

Q And Paragraph 46 is describing alternative ways that one might perform the isomerizing procedure of Liu?

A I'd word it a little differently. It gives a range of conditions in Paragraph 73. It gives precise conditions.

Q And some of the conditions in Paragraph 46 are different than those in Paragraph 73, right?

A Well, I'd have to look at them side by side, but as I recall, Paragraph 46, is it?

Q Yes.

A Paragraph 46, for example, says -- I think says one to four hours.

Q .5 to four hours.

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A Okay. So it's a range, whereas Paragraph 76, was it?

Q 73.

A Okay. Too many numbers. 73 says for two hours, right?

Q Yes.

A Yeah. So it's more specific, and it gives the exact amount of endoxifen and the ratio. It gives the details.

Paragraph 43, is that the other one?

Q 46.

A Okay. I'm going to write these down, if you don't mind.

Q Okay.

A It's 46 and 73, right?

Q Yes.

A Okay. So 73 gives -- gives the exact quantities, volumes, temperature, time. 43 is broader. It gives a range of temperatures. It gives how rapid cooling can be, very broad range. Where did the -- where did the hours go on Paragraph 43?

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Q Paragraph 46 you mean, right?
A No wonder. Okay. Sorry. Yeah.
Let me -- let me start that analysis all over in case I made a mistake.
So the process in 46 is described as an isomerization step, and it gives the ratio of the starting mixture of E and Z, and it says that you heat between 60 and 100 degrees.
And in contrast, in Paragraph 73, it's the boiling point of isopropyl acetate, which is 89 degrees. So it falls within this range.
Paragraph 46 says 0.5 to four hours, and Paragraph 73, I believe, says two hours. So, again, it's midway between the range here.
Q So the ranges in Paragraph 46 are broader than the specific values in Paragraph 73, right?
A Yes, as is, in my experience, typical in patents.
Q And so it's possible to follow Paragraph 46 without following Paragraph 73?
A It would be possible literally to do so. One would have to do experiments to see what that

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gave you, because the only -- to my knowledge, the only experimental result about what you get is in Paragraph 73.

Q Right. But you could, for example, following Paragraph 46, use a temperature of 60 degrees and a time of .5 hours, and that would be a different experiment than was disclosed in Paragraph 73, right?

A Yes.

Q Okay. I want to look at the second entry on Page 32 of your lab notebook, please.

A Okay.

Q And this one, it looks like you're now dissolving a sample 15-30-3P in refluxing acetone.

Is that right?

A Yes.

Q Is this -- withdrawn.

What example of Liu are you attempting to follow here?

A Well, first, it's really much easier with the flowchart, but if you don't want to do -- if you do want to do that, that would be great.

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Q Well, I'm happy to look at the flowchart. It's a lot of flipping back and forth, which I was trying to avoid, but I want to make this as easy as possible for you.

So we can look at the flowchart, and that's Paragraph 71 of your declaration.

A Yes. Okay. Great. So the experiment you're asking about is the generation of -- I believe of 15-30 -- no. You're asking me about 15-32-2P, right?

Q Yes.

A Okay. That's not on here. That's not on the flowchart because even though it generated Form 1, the purity -- the ratio of Z to E was 88 to 12, which is below the 90 percent that is specified by Atossa.

But it did -- did get Form 1, and I'm certain that if I recrystallized this again from acetone that I would still get Form 1 and a higher percentage of Z than 88 percent.

That's -- that's why this is, unfortunately, not -- well, to prevent confusion,

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that's why it's not on this flowchart.

Q What example of Liu were you trying to follow here?

A In which experiment?

MR. MAHON: Objection; form.

Q In the second -- in the second entry on Page 32.

MR. MAHON: Objection; form.

A I guess that brings us back to the notebook. I'd have to look at what went into this step.

There was a lot of experimentation that I performed in preliminary experiments and didn't include them in this flowchart because they only confuse them, is my opinion. But -- okay.

So if you look at Page 30 of my notebook -- we already looked at that. So I get on 15-30-1P is essentially pure E, then I reflux that with isopropyl acetate for ten hours. We discussed that. I get a mixture Z and E, predominantly E. I take that, I dissolve it in acetone, refluxing, cool, and now I get a

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precipitate that's 78 -- we talked about this -- 78 percent. So let's say 78 to 22 Z to E, and that is the material that is 15-30-3P, and that's the material that was used on Page 32. So there I recrystallize that material from acetone and get Form 1.

So this would be a reproduction of -- of Liu's procedure.

Q So Page 30 was a reproduction of Liu Example 6, right?

A Yes, that's correct.

Q And then you put that material, and on Page 32 in the second entry, you reflux that in acetone pursuant to Liu's example seven; is that right?

A I think that might still be 6. Want to scroll down?

Q So if we look at Paragraph 73 of Liu, which is part of Example 6, it just says that the material was suspended in isopropyl acetate that was heated at 85 degrees for two hours.

And what you did in example -- excuse me,

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in the second entry of -- on Page 32 was dissolve material in refluxing acetone, right?

A That's correct. So we have to find -- maybe -- it looks like that would be example seven, if you want to --

Q Okay.

A -- scroll up. Yeah, Paragraph 76.

Q And would dissolving something in refluxing material be the same thing as suspending it in hot material?

A What -- what are you referring to in terms of hot?

Q So in paragraph --

A Hang on --

Q I'm sorry.

A Hang on for a second. So, wait. I know that this is complex, following my notebook and my handwriting, but we were talking about the origin of sample 15-32-2P, and that was created by refluxing in acetone and then cooling.

So I'm comparing that to the percentage or two of Paragraph 76, which is refluxing in

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acetone.

Q And I was -- I was looking at Paragraph 73, just to make sure I understand all the differences between the October 24th entry and this part of Example 6, because I think you testified that it wasn't recreating Example 6, and I wanted to just understand the differences.

So in the October 24th, 2023, entry, you said you dissolved this material in refluxing acetone, right?

A Yes.

Q And in Example 6, Liu is saying that material was suspended. So that's one difference, right? You dissolved the material in the October 24th entry, and Liu suspended it in Paragraph 73. Is that a difference?

A I think you have to understand that this -- this whole thing is a process, and Liu is explaining how to get pure (Z)-isomer, and there are at least three steps which are actually in that flowchart that we're looking at.

There's first a -- I would say a

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preliminary recrystallization from acetone, followed by a recrystallization and sometimes isomerization, optionalized isomerization from hot or refluxing isopropyl acetate, followed by a recrystallization from acetone.

So I know it seems a little complicated, but that's -- that's what it is. So you're confusing this isopropyl acetate step with the acetone step.

Q I see. But just focusing on the suspending versus dissolving, are those important differences?

A Well, maybe, maybe not, but it's a different -- it's a different step of purification.

Q Okay. So you're saying that the second entry on Page 32 is an attempt to perform Liu's example seven, recrystallization procedure, which is in Paragraph 76 of Liu?

A Correct.

Q Okay. So what you found in performing Liu's example seven recrystallization procedure,

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you got (Z)-endoxifen, which was 88 percent pure, right?

MR. MAHON: Objection; form.

A Yes. 88 percent Z, 22 percent E, Form 1.

Q How did you know it was Form 1?

A As before, I think -- the only way I ever know anything is Form 1 or not Form 1 is by submitting it to H and M for XRPD.

Q And how were those results reported to you?

A The same as before. Diffractogram and a list of the peaks by degree and the intensity.

As I said before, the diffractogram, which is a visual portrayal, is easier for me to visualize than the numerical tables, but the numerical tables are more precise, but if you -- if you look at the figure of the diffractograms, you can see at a glance that the Form 1 that I obtained corresponds precisely through the Form 1 that's recorded in -- or disclosed in the two (inaudible).

If you'd like to see what that looks like,

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you could scroll down to find that in this report, my report.

Q Just to be clear, these specific diffractograms that you reference in the October 24th entry, those are not in your report, right?

A That would -- let's see. One is and one isn't. The one that's not Form 1, I saw no reason to report. The one that -- both samples were submitted at the same time. I would have those diffractograms, if you'd like.

Q Is it in your declaration, or you just have that in your files?

A I would -- I would have that at least on my computer.

Q Okay. It's not in the declaration that you submitted?

A But you -- sorry to cut you off. No, not in the declaration because the fact that a different procedure gave something that was not Form 1 was not really relevant to whether Liu was operative, and getting Form 1 but with only

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88 percent purity, I felt wasn't -- didn't justify reporting.

But, you know, it's in my notebook, and what it shows is that the experiment of recrystallizing for an acetone worked pretty well, but I thought I could do better, and I did.

Q Got it. So one of the times you followed Liu, you got the 88 percent Z at Form 1, and then another time you followed Liu, you got -- I think you said 100 percent or 93 percent, depending on which experiment of Form 1; is that right?

MR. MAHON: Objection; form.

A Yeah, 93 to 94 percent purity, in another case no detectable E. So approximately 100 percent Z.

Q So the three times you filed Liu's example seven, all three times you got Form 1 of (Z)-endoxifen, one of the times it was 88 percent pure, one of the times it was 93 or 94 percent pure, and one of the times it was 100 percent pure; is that correct?

MR. MAHON: Objection to form.

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A I think that's correct.

Q I want to turn to Example 6, please.

Example 6 of Liu, that, I believe, as we discussed, is the isomerization of (E)- and (Z)-endoxifen mixture?

A Yes.

Q Where does Liu say to use the material from Example 6 in example seven as you've done?

A Let's take a look at example seven, and while -- while trying to keep Example 6 on there, if that's possible.

Okay. So the first sentence under example seven reads -- is that 5018 grams?

Q 5013.

A Okay.

Q That's what I see.

A Okay. 5013 grams. Does it say approximately 30 to 70 E to Z ratio?

Q Yes.

A So it's enriched in Z.

Now, where did that -- the bulk of material come from?

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Okay. In Paragraph 74, you see 69 percent Z content. So that -- that fits. Right above that, I see 71 percent Z content. And at the bottom, it said -- of 74, it says, the total amount is 2348 grams.

I think -- I think elsewhere there's another number that is in the 2000 region.

Q That was Example 5 of Liu, which is Paragraph 72.

A That's --

Q 2666 grams?

A Yeah, that's great.

Q And I just added them together, and it's 5014. Them being the 2348 from Example 6?

A Yeah.

Q So is what you're saying Liu example seven combines the materials from Example 5 and Example 6?

A It looks like it, and you'll notice that the E to Z ratio is on the order of 30 to 70. Sometimes a little higher, sometimes a little lower.

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So I guess in his example he doesn't say, but you have to figure out where the -- where the material came from that he used in the next step. I think we just figured that out.

Q Okay. And so --

A And let me -- let me rephrase that.

I believe I figured that out back when I was trying to reproduce Liu a couple years ago, but we re-figured it out.

Q Okay. Let's look at Liu Example 6. And so Paragraph 73 of Liu says that in Example 6, endoxifen was suspended in isopropyl acetate. The suspension was heated --

A Which -- which paragraph?

Q I'm sorry, Paragraph 73 of Liu.

A Okay. Great.

Go ahead.

Q It says the endoxifen was suspended in isopropyl acetate, and the suspension was heated at 85 degrees for two hours.

Do you see that?

A Yes.

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Q And then let's look at Page 34 of your lab notebook, please.

A Okay.

Q And do you see there's an entry -- I believe the date is January 26th, 2024, about halfway down the page?

A Yep.

Q And it looks like it says Example 6, Paragraph 73 through 74.

A Yes.

Q And do you see it says dissolve 15-34-1P in refluxing isopropyl acetate?

A Yes.

Q And we just looked at Liu 70 -- Paragraph 73, and that said that endoxifen was suspended in isopropyl acetate that was heated at 85 degrees.

Do you recall that?

A Yeah.

Q And so Liu, on the one hand, is saying to suspend this material in hot isopropyl acetate, and you, on the other hand, dissolved material in

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refluxing isopropyl acetate; is that right?

MR. MAHON: Objection; form.

A I think this is the question that you were asking, like, 15 minutes ago, and we finally got to it.

So Paragraph 73 says suspend at 85 degrees. I say dissolve at reflux.

So, first of all, the boiling point of isopropyl acetate is 88 degrees. That, first of all, is not materially just different than 85 degrees. It wouldn't make any difference, that 3-degree difference.

Secondly, it's actually more likely that Liu was at 88 degrees, because it's easy to maintain the reflux temperature, more difficult to accurately maintain 85-degree internal temperature. So that's -- that's the temperature. The temperature difference is, in my opinion, immaterial.

Then there's the question of suspension versus dissolution. I'm just recording what I saw. I saw that all the material dissolved. If

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Liu is saying that almost all the material dissolved but some of it didn't, I -- based on my results, I would take that to be what he probably means. And, again, that wouldn't make any difference.

The reason that wouldn't make any difference is that the -- if the isomerization only occurs on the material that is in solution, on the endoxifen that is in solution, which I think would be the case, it's going to -- the material that sits in solution will be in equilibrium with whatever precipitate there is, and eventually it will all be subjected to isomerization.

Q So --

A So the bottom line is -- I'm sorry. That was a long -- a long response, but the bottom line is 73, Paragraph 73 is totally consistent with the isomerization that I performed on January 26th, 2024.

Q So is it your testimony that when Liu says 85 degrees Celsius, he means 88 degrees Celsius?

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A I would -- I would suspect so.
Q Is that a mistake in Liu?
A I can only speculate on, you know, did he -- did he have an internal thermometer? Was he measuring, you know, right at the center? I -- I don't know. I'm just saying it's more likely that he meant 88 degrees refluxing, and that's what I took it to mean, and that's why I refluxed.
Q Would acetone be refluxing at 85 degrees Celsius?
A No.
Q You'd be able to see that it wasn't, right?
A Well, let me rephrase that. The boiling point of acetone, which is the reflux temperature, I believe, is 65 degrees. So at 85 degrees, acetone -- it can't -- it can't generally go to a temperature higher than its boiling point unless it's pressurized, which it's not.
So if you heated acetone to a bath temperature of 85 degrees, which is not what this is implying, but if you did that, the internal

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temperature would still be the boiling point of acetone, which is 65 degrees.

Q I'm sorry. I misspoke. I meant isopropyl acetate. So let me -- let me re-ask that.

So is isopropyl acetate refluxing at 85 degrees Celsius?

A That is below its boiling point, so I would say no.

Q And regardless of where your thermometer was, you'd be able to see that it wasn't boiling, right?

A Well, you know, it's like cooking. They'll say -- sometimes on the recipes they'll say vigorously boiling. If you were for some reason right at 88 degrees, it might be difficult to see it, bath temperature. Might be difficult to see that it's refluxing.

If the bath temperature got to be, say, 10 degrees above the reflux temperature, that'd be 95 degrees. In this case, you should definitely see refluxing.

Q Right. And he specified 85 degrees, not

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88 degrees, correct?
A Yeah.
Q And he's also --
A The bottom line for me is that there's -- there's a difference between my interpretation and what Liu strictly wrote.
Q Are you saying what Liu strictly wrote?
THE REPORTER: I think we lost the witness.
MR. MILEA: Dr. Bihovsky, are you there? Maybe we can go off the record.
(A recess was taken.)
BY MR. MILEA:
Q So this --
A I got cut off. I think the bottom line is that I was saying that there's not a significant difference between what Liu lays out in Paragraph 73 and the experiment that I did.
Q But there is a difference; is that fair?
A There appears to be a difference, but I don't think it's of any significance.
Q Okay. And then the other difference we

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were talking about between what you did and what Liu did was that Liu created a suspension in his Example 6 and you dissolved the material in Example 6 as reported on Page 34 of your lab notebook; is that right?

MR. MAHON: Objection; form.

A So I -- I wouldn't say that I dissolved. I just reported what I observed, which was that when I put the material into isopropyl acetate, as far as I could see, there was complete dissolution.

Apparently Liu observed a suspension. So some material apparently in Liu's case was in suspension. But as I already stated, I don't think that's of any significance for the reasons that I went into before.

Again, the proof is in what you get out of it, and on -- in the flowchart, I show that I obtained (Z)-endoxifen with a purity of greater than 90 percent.

Q Is it possible that in -- withdrawn.

So you -- you observed that all of your

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material in Example 6 dissolved, right?

A Yes.

Q And Liu says that he observed that not all of his material dissolved and some of it was suspended, right?

MR. MAHON: Objection; form.

A That -- that seems to be what -- what Liu is describing, that is consistent with the suspension.

Q And is it possible that different proportions of -- withdrawn.

And so in Liu's Example 6 mixture, which was a suspension, is it possible that there was some undissolved (Z)-endoxifen.

A Again, that's possible, but I don't think that would change the result, and the -- my -- my assumption is proven by the fact that the isomerization worked in Liu's hands and also in my hands.

Q And is it possible that in Liu's Example 6 mixture, which was a suspension, that the undissolved material was (E)-endoxifen?

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A It would have to be either E or Z. I -- I would -- I would be pretty sure that it was either E or Z or a mixture of the two that was not fully dissolved.

Q And is it possible that whatever the undissolved material was that Liu observed in his Example 6, that that undissolved material seeded the crystallization process and increased the formation of either the (Z)-endoxifen or the (E)-endoxifen in Liu's example?

A We're talking about Paragraph 73, right?

Q Yes.

A Well, in about the fourth line, he says that the mixture was cooled, that the mother liquor contained the (Z)-isomer, but he also says that the crystals were E, preferentially E. I don't think he gives a ratio.

So I don't know. It's possible that the suspension was E. It's possible that the suspension was caused by mixture of E and Z. There's no data in Paragraph 73 to -- to tell, and I don't think it really makes much difference

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because in the end, he obtains a good yield of the (Z)-isomer, 48 percent, and its Z content is 73 percent, which is an improvement.

Q And is it possible that suspended Z -- withdrawn.

Is it possible that there was some (Z)-isomer suspended in Liu's mixture in Example 6 that seeded the crystallization in Example 6, and wound up producing more (Z)-isomer than would have otherwise been produced?

A I think we know from other data from -- both from Liu and other sources that the (Z)-isomer is more soluble in most solvents, including isopropyl acetate. Z is more soluble than E.

So if -- if -- if anything, it's -- I'm speculating, but it's more likely that the suspension, if any, was caused by the (E)-isomer, and it's -- it's -- as I've said, it's also likely that any suspended (E)-isomer would actually be converted or isomerized to a large extent to the (Z)-isomer, and that the whole thing would become

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soluble as the isomerization continued.

That is not what Paragraph 73 implies, but that would require the person that did the experiment to look at the -- look for evidence of suspension at the beginning of the isomerization and after two hours.

And also remember that however they heated this material, it says two hours, but the mixture would have taken a long time to cool, so the two hours is actually, in practice, longer than two hours heating.

Q It sounds like you think that if there was a suspension in Liu, it probably would have been more of the (E)-endoxifen material that was suspended and more of the (Z)-endoxifen material that was actually dissolved; is that right?

A I'm speculating a bit, but based on other data, I think that would be correct.

Q Is it possible that the undissolved (E)-endoxifen in Liu's Example 6 could have seeded the crystallization steps in Liu such that Liu produced more (E)-endoxifen than it would have had

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the (E)-endoxifen all been dissolved in a solution in Example 6?

A That's an interesting idea; however, I think my results with the percentage of E and Z correspond with Liu's. So it doesn't look like that's the case.

Q Is it possible that that could have happened, though?

A Well, there's no evidence to support that.

Q Is there any evidence -- withdrawn.

But it is a possibility?

A I think it's an unlikely possibility.

Q But a possibility, nonetheless?

A Yeah. I'm looking at -- my isomerization experiment is on Page 34, and just -- just looking at the ratios real quickly, and I'm seeing ratios of 69 to 31, Z to E. 67 to 33. This corresponds pretty closely to the ratio that Liu reports in Paragraph 73.

So what I'm saying is that I don't -- I don't see the slight differences between what Liu did and what I did to be significant, and the end

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result, there is no -- there is no difference.

Q You agree that by creating a solution rather than a suspension in your recreation of Example 6 you avoided the potential problem of undissolved (E)-endoxifen seeding the crystallization process?

MR. MAHON: Objection; form.

A I -- I disagree with the premise that if -- if there was undissolved E at 85 degrees or reflux, that that would be a bad thing. On the contrary, if the E precipitated out, then that leaves more Z in the mother liquor and gives more E to use in an (E)-isomerization.

Q What is the mother liquor used for -- withdrawn.

You just mentioned the mother liquor. What is that used for?

A That's -- the mother liquor is -- which is the filtrate, is enriched in the (Z)-isomer. There's a step that maybe I didn't mention, and that involves removing a solvent, which is isopropyl acetate, from the mother liquor. That

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creates -- that gives you a material that would be a solid, as it says at the bottom of Paragraph 73.

And then that can be used and recrystallized from acetone to provide the even more enriched, greater than 90 percent enriched (Z)-endoxifen.

That's the whole purpose of the isomerization.

Just so we're clear, the initial formation gives approximately a 50/50 mix of Z and E. You can throw away all of the (E)-isomer, or you can isomerize it in isopropyl acetate followed by the crystallized form acetone, and you can do that cyclicly, repeatedly, and thereby not throw away thousands of grams, in this case, of endoxifen. That's the purpose.

MR. MILEA: Okay. Why don't we take a break, and I will hopefully finish up soon after that.

(A recess was taken.)

BY MR. MILEA:

Q Doctor, do you remember exactly how many

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samples of material you sent to Dr. Miller?

A The samples that I sent to Dr. Miller are recorded in my notebook when I say either Form 1 or not Form 1. I think there were four.

Q Okay. And so there were no other samples other than the ones where you noted Form 1 or not Form 1?

A I'm sure that's correct.

Q Do you recall if you sent him any samples for which you didn't receive results?

A No. I always received results.

Q Okay. I'd like to switch gears a little bit and look at the '391 patent, which is the patent that's at issue in the PGR, and specifically claim 16.

MR. MILEA: So if we're, please, able to pull up PGR Exhibit 1034, which is the declaration in the PGR.

(PGR Exhibit 1034 was marked for identification and is attached to the transcript.)

BY MR. MILEA:

Q And, Doctor, I believe this is the

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document which you had which is unsigned, so if you're okay to just look at the exhibit that we pull up on the screen rather than your unsigned copy, let's do that.

Oh, we do have that up. Okay.

Doctor, do you see that on the screen?

A Yes.

Q Let's please turn to Paragraph 74.

We may have touched on this many hours ago, but -- withdrawn.

Do you see claim 16 here up at the top, right above Paragraph 74?

A I do.

Q And do you see claim 16 requires the composition of claim 1 wherein the compound of Formula 3 is stable in the composition for at least 10 days at about 25 degrees Celsius?

A Yes.

Q And what that's saying is the (Z)-endoxifen has to be stable in the claim composition of claim 1, right?

MR. MAHON: Objection; form.

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A That would be my understanding.

Q And that composition could include things that are part of the formulation of the composition, right?

A To be sure, we would have to look at the wording of claim 1.

Q Sure, so let's do that. A good place to find claim 1 would be in this same document on Page 6, if you use the bottom middle, or Page 9 if you're using the exhibit stamp.

A Okay. This is claim 1. Independent claim 1, composition comprising an endoxifen and an enteric material wherein... (reading document to self).

So I'll just point out that my understanding of comprising means that it contains, in this case, endoxifen and an enteric material, and it may contain other things as well. It's not limiting.

Okay. Endoxifen, comprised compound Formula 3, which is shown there. The wiggly line indicates -- it could be a mixture of E and Z.

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Then it continues, or a pharmaceutically acceptable salt thereof, and at least 90 percent by weight, is (Z)-endoxifen.

Okay. I understand claim 1.

Q And so my question was: Does the composition of claim 1 include other things that are part of the formulation of the composition?

A That appears to be the case, that it would include at least an enteric material.

I'm -- that's a legal question. I'm not sure if the enteric material is optional, but my understanding from this would be that it's included in the claim 1.

Q Do you agree that the components of a formulation can affect the stability of the active ingredient in that formulation?

A Yes. In this specific case here, my understanding is the purpose of the enteric material is to decrease its susceptibility to isomerization.

Q You performed stability testing for the PGR, right?

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A Yes.

Q And your stability testing was of the same (Z)-endoxifen material that you synthesized based on your recreation of Liu, right?

A That's correct. I believe it was the 100 percent Z sample.

Q So you tested -- withdrawn.

Because you tested the 100 percent Z sample, you tested the stability of (Z)-endoxifen on its own, right?

A That's correct. What would be -- what would be called the bulk.

Q And so your test was not of (Z)-endoxifen as part of any formulation, right?

A Correct.

Q And so fair to say that you didn't test whether enteric material affected the stability of the (Z)-endoxifen you tested?

A I did not test it with the enteric material, but the enteric -- I'm sorry. The enteric material would only increase the stability.

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So the stability testing that I did, excluding any enteric material, would be more sensitive as -- of stability. In other words, if my material was stable, the material that included the enteric coating or enteric material would be even more stable, and almost completely stable under these conditions.

Therefore, my reasoning would be that -- that Liu's procedure provides the material which inherently is as stable or more stable than claim 1 of the -- which is this?

Q '391 patent.

A '391 patent, yes.

Q When you say enteric material, what are you referring to?

A Well, it's a term of art in formulations. Enteric refers to the gastrointestinal system and the idea of enteric -- so-called enteric material is to shield the drug from the acidic environment of the stomach and allow it to pass into the more neutral, higher pH environment of the intestines.

To put it simply, in this case, the idea

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is to maintain the Z confirmation and prevent it or greatly slow down its conversion into E.

Q The enteric material you're talking about, are you referring only to a coating, or are you referring to something else?

A You know, I think I'm getting outside of my area of expertise, which from -- just the expertise here would be pharmacology and formulation, which -- and I -- it's outside the scope of my report.

But I'll just tell you from my lay knowledge that many tablets and capsules contain a coating on the outside to protect them from stomach acid.

Q I'm just trying to understand. When you say enteric material, what are you including in that?

A Again, that's purely outside the scope of what I'm prepared to testify, but you can read in -- probably in the disclosure for this patent -- this is '391, did you say?

Q Yes.

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A Yeah. I think you can read there or in other POSITA patent applications, you can read what they consider to be enteric materials.

I seem to recall them mentioning a whole list of them. Most of them are polymers that are well-known in the art. It is not something that's unique here. They're very common when used in drugs that have been on the market for decades.

Q In your -- several of your answers, you used the words "enteric material," and I'm just trying to understand what did you mean when you said that?

A Understood. I think I already answered that. It's -- in general terms, it's a material, polymeric, that shields the active drug -- the active pharmaceutical ingredient from degradation by acid of the stomach.

Q And did you mean that it was a coating or something else?

MR. MAHON: Objection; form.

A I guess I'm going to say that's outside my area of expertise.

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Q Okay. With the remaining time, I'd like to talk about example seven. I was hoping we can get through this before I actually run out of time, that way everybody can go home or go away from their desks.

But let's go back, please, to your IPR declaration, which is Exhibit 1033. And I want to look at Paragraph 61, please.

Do you see Paragraph 61 on the screen, Doctor?

A Yes.

Q Do you see in Paragraph 61 you cite to Liu Paragraph 26?

A Where do you see that?

Q It's six lines from the bottom.

A Yeah, okay. Let me familiarize myself with this whole paragraph, and then I'll get back to you.

Q Sure.

A Okay. This is how -- equivalent to the experiments that we were discussing before the break.

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Q And by that, do you mean that Paragraph 26 of Liu is describing an alternate set of procedures that one might follow?

A What I meant when I said that was that the procedure that I use is what we were talking about before the break. In terms of whether that is consistent with Paragraph 26, that's quoted here within the -- within the quotation marks. I'll take a look at that again.

So my understanding of this is that, again, Liu is giving a range of conditions, which is broader than those used in the actual example, but -- broader than but includes.

Q So it's possible to follow Paragraph 26 of Liu but not follow example seven of Liu? Is that fair?

A I think not fair. Here's what I do when I look at patents, whether it's for a litigation or for attempting to just follow them to provide a customer with a material.

I would -- I would look to some extent at the main part of the disclosure, and I would look

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much more seriously at the actual examples. And as all of us know, the purpose of the disclosure, excluding the examples, is to teach the widest variety of possibilities, and the purpose of the examples is -- at least in the old days was to -- what was it called? -- show the -- what was the word? There's a legal term. Best --

Q Best mode, probably?

A Yes, best mode. I would go with the best mode.

Q Okay. I think you said that Paragraph 26 gives some broader parameters than example seven, right?

A Yes.

Q And so it'd be possible to be within those broader parameters of Example 26 and not be within example seven's precise parameters, right?

A Right. And I would -- I would defer, if that's the right word, to the actual examples.

Q Okay. Paragraph 26, the part that you quote here, says that the solution can be held at a second temperature for .5 hours to 10 days, or 2

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to 72 hours, and in some cases, longer holding times at the second temperature may be required.

Do you see that?

A Yes.

Q Does that anywhere say that someone performing -- withdrawn.

Does that mention scratching the flask anywhere?

A I don't see the word "scratching," but as I've said several times before, the scratching is a well-known technique taught in undergraduate organic laboratory.

Q And does that Paragraph 26 that you quote in Paragraph 61 of your declaration mention adding any additional stirring time?

A You're asking me if the quotation says anything about stirring?

Q Right. Does the part of Paragraph 26 of Liu that you've selected to put in Paragraph 61 of your declaration, does it mention anything about stirring?

A I don't see "stirring."

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Q Let's look at Paragraph 62 of your declaration, please. And I want to also have open, if possible, Paragraph 76 of Liu side by side with this.

A I hate to interrupt your train of thought, but I just want to repeat what I said hours ago, that in recrystallization or crystallization, it is generally my practice not to stir, but it's other people's practice to stir, and I don't think it makes a whole lot of difference. It's really not a -- not a major point here.

Q Okay.

A In my -- in my opinion.

Q So on the left, we should have Exhibit 1033 -- I'm seeing 1034. Thank you. And on the right, we should have Paragraph 76 of Liu, please.

MR. MILEA: I think you passed it.

Okay. Thank you.

Q Doctor, do you see on part of your screen Paragraph 62 of your IPR declaration, and hopefully on part of your screen Paragraph 76 of

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Liu?

A Yes.

Q Paragraph 62 of your IPR declaration says -- withdrawn.

Is Paragraph 62 of your IPR declaration describing how you performed part of Liu Example 7?

A Let me make sure. Let me read Paragraph 62 to myself.

Okay. I'm up to speed on Paragraph 62.

Q Is Paragraph 62 of your IPR declaration describing part of how you performed Liu Example 7?

And if it's helpful, you can look at Paragraph 61, which may provide context.

A I don't think I have to look at 61 right now.

Okay. I think I have an overview of the two paragraphs of text.

Q Okay. And so is Paragraph 62 of your IPR declaration describing how you performed part of Example 7 of Liu?

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A Yes.

Q Do you see in the first line you write, This precipitate was then dissolved in refluxing acetone, filtered while hot to remove a slight precipitate, then cooled and stirred for 50 hours at 4 degrees?

And I left out some of the amounts, but was that right otherwise?

A Yes.

Q Do you agree that Example 7 of Liu does not disclose filtering the precipitate while hot to remove anything?

A Yeah. This is actually the opposite of the suspension question that we went through before the break. So in this case, Liu apparently had a solution in acetone. I had a very small amount of precipitate.

It would be standard practice -- it is standard practice to remove a precipitate from the hot solvent before you cool it down and initiate precipitation.

Q Do you know what it is that you removed

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from your mixture when you did that additional filtering step?

A I did not characterize it.

Q Was it --

A I -- you know, actually, I could check on that. I don't recall that I characterized it, but if I did, it would have been a very small amount, and the only thing I could have done, I think, would be TLC.

But I can take a look in my notebook if you're interested and see if I did run TLC on it.

Q All right. Let's do that. So I believe it's going to be the second-to-last page of your lab notebook, which is Page 35 of your lab notebook. And if you're using the exhibit stamps, it's Page 95.

A Yeah. There's -- there's no information there that even gives that initial small, slight precipitate. There's not even a notebook number for it.

So I think I simply discarded it knowing that (Z)-endoxifen is soluble in hot acetone.

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Q So fair to say you removed something other than (Z)-endoxifen from your material when performing Example 7?

A I -- I think that's fair to say. And, remember, it's a slight amount of precipitate.

Q Would it have been impurities that you removed?

A Probably. That -- that would be my intention.

Q Had you followed Liu as written, those impurities would have been present in the final product that you synthesized following Example 7; is that fair?

A That's presumably -- that's presumably the case. But an experienced chemist, even an undergraduate, would -- would know that if there is a precipitate in the hot solvent that it should be removed to prevent exactly what you just said, contamination with whatever that precipitate is.

Q Right. So by removing the precipitate from your mixture, you likely or possibly prevented contamination of your final product?

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A Yeah. Again, as -- as an experienced chemist would know to do.

Q Let's look at Page 95 of your lab notebook, please. Page 36. I'm sorry.

This is -- at the top it says Example 7, right?

A Yes.

Q Is this the Example 7 that you performed using your material from your Example 6 experiments?

A The materials were obtained from Page 34, and they are 15-34-2S and 4S. These are -- on Page 34, isomerization was performed. The filtrates are -- are 2S and 4S on Page 34. They were combined and recrystallized from refluxing acetone.

So that would be equivalent to example -- you know, I may have the wrong citation here. No, that's okay.

Paragraph -- I'm sorry. Paragraph 30 -- Paragraph 76 describes recrystallization from acetone. That's what we just looked at.

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Q Okay. And so that would be Example 6?
A I think it's Example 7, Paragraph 76.
Q Okay. Oh, I'm sorry. I'm asking whether the materials that you're using in that version of Example 7 on Page 36 of your lab notebook, whether that's taking the materials you made in Example 6 and recrystallizing them?
A I think that's correct.
Q Okay. Going back to our discussion about the additional filtering of Example 7 that you did, would the removal of the impurities by that additional step have affected the final polymorphic form of the material that you generated?
A I'd say that's extremely unlikely for many reasons.
Q Why?
A Well, for one thing, on -- if the material is insoluble, it probably would not -- it would probably remain as a solid, and such solids are notoriously much slower to react with other solids than a liquid would be.

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The other reason is that I don't think it would change the form because a great, great majority of the material is the material that's soluble in acetone and precipitates giving Form 2 -- Form 1. So I -- no, I don't think it would change -- change the form at all.

Q And you said at the beginning -- or maybe the last answer -- that it would be extremely unlikely to change the form. Do you recall that?

A Yes.

Q Is it possible it could change the form?

A There certainly isn't any evidence from the work that I've done or I cite in Liu that that would be the case.

Q But it is possible that the impurities you removed from Example 7 of Liu could have altered the final polymorphic form that the material you synthesized adopted?

A It's my opinion that that's not going to happen.

Q So it's impossible in your view?

A It's also my opinion that nothing in

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chemistry is impossible. There are always surprises, but it's my opinion that it's extremely unlikely.

Q Extremely unlikely does leave open the possibility that it could happen, though, right?

A I'm -- I'm being a scientist and trying to not say anything that can be proven to be correct, but it is my strong opinion that it would not change the form.

Q If we go back to your lab notebook, please, there's a series of experiments reported on Pages 33, 34, 35, and 36.

These are the experiments on which you rely in your flowchart at Paragraph 71 of your declaration, right?

A I think that's correct.

Q And you arrived at these experiments by doing all of the prior experiments described in the earlier pages of your lab notebook, right?

MR. MAHON: Objection; form.

A I wouldn't put it exactly that way. I would say that I did some preliminary experiments,

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for example, based on Song, which were totally -- I don't want to say useless, but weren't -- do not lead to the expected or desired result based on Song.

I did some other experiments where I thought I could do simpler -- where I thought I could simplify Liu, the procedure of Liu, and those were not entirely successful.

And, frankly, I eventually decided that I better follow Liu as closely as possible, and that led to the desired results.

I would just add to that, you know, I think from the questions that you were asking me about, I think, Examples 6 and 7, that Liu describes what he does, I think, pretty well, but the first time you look at it, it is a little bit confusing. I don't know if he could have done any better. My notebook is probably even more confusing.

But, you know, once you look at it and digest it, comprehend what Liu is doing, and follow the procedure, the results come out very

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much as he has stated, which is that you get greater than 90 percent (Z)-endoxifen and -- and, not as he stated, but in my hands, you get Form 1.

Q Is it fair to say that preceding the experiments on Pages 34 through -- excuse me, Pages 33 through 36 of your lab notebook, you performed different versions of Liu Example 2, Example 3, Example 4, Example 5, and Example 6?

A I guess we'd have to go through them individually, you know, which we already did at the beginning.

There's Example 2, in which in my hands the temperature had to be increased -- as I said, I don't know if you want to go through all of this again. There's Example 3, there's Example 4.

At the end of Example 4, before there was any recrystallization, I got a, as I recall it, 52 to 48 percent mixture of E and -- what was it? Yeah, E and Z. E to Z. I'm sorry. I'm going back between E and Z and Z and E. Anyway, roughly 50/50, as did Liu.

And then the recrystallization

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experiments, we've talked about. And, ultimately, when I followed Liu's procedure closely, I got Liu's results.

Does that answer the question?

Q My question was a little different. All I was asking is you performed a number of different -- I think what you said, preliminary experiments, with various examples of Liu before you arrived at the experiments that are on Pages 33 through 36, which are the experiments that you relied on in your purification chart at Paragraph 71 of your declaration; is that fair?

A Yeah. I guess I got thrown off because you were talking about Examples 2, 3, and 4 as well.

Q Okay. So is it fair to say that you performed what you called preliminary experiments with various different examples of Liu before you arrived at the experiments that you describe on Pages 33 through 36 of your lab notebook, which are the experiments that you rely on in your purification scheme at Paragraph 71 of your

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declaration?

A I think that's reasonably fair.

MR. MILEA: All right. Thank you very much, Doctor. I really appreciate the late evening. I have no further questions at this time.

THE WITNESS: Okay. No problem.

MR. MAHON: None from us.

(Off the record at 7:20 p.m.)

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ACKNOWLEDGMENT OF DEPONENT

I, RON BIHOVSKY, Ph.D., do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me and any corrections appear on the attached errata sheet signed by me.

_____ _____

(DATE) (SIGNATURE)

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CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Brooklyn E. Schweitzer, Registered Professional Reporter and Notary Public in and for the Commonwealth of Pennsylvania, do hereby certify:

That RON BIHOVSKY, Ph.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me before the commencement of such deposition and that such deposition was taken before me and is a true record of the testimony given by such witness.

I further certify that the adverse party, INTAS PHARMACEUTICALS LTD, was represented by counsel at the deposition. I further certify that the deposition of RON BIHOVSKY, Ph.D., occurred remotely on Tuesday, January 20th, 2026, at 10:02 a.m. to 7:20 p.m.

I further certify the inspection, reading and signing of said deposition was not waived on the record by agreement of all parties. I further certify that I am not related to any of the parties to this action by blood or marriage, I am not employed by or an attorney to any of the parties to this action, and that I am in no way interested, financially or otherwise, in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 22nd day of January, 2026. My commission expires: May 20th, 2026.



BROOKLYN E. SCHWEITZER, RPR, CRR
NOTARY PUBLIC IN AND FOR THE COMMONWEALTH OF PENNSYLVANIA

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